California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Discussion and Consideration of Proposed Regulations to Amend and Add Title 16 CCR sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements

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Attachment 1

Background:

At the July 2013 Board Meeting, the board approved proposed text to amend and/or add Title 16 CCR sections 1702, 1702.1, 1702.2, and 1702.5 related to standardized reporting of convictions and discipline at the time of renewal for pharmacists, pharmacy technicians and designated representatives, as well as require nonresident wholesalers and nonresident pharmacies to report disciplinary actions by other entities at the time of renewal.

The 45-day comment period began on August 12, 2016 and ended September 26, 2016 and the Board received a few comments. At the October 2016 Board Meeting, the board approved a modified text to address concerns expressed by stakeholders and initiated a 15-day comment period.

The 15-day comment period began on October 27, 2016 and ended on November 11, 2016. The board received no comments during the 15-day comment period.

At this Meeting
The board will have the opportunity to discuss the regulation and formally adopt the regulation as noticed for comment on October 27, 2016

The attachment contains:

1. A copy of the noticed text as approved at the October 2016 Board Meeting.

Staff Recommendation: Adopt the regulation language as noticed on October 27, 2016, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Office of Administrative Law or the Department of Consumer Affairs to complete the rulemaking file.

Attachment 1

Renewal Requirements 16 CCR §§ 1702, 1702.1, 1702.2, and 1702.5

Renewal Requirements

16 CCR §§ 1702, 1702.1, 1702.2, and 1702.5

Modified Text as Approved on October 26, 2016

Board of Pharmacy
Modified Text

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and double underline for added language. Additionally, the changes are shown in red for color printing.

Amend Section 1702 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date ~~that occurs on or after December 7, 2010~~.

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . ~~omitting t~~Traffic infractions ~~under~~ ~~$300~~ ~~$500~~ not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.
Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Adopt Section 1702.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 1 Pharmacy Technician Renewal Requirements

(a) A pharmacy technician applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2017~~4~~.

(1) A pharmacy technician shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacy technician applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal . Traffic infractions ~~under $500~~ not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacy technician applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority: Sections 4001.1 and 4005, Business and Professions Code.
Reference: Sections 490, 4038, 4115, 4202, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Adopt Section 1702.2 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. 2 Designated Representative Renewal Requirements

(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after July 1, 2017~~4~~.

(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions ~~under $500~~ not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Authority : Sections 4001.1 and 4005, Business and Professions Code.
Reference: Sections 490, 4022.5, 4053, 4207, 4301, 4301.5 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Adopt Section 1702.5 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.

(a) As a condition of renewal, an applicant seeking renewal of a license as a nonresident wholesaler or as a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since the last renewal of the license. An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license. Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation or public reprimand or reproval.

Authority: Section 4005, Business and Professions Code.
Reference: Sections 4112, 4161, 4300, and 4301, Business and Professions Code

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Discussion and Consideration of Proposed Regulation to Add Title 16 CCR Section 1715.65 Related to Inventory Reconciliation Report of Controlled Substances

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Attachment 2

Background:

At the July 2016 Board Meeting, the board approved proposed text to add Section 1715.65 of Title 16 CCR, related to Inventory Reconciliation Reporting. The 45-day comment period began on September 16, 2016 and ended October 31, 2016.

The Board received several comments during the comment period.

At this Meeting
The board will have the opportunity to discuss the regulation, the comments received and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation as approved at the July 2016 Board Meeting
2. Amend the regulation to address the concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

The attachment contains:

1. A copy of the noticed text as approved at the July 2016 Board Meeting.
2. A modified text with staff recommended changes dated December 2, 2016.
3. A compilation document of the comments received during the 45-day comment period with staff recommendations.
4. The actual comments received during the 45-day comment period.

Staff Recommendation: Amend the regulation language as recommended by staff and to address the concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

Attachment 2

Inventory Reconciliation of Controlled Substances

16 CCR § 1715.65

Proposed Text

Approved July 28, 2016

Title 16. Board of Pharmacy
Proposed Text

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Inventory Reconciliation Report of Controlled Substances

a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
c) A pharmacy or clinic shall compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. This compilation shall require:
    1) A physical count, not an estimate, of all quantities of Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
    2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;
    3) A comparison of (1) and (2) to determine if there are any variances; and
    4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
d) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration. Likely causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.
e) The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge, and be readily retrievable in the pharmacy or clinic for three years.
f) A new pharmacist-in-charge of a pharmacy shall complete an inventory within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
g) For inpatient hospital pharmacies, a separate Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.
h) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:
    1) All controlled substances added to an automated drug delivery system are accounted for;
    2) Access to automated drug delivery systems is limited to authorized facility personnel;

3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed;
4) Confirmed losses of controlled substances are reported to the board; and
5) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.

Inventory Reconciliation of Controlled Substances 16 CCR § 1715.65

Staff Recommended Modified Text Dated 12/2/2016

Title 16. Board of Pharmacy
Modified Text

Changes made to the originally proposed language are shown by strikethrough for deleted language and underline for added language.

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Inventory Reconciliation Report of Controlled Substances

a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
c) A pharmacy or clinic shall compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. This compilation shall require:
   1) A physical count, not an estimate, of all quantities of Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
   2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;
   3) A comparison of (1) and (2) to determine if there are any variances; and
   4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
d) A pharmacy or clinic shall report in writing identified ~~L~~ losses and possible causes, ~~shall be identified in writing and reported~~ to the board ~~and, when appropriate, to the Drug Enforcement Administration~~ within 30 days unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and security improvements necessary to prevent additional losses of controlled substances.
e) ~~Likely~~ Possible causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.
~~e)~~ f) The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director, if a clinic, and be readily retrievable in the pharmacy or clinic for three years.

~~f)~~ g) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory reconciliation report as required in subdivision (c).

~~g)~~ h) For inpatient hospital pharmacies, a separate quarterly Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

~~h)~~ i) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

1) All controlled substances added to an automated drug delivery system are accounted for;
2) Access to automated drug delivery systems is limited to authorized facility personnel;
3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed;
4) Confirmed losses of controlled substances are reported to the board; and
~~5) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104, 4105.5, 4119.1, and 4332, Business and Professions Code and 1261.6, Health and Safety Code.

Inventory Reconciliation of Controlled Substances
16 CCR § 1715.65

45-Day Comment Compilation
Comment Period Closed
October 31, 2016

Code Section	Commenter	Comment	Staff Recommendation
1715.65(a)	Community Regional Medical Center	Commenter expressed concern that this section is vague. They recommend that the term reconciliation be removed and that "inventory functions" be defined.	Reject this comment. The regulation itself specifies what the inventory reconciliation requirements are.
1715.65(b)	Community Regional Medical Center	Commenter expressed concern that it is not possible to review what is coming in and what is being used by nursing staff. They recommended that "inventory reconciliation reports taken" be removed. They believe that the invent of the regulation is only to take an inventory and have policies and procedures in place to mitigate the risk of drug losses.	Reject this comment. The Board's position has been to require inventory be completed and that a reconciliation be done to indentify loss and take action.
1715.65(b)	Providence Health	Commenter recommended that the language be modified to match the significant loss reporting requirement of the DEA. They recommended changing the language to "maintain secure methods to prevent theft or significant loss of controlled drugs".	Reject this comment. This change would cause a conflict with existing law (including 16 CCR section 1715.6).
1715.65(c)	Community Regional Medical Center	Commenter expressed concern that this section is vague. They recommend that the term "reconciliation" be defined to eliminate confusion.	Reject this comment. This regulation explains what an Inventory Reconciliation Report needs to include.
1715.65(c)(2)	Community Regional Medical Center	Commenter expressed concern about the need to review the disposition of waste and administrations by nursing staff. They indicated hospitals would not have the resources necessary to meet this requirement and recommended that (c)(2) be removed or further clarified as to what dispositions records need to be reviewed.	Reject this comment. Waste disposition and nurse administrations must be reviewed in order to have an accurate reconcilication report as such all dispositions need to accuated for.
1715.65(c)(2)	NACDS	Commenter requested clarification if comparing a perpetual inventory to acquisition and disposition records is sufficient for compliance. Additionally, Commenter requests that the comparison only be required if variances are found and not for all schedule II drugs.	Yes, a perpetual inventory meets to requirements of (c)(1). The perpetual inventory would be compared with the acquisition and disposition of all CII drugs for an accurate report.

Code Section	Commenter	Comment	Staff Recommendation
1715.65(c)(4)	NACDS	Commenter requested clarification on what "readily retrievable" means. Commenter asked if the records need to printed and stored in a packet or it electonic records are acceptable.	Readily retrievable is used to maintain consistency in Board statutes and regulations. See B&P section 4105 for electronic records and 4105(f) for time frames.
1715.65(d)	NACDS	Commenter asked if reporting of losses needs to be done separately for this regulation or if standard loss reporting is compliant.	Losses are reported in the same manner as other drug losses and do not need to be reported to the Board more than once. See 16 CCR section 1715.6.
1715.65(d)	Providence Health	Commenter recommended that the language be modified to match the significant loss reporting requirement of the DEA. They recommended changing the language to "~~Losses~~ Theft or significant loss..."	Reject this comment. This change would cause a conflict with existing law (including 16 CCR section 1715.6).
1715.65(d)	Community Regional Medical Center	Commenter expressed concern that the term "losses" is not clear and requested that the term be defined. Additionally, commenter asked which classes of drugs section (d) applied to.	Reject this comment. For the purposes of this regulation, (d) applies to CII; however, 16 CCR section 1715.6 requires that all controlled substance losses be reported. Additionally, nothing in this regulation prevents a pharmacy or clinic from expanding their inventory reconciliation to other scheduled drugs.

Code Section	Commenter	Comment	Staff Recommendation
1715.65(e)	NACDS	Commenter requested clarification that a countersignature is not needed if the PIC is the one conducting the inventory.	Agree with this comment. Staff recommends the language be modified for clarity to: The inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge, and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.
1715.65(e)	CVS	Commenter requested clarification that a countersignature is not needed if the PIC is the one conducting the inventory.	Agree with this comment. Staff recommends the language be modified for clarity to: The inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge, and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.
1715.65(g)	Community Regional Medical Center	Commenter expressed concern that this section is vague. They recommend that the term "reconciliation" be defined to eliminate confusion. Additionally, commenter requested that an example be provided in the regulation.	Reject this comment. This regulation explains what an Inventory Reconciliation Report is.

Code Section	Commenter	Comment	Staff Recommendation
1715.65(h)(1)	Community Regional Medical Center	Commenter expressed concern that they are unsure which schedule this section applies to. Additionally, commenter expressed concern about what this section is requiring and asked for examples to be provided.	Reject this comment. All controlled substances need to be accounted for. Additionally, this section is reiterating the responsibilites and not prescribing how it is done. It is up to the locations policy and procedure to specify how it is done.
1715.65(h)(4)	Community Regional Medical Center	Commenter expressed concern that the term "losses" is not clear and requested that the term be defined. Additionally, commenter asked which classes of drugs this section applies to.	Reject this comment. Please refer to 16 CCR section 1715.6. All controlled substance losses must be reported.
1715.65(h)(4)	Providence Health	Commenter recommended that the language be modified to match the significant loss reporting requirement of the DEA. They recommended changing the language to "~~Confirmed~~ Theft or significant loss..."	Reject this comment. This change would cause a conflict with existing law (including 16 CCR section 1715.6).
1715.65(h)(5)	Community Regional Medical Center	Commenter expressed concern that the term "losses" is not clear and requested that the term be defined. Additionally, commenter asked which classes of drugs this section applies to.	Reject this comment. Please refer to 16 CCR section 1715.6. All controlled substance losses must be reported.
1715.65(h)(5)	Community Regional Medical Center	Commenter requested that "taking additional steps" be removed and replaced with a requirement to review current security and determine if additional steps are necessary.	Reject this comment; however staff recommends that this section be combined with 1715.65(d). Please see recommended language for changes.
1715.65(h)(5)	Providence Health	Commenter recommended that the language be modified to match the significant loss reporting requirement of the DEA. They recommended changing the language to "identifying theft or significant loss~~es~~..."	Reject this comment. This change would cause a conflict with existing law (including 16 CCR section 1715.6).

Code Section	Commenter	Comment	Staff Recommendation
Overall	Providence Health	Commenter requested clarification on how the regulation will be enforced on facilities licensed by CDPH.	Pharmacies control the automated drug delivery devices within health care facilities, as such, the Board has jurisdicition over these devises.
Overall	NACDS	Commenter requested that the proposed regulation be amended and only apply to the pharmacies that have multiple loss reports or failure to report losses to the Board. Commenter believes that the Board should target pharmacies with a history of drug losses and not every pharmacy. Additionally, Commenter requested clarification if this regulation applies to all controlled substances or only schedule II controlled substances.	Reject this comment. With this suggestion, problem Pharmacies could get around the inventory requirement by simply not reporting their losses. This reconciliation report is specific to schedule II; however, losses for all schedules must be reported per 16 CCR section 1715.6.
Overall	CVS	Commenter requested clarification if this regulation applies to all controlled substances or only schedule II controlled substances. They requested that the title and sections (a) and (b) be amended to specify schedule II only. Additionally, commenter requested that the Board allow pharmacies that use perpetual inventory to be deemed compliant with this regulation.	The reconciliation report is specific to CII. Additionally, perpetual inventories would meet the requirements of 1715.65(c)(1).
Overall	K. Scott Guess, PharmD	Dr. Guess recommended that the language be amended to allow pharmacies that use a perpetual inventory to be deemed compliant. He recommended the following language: If the pharmacy employs a perpetual inventory for Schedule II drugs the requirement for every 90-day physical count is waived" or "A current and up to date Schedule II perpetual inventory will satisfy the physical count requirement." Commenter indicated that it would take him to 1.5 - 3 hours to count his scheduled II drugs each day, which is unreimbursed. He expressed concern that the regulation is overly burdensome and costly. Finally, commenter asked how the board is going to address the issue of the person doing the audit being the same person diverting the drugs. Commenter also recommended that the board enact regulations requiring wholesalers to accept all valid, sealed controlled substances back from pharmacies.	Perpetual inventories would meet the requirements of 1715.65(c)(1). The regulation calls for a quarterly physical count, not a daily one.

Code Section	Commenter	Comment	Staff Recommendation
Overall	AmeriPharma	Commenter expressed concern that the proposed regulation will amount to two full days of work within a one year period. The commenter indicated that the loss of two days of work a year to compile the quarterly report will be considerable. The commenter does not believe the proposed regulation will combat drug diversion and indicated mandatory perpetual inventories already serve the purpose the Board is trying to achieve. Commenter believes the quarterly requirement was chosen arbitrarily and recommends that the language be amended to require yearly counts, especially when perpetual inventories are already required.	Reject this comment. Staff does not agree that two days of work a year is excessive and a burden. Additionally, perpetual inventories are not mandated by law.
		LATE COMMENTS	
Overall	John Teague, PharmD	Commenter expressed concern that the regulations place a heavy burden on pharmacy staff as it will be difficult to inventory 20+ automated delivery devices at the same time. This will cause discrepancies with the reports and require research when no losses are actually present. Dr. Teague provided the following AHSP information: ASHP Publishes Controlled Substances Diversion Prevention Guidelines http://www.ashp.org/menu/AboutUs/ForPress/PressReleases/PressRelease.aspx?id=950&utm_source=Real%20Magnet&utm_medium=Email&utm_campaign=104498696	Reject this comment. While it was received late, staff recommend that this pharmacy include a set schedule for when ADS are inventoried in its P&P. They do not need to be inventoried at the same time and can be done on a rotating basis as long as they are completed quarterly.

Inventory Reconciliation of Controlled Substances

16 CCR § 1715.65

45-Day Comments

Comment Period Closed

October 31, 2016

Martinez, Lori@DCA

From: AmeriPharma Legal <legal@harperspharmacy.com>
Sent: Thursday, October 27, 2016 1:55 PM
To: Martinez, Lori@DCA
Cc: Andrew Harper, Pharm.D
Subject: Re: Costs and Alternatives of Proposed Amendment Section 1715.61
Attachments: 82E09890-5C3C-4740-BF0B-9FA0A9141ED1[33].jpg

Dear Ms. Martinez:

We have reviewed the proposed language of the Amendment referenced above and would like to express our concerns regarding the noticeable increase in operating costs that this adoption will result in for pharmacies (especially significant for privately owned small pharmacies). We believe that the goals set by the Board of Pharmacy associated with this proposed amendment may be effectively achieved with a less costly alternative.

Considering the required frequency ("at least every three months") and the time consuming nature of the required task, we estimate that compliance with this rule will require a dedication of at least two full days of work to be performed by a Pharmacist in Charge within a one year period. Please note that our calculation is conservative and, depending on the nature of a particular pharmacy's business, the required time to perform this task can be considerably more in addition to requiring the efforts of more than just the PIC. The loss of two full days of work by a small pharmacy's Pharmacist in Charge and other costs associated with compiling an Inventory Reconciliation Report of Schedule II controlled substances on a quarterly bases will add considerable pressure on small pharmacies throughout California.

We have read and understand the important concerns as well as the serious nature of the problem that the Board is trying to address with the adoption of this proposed language. However, we are not convinced that in itself this new regulation will or is even intended to eliminate the problem of drug loss and diversion. This is an on-going issue and there are other regulations currently in effect that have been effectively combating the same problem. Note that current standards already require all pharmacies to perform perpetual inventories, which already serves the purpose of regular documentation and written records associated with Schedule II controlled substances. The proposed adoption of course offers the added benefits of more regular and complete inventory count. While we acknowledge the benefits of the proposed amendment, we believe the required frequency of physical counts has been chosen arbitrarily.

We respectfully recommend an alternative adoption of a language that will require yearly physical counts of all quantities of Schedule II controlled substances. We believe that this method would sufficiently meet the current goals set by the Board, especially when combined with the already existing requirement of maintaining perpetual logs. Importantly, public safety and other BOP concerns can be addressed with the fraction of the cost, labor and other hardship to be imposed on pharmacies.

Yours truly,

Gor Mnatsakanyan, Esq.
General Counsel
AmeriPharma
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Orange, CA 92868

********** Confidentiality Notice **********

Martinez, Lori@DCA

From: LauraBeth Antone <LAntone@communitymedical.org>
Sent: Wednesday, October 19, 2016 2:43 PM
To: Martinez, Lori@DCA
Cc: Bruce Lepley; Timothy Lopez
Subject: CRMC Pharmacy_BOP Proposal of Controlled Substance Inventory_October 2016
Attachments: BOP Proposal of Controlled Substance Inventory October 2016 - CRMC Pharmacy.docx

Good afternoon Lori,

Please find our documents attached for review regarding proposed modifications. If there are any further questions, please feel free to let me know.

Thank you.

LauraBeth Antone
Executive Secretary to:
Bruce Lepley, RPh
Director of Pharmacy

Community Regional Medical Center
2823 Fresno Street
Fresno, CA 93721
Office: 559-459-2101; ext52101
Cell: 559-287-0984
lantone@communitymedical.org

Community Regional Medical Center **Bruce Lepley, Director of Pharmacy**		
Section, Subdivision	**Proposed Language**	**Recommendation/Comments**
Section 1715.65. paragraph (a) Pharmacy must perform inventory of controlled substances	"Every pharmacy... shall perform... **inventory reconciliation functions...**"	**Reason for Concern:** The section is vague regarding the term reconciliation. The true definition of the word means to include nursing drug administration transactions. In a facility such as ours we have close to 500,000 drug administration transactions per month that would need to be accounted for to perform a true reconciliation which is just not feasible in the way this section implies. Clinical pharmacists performing patient care activities would have to be repurposed for perform medication inventory reconciliation. **Solution:** Remove the term reconciliation and more clearly define what is meant by "inventory functions". Define the word reconciliation to include true meaning of what is being asked.
Section 1715.65. paragraph (b) Review of inventory reconciliation report	"The pharmacist-in-charge of a pharmacy...**shall review all...inventory reconciliation reports taken...**"	**Reason for Concern:** It would not be feasible for someone or even a small team of people to review all reconciliations. True reconciliation means to review not only medications coming in but also medication that is being used (i.e. nursing drug administrations). **Solution:** Remove "inventory reconciliation reports taken" from this paragraph. We believe that this would still achieve the intent of this proposal which is for a facility to take inventory and develop policies and procedures that describe how a facility mitigates the risk of preventing losses of controlled substances.
Section 1715.65. paragraph (c) Inventory report requirements	"A pharmacy.....shall compile an Inventory reconciliation report of **all Schedule II controlled substances....**"	Reason for Concern: The term "reconciliation" is used throughout the entire proposed section. Again, this word has multiple meanings which may include validating the documented transaction of medication administration. With a facility that has over 500,000 medication administration transactions it would not be feasible to compile and validate a report that has each Schedule II medication administration that has occurred over a period of three months. It seems as if this part of the proposed regulation would be better suited for smaller clinics where the number of medication administrations would be more manageable to review.

		Solution: There needs to be a clear definition of the term "reconciliation" in order to mitigate the risk of confusion. In addition, we believe that if a pharmacy would be allowed to audit a certain proportion of inventory transactions that this would accomplish the original intent of this entire proposed rewording of this section which is to have the pharmacy be aware of inventory transactions in order to establish and maintain secure methods to prevent losses of controlled substances.
Section 1715.65. paragraph (c) part (2) Pharmacist-in-charge shall review acquisitions	"A review **of all acquisitions and dispositions of Schedule II controlled substances...**"	**Reason for Concern:** Reviewing dispositions of controlled substances includes reviewing medications that are not only wasted or sent to automated dispensing cabinets, but it also means reviewing drug administrations performed by nursing. Again, a facility such as ours has approximately 500,000 drug administrations per month that would need to be included in a disposition review. Pharmacy administrations that operate large hospital facilities would not be able to maintain the resources necessary to fulfill these proposed requirements. **Solution:** Clarify the expectation for disposition review and all transactions that would be included in the expectation and/or remove part (2) of paragraph c entirely.
Section 1715.65. paragraph (d) Reporting losses	"**Losses** shall be identified in writing and reported to the board and, when appropriate to the Drug Enforcement Administration."	**Reason for Concern:** It could be interpreted that "losses" mean that after completing an investigation that it is uncertain where the controlled substance went. Some times after investigations it is determined that a controlled substance was accidentally thrown in the trash or was put in a place that renders it non-usable. It is also not clear this is specific to Schedule II controlled substances or all controlled substances. **Solution:** Provide a definition of loss. For example "Losses are defined as circumstances where a discrepancy is created in the inventory and the whereabouts of the Schedule II controlled substance in question is unknown after an investigation performed by the pharmacist in charge." Also, please

		clarify which classes of controlled substances paragraph (d) is referring to.
Section 1715.65. paragraph (g) Separate Inventory Reconciliation Report	"For inpatient hospital pharmacies, a **separate Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.**"	Reason for Concern: The section is vague regarding the term reconciliation. The true definition of the word means to include nursing drug administration transactions. In a facility such as ours we have close to 500,000 drug administration transactions per month and of these approximately 10% are CII drug administration's that would need to be accounted for to perform a true reconciliation which is just not feasible in the way this section implies. Pharmacy administrations that operate large hospital facilities would not be able to maintain the resources necessary to fulfill these proposed requirements. Clinical pharmacists performing patient care activities would have to be repurposed for perform medication inventory reconciliation. Solution: Provide a clear definition of the term "reconciliation". In addition, provide an example in the section that would make it clear what the expectations are for hospitals to fulfill this requirement. Most of us Pharmacy Directors believe that hospitals generally operate in the same general manner so providing an example in this proposed section would help make it clear of the expectation in this paragraph.

Section 1715.65. paragraph (h) part (1) Accounting for automated drug delivery systems	"The pharmacist-in-charge of an inpatient hospital pharmacy...shall ensure that:...**All controlled substances added to an automated drug delivery system are accounted for;**"	**Reason for Concern:** We are not sure if this section is referring to all schedule classes of controlled substances. In addition, there are innate measures in place when using automated dispensing cabinets to account for controlled substance inventories. Uncertain if this section is referring to those inherit measures already in place when using automated dispensing cabinets. Depending upon what is being asked could lead to more comments from hospital pharmacies. **Solution:** Most Hospital Pharmacy Directors agree that in terms of automated dispensing machines there is a general/common workflow that is used in hospitals. Therefore, it would be extremely beneficial for this section to provide some specific examples of what is meant to meet the expectation in this paragraph (h) part (1). This would mitigate the risk of misinterpreting of what is being requested.
Section 1715.65. paragraph (h) part (4) Confirming Losses of Controlled Substances	"**Confirmed losses** of controlled substances are reported to the board; and"	**Reason for Concern:** It could be interpreted that "losses" mean that after completing an investigation that it is uncertain where the controlled substance went. Some times after investigations it is determined that a controlled substance was accidentally thrown in the trash or was put in a place that renders it non-usable. In these instances we know what happened to the medication and at times we actually have the medication but it is no longer usable and has to be placed out of service. Lastly, in this section, it is also not clear if this is specific to Schedule II controlled substances or all controlled substances. **Solution:** Provide a definition of loss and which controlled substances this applies to. For example "Losses are defined as circumstances where a discrepancy is created in the inventory and the whereabouts of the controlled substance in question is unknown after an investigation performed by the pharmacist in charge." This part could also be combined with paragraph (d).

Section 1715.65. paragraph (h) part (5) Reporting losses	"...controlled drugs but **unable to identify the cause** within 30 days **shall take additional steps to identify the origin of the losses, and improve security** of controlled substance access to prevent losses."	**Reason for Concern:** It could be interpreted that "losses" mean that after completing an investigation that it is uncertain where the controlled substance went. Some times after investigations it is determined that a controlled substance was accidentally thrown in the trash or was put in a place that renders it non-usable. In these situations when the medication is accounted for but not usable, this should be excluded from the term "loss". In addition, the recourses described for taking "additional steps" to step up security are limited after periods of time that go by. A good system could continue to exist without having the exact requirement of "taking additional steps" to your security control/surveillance. When you look at the number of transactions that occur in large hospital facilities, even a 0.00001% occurrence rate of loss would translate to possibly more than one discrepancy in a given year. Therefore to mandate that each time that an additional measure is taken when a loss occurs would mean that the facility would run out of additional steps to take after one year of evaluating. Lastly, it is also not clear this is specific to Schedule II controlled substances or all controlled substances. **Solution:** Provide a definition of loss. For example "Losses are defined as circumstances where a discrepancy is created in the inventory and the whereabouts of the Schedule II controlled substance in question is unknown after an investigation performed by the pharmacist in charge." Lastly, remove the requirement of "taking additional steps" and replace the verbiage with the facility having to defend/explain the current measures that are in place and to explain the rationale if additional measures are not taken or put into place.

Martinez, Lori@DCA

From: Berton, Lauren N. <Lauren.Berton@CVSHealth.com>
Sent: Thursday, October 27, 2016 8:25 AM
To: Martinez, Lori@DCA
Subject: CVS Health Comments on Proposed Regulation Section 1715.65
Attachments: CVS Health Comments on Proposed Regulation Section 1715.65.pdf

Good Morning Lori,

Please find attached CVS Health comments in regards to proposed regulation 1715.65.

Thank you,

Lauren

Lauren Berton, PharmD | Director, Pharmacy Regulatory Affairs
c 540-604-3661 | **f** 401-733-0479
CVS Health | One CVS Drive, Mail Code 2325, Woonsocket, RI 02895

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CVSHealth

Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

October 26, 2016

Lori Martinez
California State Board of Pharmacy
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834

Re: CVS Health Comments on Proposed Regulation Section 1715.65, Inventory Reconciliation Report of Controlled Substances

Dear Ms. Martinez:

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies located across the United States. CVS Health appreciates the opportunity to submit comments on the California State Board of Pharmacy proposed regulation section 1715.65 regarding inventory reconciliation reports of controlled substances. We would also like to thank the Board for their continued vigilance to continuously improve the laws and regulations that guide pharmacists and pharmacy technicians serving California patients.

CVS Health is requesting clarification on the applicability of this regulation to all controlled substances or only Schedule II controlled substances. The title of the proposed regulation along with proposed language in 1715.65(a) and (b) refers to inventory and reconciliation functions being performed and requires the pharmacist-in-charge or the consultant pharmacist to review the inventory reconciliation reports for controlled substances. However, language in 1715.65(c) only requires the inventory report to be prepared for all Schedule II controlled substances at least every three months. We request that the board amend the language in the title as well as sections (a) and (b) to indicate applicability only to Schedule II controlled substances, as has been discussed in previous board meetings.

Additionally, CVS Health requests that the board allow pharmacies with perpetual inventories to be deemed compliant with 1715.65(a), (b), (c), and (e). When a perpetual inventory is kept, acquisitions are added to the inventory on the day the pharmacy receives the Schedule II controlled substance and the remaining balance on hand is confirmed and counted with each disposition. This allows pharmacies with perpetual inventories to identify any drug loss or diversion of Schedule II controlled substances much sooner than the current requirement of at least of every three months. If the board feels that the inventory report must be generated and completed at least every three months, we do request that the board consider allowing pharmacies to compare their acquisitions and dispositions to their perpetual inventory log rather than a physical count be completed and compared.

In subsection (e), the proposed regulation requires that the inventory reconciliation report be dated and signed by those performing the inventory and countersigned by the pharmacist in charge. We request that the board clarify that if the pharmacist in charge is the individual completing the inventory, that no counter signature is needed.

CVS Health appreciates the opportunity to submit comments for proposed regulation 1715.65 Inventory Reconciliation Report of Controlled Substances. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,

Lauren Berton PharmD

CVSHealth

Lauren Berton, PharmD | One CVS Drive | Mail Code 2325 | Woonsocket, RI 02895 | T: 540-604-3661

Lauren Berton, PharmD.
Director, Pharmacy Regulatory Affairs
CVS Health

K. Scott Guess, Pharmacist
Pharm.D., MS Pharm., RPh., DAAPM
2003 S. Miller St. Santa Maria, CA 93454
Voice: 805-928-4700 Fax: 805-928-4710 Cell: 805-714-3908
KSG.PharmD@outlook.com

Received
SEP 30 2016
California State
Board of Pharmacy

California Board of Pharmacy
1625 North Market
Sacramento, CA 95834

27 September, 2016

Regarding: Public comments for the proposed modifications to the text of Title 16 CCR § 1715.65, related to Reconciliation and Inventory Report of Controlled Substances.

Dear Members of the California Board of Pharmacy;

I propose a modification to the text of 1715.65 to include that "*If the pharmacy employs a perpetual inventory for Schedule II drugs the requirement for every 90-day physical count is waived*" or "*A current and up to date Schedule II perpetual inventory will satisfy the physical count requirement*".

In medicine there are usually two types of tests; inexpensive high-sensitivity, low-specificity test used for screening, and costlier high-sensitivity, high-specificity tests use for confirmatory diagnostics. It appears to me that the Board is going straight to the costlier high sensitivity-high specificity test to detect internal controlled substances diversion when a less costly screening test would suffice in most (90% per Board statements) cases.

I performed a simple experiment. I timed how long it took to count my Schedule II inventory; 90 minutes to count 120 SKU's. I have an electronic tablet counter that accelerated this process, hand counting would double that time. Since controlled substances counts must be done before or after the business day; that means 1.5-3 hours of unreimbursed overtime! This is a level of sensitivity that is not needed until a shortage is discovered; at which point we move to the high-sensitivity, high-specificity, short interval test which are: full count and weekly in-out audit to narrow in on the diversion event(s). Regulation that is overly burdensome, or costly may no longer benefit the public as intended.

A note about In-Out Audits. The purchases numbers (In) must come directly from the supplier web-site or summary report, and cannot rely on in-store invoices that could be incomplete because of diversionary practices by staff.

Question. How does the board intend to address the potential issue that the person responsible for performing this audit IS the person that is diverting the drug?

Received
SEP 30 2016
California State
Board of Pharmacy

Respectfully,

RPH 37953

K. Scott Guess

Martinez, Lori@DCA

From: scott guess <KSG.PharmD@outlook.com>
Sent: Friday, September 30, 2016 11:54 AM
To: Martinez, Lori@DCA
Subject: an anti-diversion consideration for the Board

Dear Ms. Martinez,

I have mailed a public comment for 1715.65. But with internal diversion being such a problem I would like to offer an additional solution for the Board to consider.

Wholesalers, with very few exceptions, do not/will not accept Schedule II drugs back for return of overstock, deceased patient, order error, or any reason. Once a C-II drug is purchased by a pharmacy that pharmacy owns the drug until it either sells, is stollen or expires. This puts unwanted drug in pharmacies all over the state, and creates an opportunity ripe for diversion.

I propose the Board enact regulation that **requires wholesalers, suppliers, et. al., to accept all in date, sealed container, controlled substances, purchased from them, as returned goods for any reason using the same returns policies in place for legend drugs.**

The financial impact would be minimal since all wholesalers have legend and C 3-5 drug returns structures and processes in place.
The risk of diversion is greatly decreased when unwanted stock is removed from the pharmacy.
Product availability is increased when unwanted drug is retuned to the supply chain.

Thanks for your time,
Scott

K. Scott Guess, Pharm.D., MS Pharm., RPh., DAAPM.
RPh 37953
e-mail: KSG.PharmD@outlook.com
Cell: 805-714-3908

Martinez, Lori@DCA

From:	Mary Staples <mstaples@NACDS.org>
Sent:	Friday, October 14, 2016 8:19 AM
To:	Martinez, Lori@DCA
Cc:	Sodergren, Anne@DCA
Subject:	NACDS Comments on Proposed Regulation Section 1715.65, Inventory Reconciliation Report of Controlled Substances
Attachments:	CA NACDS Cmts CS 10-15-16.pdf

Please accept our comments on the proposed regulation on controlled substance reporting for the record.

Mary Staples
Director, State Government Affairs

NACDS
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Southlake, TX 76092
817.442.1155
817.442.1140 Fax
817.308.2103 Cell
mstaples@nacds.org

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 11, 2016

Lori Martinez
California State Board of Pharmacy
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834

Re: NACDS Comments on Proposed Regulation Section 1715.65, Inventory Reconciliation Report of Controlled Substances

Dear Ms. Martinez:

On behalf of our twenty chain pharmacy member companies that operate more than approximately 4,117 pharmacies in the state of California, the National Association of Chain Drug Stores (NACDS) is writing to submit comments on the Board of Pharmacy's proposed changes to regulations addressing controlled substances inventory requirements. We are asking the Board to change its approach towards inventory reconciliation and loss reporting to target only careless or bad actors. In the alternative, if the Board is unwilling to alter the proposed approach, we are asking for several points of clarification and a few modifications to the proposed language to help pharmacies more effectively implement the regulation.

As a better course of action than the Board's proposed Inventory Reconciliation Report system (IRR) that would be applicable to all pharmacies, we ask the Board to develop a higher regulatory standard or additional standards for loss reporting for only those pharmacies that have multiple loss incidents and have not provided timely notice of theft or loss to the Board. These pharmacies should be the target of additional regulatory oversight, not all pharmacies within the state. Looking at NACDS' California members, many of our pharmacies have existing processes for identifying potential losses and taking appropriate action. The Board's proposed system would be duplicative. Instead of implementing a standard that would impose additional administrative burdens on all California pharmacies, we believe that the Board should target its approach to pharmacies with a history of loss reporting problems.

In the alternative, if the Board does not alter its approach to loss reporting, we seek the following modifications and clarifications to the Board's proposal. First, as a matter of clarification, we ask the Board to specify whether the proposed regulation applies to all controlled substances or only Schedule II drugs. In subsection (a), the proposal references all controlled substances, but throughout the rest of the proposal, the language refers mostly to Schedule II drugs. Pharmacies will have trouble complying with the proposal without some form of clarification as to the scope of the proposed regulation.

Second, as to subsection (c)(2), NACDS asks for clarification as to whether compliance is met if a pharmacy compares their acquisitions and dispositions against their perpetual inventory logs rather than comparing a physical count against invoices and dispensing data. The latter would be very labor intensive and missing or misfiled invoices could lead to falsely reported discrepancies. Along the same lines of efficiency, NACDS requests that the Board only require this comparison for variances and not all Schedule II drugs, as doing so would be very time-consuming.

Third, with regard to subsection (c)(4), we seek clarification from the Board. The language references maintaining Inventory Reconciliation Report (IRR's) in a readily retrievable form for at least 3 years. However, NACDS members are unclear as to whether or not the Board is asking for records to be pulled out or duplicated to create a "packet" for each IRR. If so, we would ask that the Board reconsider such an interpretation. Rather, pharmacy compliance with subsection (c)(4) should be met by the fact that pharmacy inventories, purchase invoices, returns, and related documents are already readily retrievable within the pharmacy and that dispensing data is already maintained in an electronica readily retrievable format. We ask the Board to recognize that running and filing additional reports would be duplicative and unnecessary.

Fourth, subsection (d) would require losses to be identified in writing and reported to the Board. NACDS members already file standard loss reporting files with the Board and, when appropriate, the DEA. Our members seek clarification as to whether the Board expects loss reports tied to reconciliation to be filed separately from the standard loss reporting files.

Finally, in subsection (e) the Board proposes requiring the IRR to be signed by the person doing the inventory and counter-signed by the pharmacist-in-charge (PIC). However, situations may arise where the PIC is the person doing the inventory. In such a situation, we request clarification that there is no need for a counter-signature, where the PIC is the person doing the inventory. We also request modification to the proposed language to make clear that either manual or electronic signatures are acceptable in signing the IRR.

We thank you for considering our comments. We hope the Board will change its approach towards inventory reconciliation and loss reporting to target only careless or bad actors, or at least clarify and modify the proposed language.

Sincerely,

Mary Staples
Director, State Government Affairs

cc: Anne Sodergren

Martinez, Lori@DCA

From: Tou, Michael P <Michael.Tou@providence.org>
Sent: Wednesday, October 12, 2016 5:15 PM
To: Martinez, Lori@DCA
Subject: Providence Health & Services | Inventory Reconciliation Report of Controlled Substances | Proposed Rule
Attachments: image001.jpg; image002.jpg; image003.jpg; image004.jpg; image005.jpg; 10.12.16 Providence Comments on Inventory Reconciliation Report of Controlled Substances.pdf

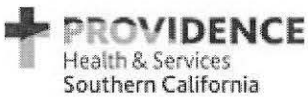
Good afternoon Lori,

On behalf of Providence Health & Services, I am submitting comments in response to the proposed rule on Inventory Reconciliation Report of Controlled Substances. We greatly appreciate the Board's efforts to incorporate our recommendations from the prior version in the current draft.

Thank you,

Michael

Michael Tou, MPA | Director, Government Relations | Providence Health & Services, Southern California |
Office: (310) 793-8093 | Mobile: (818) 512-4837 | 20555 Earl Street, Torrance CA 90503



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Southern California Region
20555 Earl Street
Torrance, CA 90503

california.providence.org

PROVIDENCE
Health & Services
Southern California

October 12, 2016

California State Board of Pharmacy
Attn: Ms. Lori Martinez
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

RE: Inventory Reconciliation Report of Controlled Substances, Notice of Proposed Action, Articles 2 of Division 17 of Title 16 of the California Code of Regulations, Section 1715.65. Comment Period: September 16, 2016 to October 31, 2016.

Dear Ms. Martinez:

Providence Health & Services in Southern California appreciates the opportunity to submit comments on the proposed regulations for inventory reconciliation report of controlled substances.

Providence Southern California is a not-for-profit organization dedicated to providing quality and compassionate health care and reaching out to the poor and vulnerable in the communities it serves. Providence operates six award-winning acute-care medical centers in the Los Angeles area, providing a full continuum of health care services: Providence Holy Cross Medical Center in Mission Hills, Providence Little Company of Mary Medical Centers in Torrance and San Pedro, Providence Saint John's Health Center in Santa Monica, Providence Saint Joseph Medical Center in Burbank, and Providence Tarzana Medical Center. Providence operates pharmacies at each of our six medical centers and another pharmacy at the Disney Family Cancer Center in Burbank.

DETAILED RECOMMENDATIONS AND COMMENTS

For ease of reference, we have organized our detailed comments in a matrix. On the left is the location of the language as proposed in the rule; in the center column is the language contained in that section. On the right, we propose new language either by tracked deletions or by additions in red italics.

Section	Proposed Language	Providence Health & Services Comments/Recommendations
1715.65(b)	"The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section."	*"The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent theft or significant loss ~~losses~~ of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section."*

		Providence recommends that the Board amend section 1715.65(b) to align with DEA Form 106 ("Report of Theft of Loss of Controlled Substances" and **21 C.F.R. § 1301.76**(b).
1715.65(d)	"Losses shall be identified in writing and reported to the board, when appropriate, to the Drug Enforcement Administration. Likely causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report."	*"~~Losses~~ Theft or significant loss shall be identified in writing and reported to the board, when appropriate, to the Drug Enforcement Administration. Likely causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report."* Providence recommends that the Board amend section 1715.65(d) to align with DEA Form 106 ("Report of Theft of Loss of Controlled Substances" and **21 C.F.R. § 1301.76**(b).
1715.65(h)(1)(2)(3)(4)(5)	The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that: 1) All controlled substances added to an automated drug delivery system are accounted for; 2) Access to automated delivery drug systems is limited to authorized facility personnel; 3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; 4) Confirmed losses of controlled substances are reported to the board; and 5) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.	*The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:* *1) All controlled substances added to an automated drug delivery system are accounted for;* *2) Access to automated delivery drug systems is limited to authorized facility personnel;* *3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed;* *4) ~~Confirmed~~ Theft or significant losses of controlled substances are reported to the board; and* *5) A pharmacy or clinic identifying theft or significant losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of*

		controlled substance access to prevent losses. Providence recommends that the Board amend section 1715.65(d) to align with DEA Form 106 ("Report of Theft of Loss of Controlled Substances" and **21 C.F.R. § 1301.76**(b). The proposed rule imposes requirements on a pharmacist-in-charge for offsite automated drug delivery systems, such as skilled nursing facilities. Providence requests clarification from the Board as to how it will enforce this requirement on facilities licensed by the California Department of Public Health (CDPH).

Thank you for this important opportunity to comment on the proposed regulations. Providence asks the Board of Pharmacy to give full and careful consideration to our comments and recommendations.

Sincerely,

Michael Tou
Director, Government Relations

Martinez, Lori@DCA

From:	John P Teague <JTeague@pmhd.org>
Sent:	Monday, October 31, 2016 6:18 PM
To:	Martinez, Lori@DCA; Sodergren, Anne@DCA
Cc:	PHARMACISTS; ken.fukushima@cpspharm.com
Subject:	Comment regarding 1715.65
Attachments:	image001.jpg

Sorry for the late and quick response, but I feel the need to comment regarding this pending change. While I do feel there is a need to ensure controlled substances are properly secured, reconciled and inventoried the boards proposed change will place a heavy burden on hospital pharmacies especially those that are Pharmacist in Charge with minimal staffing.

Currently many hospital pharmacies and at least at my hospital we maintain a perpetual inventory in our CS (all schedules) safe that is checked monthly by 2 RPh's and we perform a district wide physical CS (all schedules) inventory annually. Together with our RN's (either 2 RN's or 2 Pharm employees) we also perform weekly inventory of all automated dispensing machines on our nursing units. Compliance is our number one goal, but having to inventory each satellite automated dispensing machine every 3-months using pharmacy staff would entail having to schedule time in the early morning or late evening in order to cover approximately 20+ automated machines with 2 pharmacists. It is also difficult as you cannot perform inventory in all locations at the same time, so inventory reports are often generated at the main pharmacy prior to the begin of inventory at the machine. Inevitably these differences in time between inventory report generation and the start of the machine inventory creates differences between the report and inventory at the machine; these discrepancies are not theft/loss diversion issues but they do take time to validate discrepancy in dating and to generate the reports that must be attached to the inventory which validate the discrepancy with a valid removal of medication

Thank you,

John P. Teague, Pharm.D.
Director of Pharmacy
Pioneers Memorial Healthcare District
207 West Legion Rd.
Brawley, CA 92227
760-351-3367
jteague@pmhd.org

PIONEERS
MEMORIAL HEALTHCARE DISTRICT

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Martinez, Lori@DCA

From: John P Teague <JTeague@pmhd.org>
Sent: Monday, October 31, 2016 7:04 PM
To: John P Teague
Cc: Martinez, Lori@DCA; Sodergren, Anne@DCA; PHARMACISTS; ken.fukushima@cpspharm.com
Subject: Re: Comment regarding 1715.65
Attachments: image001.jpg

http://www.ashp.org/menu/AboutUs/ForPress/PressReleases/PressRelease.aspx?id=950&utm_source=Real%20Magnet&utm_medium=Email&utm_campaign=104498696

I encourage the board to review ASHP guideline attached above prior to ruling. Below is a message from ashp

ASHP Publishes Controlled Substances Diversion Prevention Guidelines

ASHP on Friday published the first set of national guidelines designed to help healthcare organizations devise and implement strategies to prevent the diversion of controlled substances. The guidelines include a framework for creating a collaborative, comprehensive controlled substances diversion prevention program to protect patients, employees, organizations, and the community.

Thanks,
John Teague
Director of Pharmacy
PMHD
(760)351-3367

On Oct 31, 2016 at 6:18 PM "John P Teague" <JTeague@pmhd.org> wrote:

Sorry for the late and quick response, but I feel the need to comment regarding this pending change. While I do feel there is a need to ensure controlled substances are properly secured, reconciled and inventoried the boards proposed change will place a heavy burden on hospital pharmacies especially those that are Pharmacist in Charge with minimal staffing.

Currently many hospital pharmacies and at least at my hospital we maintain a perpetual inventory in our CS (all schedules) safe that is checked monthly by 2 RPh's and we perform a district wide physical CS (all schedules) inventory annually. Together with our RN's (either 2 RN's or 2 Pharm employees) we also perform weekly inventory of all automated dispensing machines on our nursing units. Compliance is our number one goal, but having to inventory each satellite automated dispensing machine every 3-months using pharmacy staff would entail having to schedule time in the early morning or late evening in order to cover approximately 20+ automated machines with 2 pharmacists. It is also difficult as you cannot perform inventory in all locations at the same time, so inventory reports are often generated at the main pharmacy prior to the begin of inventory at the machine. Inevitably these differences in time between inventory report generation and the start of the machine inventory creates differences between the report and inventory at the machine; these discrepancies are not theft/loss diversion issues but they do take time to validate discrepancy in

dating and to generate the reports that must be attached to the inventory which validate the discrepancy with a valid removal of medication

Thank you,

John P. Teague, Pharm.D.

Director of Pharmacy

Pioneers Memorial Healthcare District

207 West Legion Rd.

Brawley, CA 92227

760-351-3367

jteague@pmhd.org

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California State Board of Pharmacy
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Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item V: Discussion and Consideration of Proposed Regulation to Amend 16 CCR Sections 1735.2 and 1751 Relating to the Compounding Self-Assessment Form

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Attachment 3

Background:

The purpose of a self-assessment is to promote compliance of businesses regulated by the board through self-examination and education. Because the board's self-assessments forms are a compilation of Pharmacy Law, modifications must be made on an annual basis to incorporate changes in the law that are enacted since the last revision to the self-assessment forms.

Because of the mandate to have these forms completed no later than July 1, 2017 of each odd-numbered year, it is necessary to update these forms via regulation adoption prior to July 2017.

Regarding the compounding self-assessment form:

At the August 31, 2016, Enforcement and Compounding Committee Meeting, the committee reviewed and discussed a new compounding self-assessment form that would reflect new regulation requirements and new compounding law enacted since the last iteration of the compounding self-assessment form. The proposed new form includes the new compounding regulation components that will take effect January 1, 2017.

At the October 2016 Board Meeting, the meeting agenda inadvertently did not include the compounding self-assessment form. As a result, the board could not consider this self-assessment form when it reviewed and moved to public notice the self-assessment forms for pharmacies and wholesalers.

At this meeting:

The board is asked to motion and move to the initial 45-day notice period the compounding self-assessment form provided in **Attachment 3.** Staff also specifically request the following amendment to 16 CA Code of Regulations section 1735.2:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. ~~02/12~~ 12/2016.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Attachment 3

California State Board of Pharmacy
1625 N. Market Blvd., Suite N219, Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug preparations to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed, readily retrievable and retained in the pharmacy. Do not copy a previous assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Fax: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

License #: _____ Exp. Date: _____ Other License #: _____ Exp. Date: _____

Licensed Sterile Compounding License # _____ Expiration: _____

Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging License #: _____ Exp. Date: _____

Hours: Weekdays_ _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

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PIC Initials

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties):
(Please use an additional sheet if necessary)

1. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   APP # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

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PIC Initials

COMPOUNDING SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted. Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

ALL COMPOUNDING Complete Sections 1 through 8.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

☐☐☐ 1.1 The pharmacy compounds as defined in CCR 1735(a).

☐☐☐ 1.2 Each pharmacist involved with compounding understands the definitions in CCR 1735.1.

2. Compounded Limitations and Requirements (CCR 1735.2)

Yes No N/A

☐☐☐ 2.1 The pharmacy does not compounded drug preparations prior to receipt of a valid prescription unless under the following conditions as allowed in CCR 1735.2 (b-c) (CCR 1735.2(a)). See sections 2.2 and 2.3

☐☐☐ 2.2 The pharmacy prepares and stores a limited quantity of a compounded drug preparation in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified population as defined in CCR 1735.2(b).

☐☐☐ 2.3 The pharmacy compounds a reasonable quantity of drug preparation which is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2(c) and under all of the following requirements:

- 2.3.1 Is ordered by the prescriber or the prescribers' agent on a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient sufficient for office administration; (CCR 1735.2[c][1]) **AND**
- 2.3.2 Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; (CCR 1735.2[c][2]) **AND**
- 2.3.3 Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 120-hour supply for veterinary medical practices; (CCR 1735.2[c][3]) **AND**
- 2.3.4 The pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded preparation and the nature of the prescriber's practice; (CCR 1735.2[c][4]) **AND**
- 2.3.5 Is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; (CCR 1735.2[c][5]) **AND**
- 2.3.6 Does not exceed an amount the pharmacy can reasonably and safely compound. (CCR 1735.2[c][6])

☐☐☐ 2.4. The pharmacy does NOT compound drug preparations that: (CCR 1735.2[d])

- 2.4.1 Are classified by the FDA as demonstrably difficult to compound; (CCR 1735.2[d][1])

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PIC Initials

2.4.2 Appear on an FDA list of drugs that have been withdrawn or removed from the market; (CCR 1735.2[d][2]) or

2.4.3 Are copies or essentially copies of one or more commercially available drug products. (CCR 1735.2[d][3])

Yes No N/A

☐☐☐ 2.5 The pharmacy does not compound drug preparations until it has prepared a written master formula document that includes the following elements: (CCR 1735.2[e][1-8])

- 2.5.1 Active ingredients used.
- 2.5.2 Equipment to be used.
- 2.5.3 Beyond use date (BUD).
- 2.5.4 Inactive ingredients used.
- 2.5.5 Specific and essential compounding steps.
- 2.5.6 Quality reviews required at each step.
- 2.5.7 Post-compounding process or procedures, if required.
- 2.5.8 Instructions for storage and handling.

☐☐☐ 2.6 The master formula for a drug preparation not routinely compounded by the pharmacy may be recorded on the prescription document itself. (CCR 1735.2[f])

☐☐☐ 2.7 The pharmacists performing or supervising compounding understand they are responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed. (CCR 1735.2[g])

☐☐☐ 2.8 All chemicals, bulk drug substances, drug preparations and other components used for drug compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2[h])

☐☐☐ 2.9 Every compounded drug preparation is given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and is determined based on the professional judgment of the pharmacist performing or supervising the compounding. (CCR 1735.2[i])

- 2.9.1 For non-sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][1][A-F])
  - 2.9.1.1 The shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
  - 2.9.1.2 The chemical stability of any one ingredient in the compounded drug preparation;
  - 2.9.1.3 The chemical stability of the combination of all ingredients in the compounded drug preparation,
  - 2.9.1.4 180 days for non-aqueous formulations,
  - 2.9.1.5 14 days for water-containing oral formulations, and
  - 2.9.1.6 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.
- 2.9.2 For sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][2][A-D])
  - 2.9.2.1 The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation,
  - 2.9.2.2 The chemical stability of any one ingredient in the sterile compounded drug preparation,
  - 2.9.2.3 The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
  - 2.9.2.4 The beyond use date assigned for sterility in CCR 1751.8.
- 2.9.3 Extension of a beyond use date is supported by the following: (CCR 1735.2[i][3][A-C])
  - 2.9.3.1 Method Suitability Test,
  - 2.9.3.2 Container Closure Integrity Test, and

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2.9.3.3 Stability Studies.

2.9.4 The finished drugs or compounded drug preparations tested and studied are compounded using the same identical components or ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation. (CCR 1735.2[i][4])

2.9.5 Shorter dating is used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[i][5])

☐☐☐ 2.10 Self-assessment is completed, as required, prior to compounding a drug preparation. (CCR 1735.2[k])

☐☐☐ 2.11 Packages of ingredients, both active and inactive, which lack a supplier's expiration date are subject to the following limitations: (CCR 1735.2[l])

2.11.1 Ingredients are not used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

2.11.2 Ingredients are not used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Recordkeeping for Compounded Drug Preparation (CCR 1735.3)

Yes No N/A

☐☐☐ 3.1 The pharmacy makes and retains a record for each compounded drug preparation which includes, at least, the following: (CCR 1735.3[a][1-2])

3.1.1 The master formula document.

3.1.2 A compounding log consisting of a single document containing all of the following:

3.1.2.1 The name and strength of the compounded drug preparation.

3.1.2.2 The date the drug preparation was compounded.

3.1.2.3 The identity of the pharmacy personnel who compounded the drug preparation.

3.1.2.4 The identity of the pharmacist reviewing the final drug preparation.

3.1.2.5 The quantity of each component used in compounding the drug preparation.

3.1.2.6 The manufacturer or supplier, expiration date and lot number of each component.

3.1.2.7 The pharmacy assigned reference or lot number for the compounded drug preparation.

3.1.2.8 The beyond use date or beyond use date and time of the final compounded drug preparation.

3.1.2.9 The final quantity or amount of drug preparation compounded.

3.1.2.10 Documentation of quality reviews and required post-compounding process and procedures.

☐☐☐ 3.2 The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, components and drug preparations used in compounding. (CCR 1735.3[b])

☐☐☐ 3.3 Active ingredients are obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug components used to compound drug preparations are to be obtained, whenever possible, from FDA-registered suppliers. The pharmacy acquires and retains certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. (CCR 1735.3[c])

☐☐☐ 3.5 The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3[d]).

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4. Labeling of Compounded Drug Preparation (CCR 1735.4)

Yes No N/A

☐☐☐ 4.1 Each compounded drug preparation has at least the following affixed to the container on a label prior to dispensing: (CCR 1735.4[a][1-6])

- 4.1.1 Name of the compounding pharmacy and dispensing pharmacy (if different);
- 4.1.2 Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed intravenous (IV) solutions, the IV solution utilized shall be included;
- 4.1.3 Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;
- 4.1.4 The beyond use date for the drug preparation;
- 4.1.5 The date compounded; and
- 4.1.6 The lot number or pharmacy reference number.

☐☐☐ 4.2 Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient is labeled with the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5. (CCR 1735.4[b])

☐☐☐ 4.3 Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient also includes, on the container label or on a receipt provided to the patient, a statement the drug preparation has been compounded by the pharmacy. (CCR 1735.4[c])

☐☐☐ 4.4 Drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of CCR 1735.4(a), (b), and (c) are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and beyond use date. (CCR 1735.4[d])

☐☐☐ 4.5 All hazardous agents bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly. (CCR 1735.4[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains written policies and procedure for compounding which establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. (CCR 1735.5[a])

☐☐☐ 5.2 The policy and procedures are reviewed on an annual basis by the pharmacist-in-charge and are updated whenever changes are implemented. (CCR 1735.5[b])

☐☐☐ 5.3 The policies and procedures include at least the following: (CCR 1735.5[c][1-11])

- 5.3.1 Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.
- 5.3.2 A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan ensures

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all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

5.3.3 Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

5.3.4 Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

5.3.5 Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

5.3.6 Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

5.3.7 Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

5.3.8 Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

5.3.9 Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

5.3.10 Policies and procedures for ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

5.3.11 Policies and procedures for proper garbing when compounding with hazardous products; including when to utilize double shoe covers.

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

☐☐☐ 6.1 The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations which includes records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])

☐☐☐ 6.2 All equipment used to compound a drug preparation is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])

☐☐☐ 6.3 All equipment used to compound a drug preparation is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])

6.3.1 Documentation of each calibration is recorded in a form which is not alterable and is maintained and retained in the pharmacy.

☐☐☐ 6.4 When engaged in hazardous drug compounding, the pharmacy maintains written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs. (CCR 1735.6[d])

☐☐☐ 6.5 Hazardous drug compounding is completed in an externally vented physically separate room with the following requirements: (CCR 1735.6[e])

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6.5.1 Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when preparations are assigned a BUD of 12 hrs or less or when nonsterile products are compounded; and

6.5.2 Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

6.5.3 Each PEC in the room is externally vented; and

6.5.4 All surfaces within the room are smooth, seamless, impervious, and non-shedding.

☐☐☐ 6.6 This pharmacy has applied and was granted a waiver by the board for the following physical construction or alteration to a facility or physical environment. (CCR 1735.6[f])

☐☐☐ 6.6.1 Waiver approved the Board. Please see attached.

CORRECTIVE ACTION OR ACTION PLAN:

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7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

☐☐☐ 7.1 The pharmacy maintains documentation demonstrating personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating all personnel involved in compounding are trained in all aspects of policies and procedures. This training includes, but is not limited to, support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacists and all others whose jobs are related to the compounding process. (CCR 1735.7[a])

☐☐☐ 7.2 The pharmacy has developed and maintains an ongoing competency evaluation process for pharmacy personnel involved in compounding and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel. (CCR 1735.7[b])

☐☐☐ 7.3 Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

☐☐☐ 8.1 The pharmacy maintains, as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug preparation. (CCR 1735.8[a])

☐☐☐ 8.2 The pharmacy's quality assurance plan includes the written procedures and standards for at least the following:

8.2.1 Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])

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8.2.2 Qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality and labeled strength, including the frequency of testing. Frequency of routine testing and analysis is done on an annual basis. (CCR 1735.8[c])

8.2.3 Such reports are retained by the pharmacy and collated with the compounding record and master formula document. (CCR 1735.8[c])

8.2.4 Scheduled action in the event any compounded drug preparation is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])

8.2.5 Response to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing. (CCR 1735.8[e])

9. Duties of a Pharmacy Issuing a Compounded Drug Recall (B&PC 4126.9)

Yes No N/A

☐☐☐ 9.1 When the pharmacy issues a recall notice regarding a nonsterile compounded drug product, in addition to any other duties all of the following take place, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply: (B&PC 4126.9[a][1-2])

9.1.1 Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

9.1.2 The recalled drug was dispensed, or is intended for use, in this state.

☐☐☐ 9.2 A recall notice issued pursuant to subdivision (a) is made as follows: (B&PC 4126.9[b][1-3])

9.2.1 If the recalled drug was dispensed directly to the patient, the notice is be made to the patient.

9.2.2 If the recalled drug was dispensed directly to the prescriber, the notice is be made to the prescriber, who shall ensure the patient is notified.

9.2.3 If the recalled drug was dispensed directly to a pharmacy, the notice is be made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber ensures the patient is notified.

☐☐☐ 9.3 If the pharmacy has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy reports the event to MedWatch within 72 hours of the pharmacy being advised. (B&PC 4126.9[c])

COMPOUNDING STERILE DRUGS

Does the pharmacy compound sterile drug preparation? (B&PC 4127)

☐ **Yes** ☐ **No**

If yes, complete Sections 9 through 25.

FOR PHARMACIES THAT COMPOUND STERILE DRUG preparation:

10. Compounding Drug for Other Pharmacy for Parenteral Therapy

Yes No N/A

☐☐☐ 10.1 Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. (B&PC 4123)

10.1.1 The contractual arrangement is reported to the board within 30 days of commencing that compounding.

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11. Compounding Sterile from Nonsterile Ingredients; Requirements

Yes No N/A

☐☐☐ 11.1 The pharmacy compounds sterile preparations from one or more nonsterile ingredients in one of the following environments: (B&PC 4127.7)

- 11.1.1 An ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom. (B&PC 4127.7[a])
- 11.1.2 An ISO Class 5 cleanroom. (B&PC 4127.7[b])
- 11.1.3 A barrier isolator that provides an ISO Class 5 environment for compounding. (B&PC 4127.7[c])

12. Sterile Compounding; Compounding Area (CCR 1751)

Yes No N/A

☐☐☐ 12.1 The pharmacy conforms to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding. (CCR 1751[a])

Yes No N/A

☐☐☐ 12.2 The pharmacy has a compounding area designated for the preparation of sterile drug preparations in a restricted location where traffic has no impact on the performance of the Primary Engineering Control(s) (PEC). (CCR 1751[b])

- 12.2.1 The cleanroom, including the walls, ceilings, and floors, are constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.
- 12.2.2 The pharmacy is ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
- 12.2.3 The environments within the pharmacy meet at least the following standards: (CCR 1751[b])
  - 12.2.3.1 Each ISO environment is certified at least every six months by a qualified technician in accordance with Section 1751.4.
    - 12.2.3.1.1 Certification records must be retained in the pharmacy.
  - 12.2.3.2 Items related to the compounding of sterile drug preparations within the compounding area are stored in such a way as to maintain the integrity of an aseptic environment.
  - 12.2.3.3 A sink is included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains are not present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area.
  - 12.3.3.4 There is a refrigerator and where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan is in place to ensure continuity of available compounded drug preparations in the event of a power outage.

13. Sterile Compounding; Compounding Area (CCR 1250.4, 505.5 and 505.5.1)

TITLE 24, PART 2, CHAPTER 12, REGULATIONS

Yes No N/A

☐☐☐ 13.1 The pharmacy has designated area for the preparation of sterile products for dispensing which meets at least the following: (24 CCR 1250.4)

- 13.1.1 In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as laminar air flow hood or clean room. (24 CCR 1250.4[1])

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13.1.2 Has non-porous and cleanable surfaces, walls, floors, ceilings and floor coverings. (24 CCR 1250.4[2])

13.1.3 The pharmacy is arranged in such a manner that the laminar-flow hood (PEC) is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral preparations. There is sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials. (24 CCR 1250.4[3])

13.1.4 A sink with hot and cold running water is within the parenteral preparation compounding area or adjacent to it. (24 CCR 1250.4[4])

13.1.5 The pharmacy compounding sterile injectable preparations from one or more nonsterile ingredients, compounds the preparations in one of the following environments: (24 CCR 1250.4[5])

13.1.5.1 An ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

13.1.5.2 An ISO Class 5 cleanroom.

13.1.5.3 A barrier isolator that provides an ISO Class 5 environment for compounding.

Yes No N/A

☐☐☐ 13.2 The pharmacy has a designated area for the compounding of sterile preparations for dispensing which shall: (24 CCR 505.5)

13.2.1 Be ventilated in a manner not interfering with laminar air flow.

Yes No N/A

☐☐☐ 13.3 Pharmacies preparing parenteral cytotoxic agents, all compounding is conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag in-bag out design. The pharmacy ensures that contaminated air plenums under positive air pressure are leak tight. (24 CCR 505.5.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Sterile Compounding Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

☐☐☐ 14.1 In addition to the records required by section 1735.3 the pharmacy maintains at least the following records, which are in a readily retrievable, within the pharmacy: (CCR 1751.1[a][1-11])

14.1.1 Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.

14.1.2 Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

14.1.3 Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

14.1.4 Results of viable air and surface sampling.

14.1.5 Video of smoke studies in all ISO certified spaces.

14.1.6 Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

14.1.6.1 Controlled room temperature.

14.1.6.2 Controlled cold temperature.

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14.1.6.3 Controlled freezer temperature.

14.1.7 Certification(s) of the sterile compounding environment(s).

14.1.8 Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

14.1.9 Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment, incubator temperatures).

14.1.10 Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.

14.1.11 Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

☐☐☐ 14.2 The pharmacy compounds for future use pursuant to section 1735.2, and in addition to those records required by section 1735.3, the pharmacy makes and keeps records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber. (CCR 1751.1[b])

☐☐☐ 14.3 The pharmacy maintains and retains all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records are maintained as specified by Business and Professions Code section 4070 subsection (c). (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Sterile Labeling Requirements (CCR 1751.2)

Yes No N/A

☐☐☐ 15.1 In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, the pharmacy labels each compounded sterile drug preparations with at least the following information: (CCR 1751.2[a-c])

15.1.1 The telephone number of the pharmacy.

15.1.2 Instructions for storage, handling, and administration.

15.1.3 All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly.":

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Sterile Policies and Procedures (CCR 1751.3)

Yes No N/A

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☐☐☐ 16.1 The pharmacy maintains written policies and procedures for compounding and understands any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. CCR 1751.3[a])

16.2 In addition to the elements required by section 1735.5, there are written policies and procedures regarding at least the following: (CCR 1751.3[a][1-24])

- 16.2.1 Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
- 16.2.2 Airflow considerations and pressure differential monitoring.
- 16.2.3 An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
- 16.2.4 Cleaning and maintenance of ISO environments and segregated compounding areas.
- 16.2.5 Compounded sterile drug preparation stability and beyond use dating.
- 16.2.6 Compounding, filling, and labeling of sterile drug preparations.
- 16.2.7 Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.
- 16.2.8 Depyrogenation of glassware (if applicable)
- 16.2.9 Facility management including certification and maintenance of controlled environments and related equipment.
- 16.2.10 For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.
- 16.2.11 Hand hygiene and garbing.
- 16.2.12 Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.
- 16.2.13 Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.
- 16.2.14 Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments which include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.
- 16.2.15 Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.
- 16.2.16 Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- 16.2.17 Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- 16.2.18 Proper use of equipment and supplies.
- 16.2.19 Quality assurance program compliant with sections 1711, 1735.8, and 1751.7.
- 16.2.20 Record keeping requirements.
- 16.2.21 Temperature monitoring in compounding and controlled storage areas.
- 16.2.22 The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.
- 16.2.23 Use of automated compounding devices (if applicable).
- 16.2.24 Visual inspection and other final quality checks of sterile drug preparations.

☐☐☐ 16.3 For lot compounding, the pharmacy maintains ~~a~~ written policies and procedures which include~~s~~ at least the following: (CCR 1751.3[b][1-3])

- 16.3.1 Use of master formula documents and compounding logs.
- 16.3.2 Appropriate documentation.
- 16.3.3 Appropriate sterility and potency testing.

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☐☐☐ 16.4 For non-sterile-to-sterile batch compounding, the pharmacy maintains a written policies and procedures for compounding which included at least the following. (CCR 1751.2[c][1-2])

16.4.1 Process validation for chosen sterilization methods.

16.4.2 End-product evaluation, quantitative, and qualitative testing.

☐☐☐ 16.5 All personnel involved have read the policies and procedures before compounding sterile drug preparations. All personnel involved have read all additions, revisions, and deletions to the written policies and procedures. Each review is documented by a signature and date. (CCR 1751.3[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Facility & Equipment Standards for Sterile Compounding (CCR 1751.4)

Yes No N/A

☐☐☐ 17.1 No sterile drug preparation is compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations (CCR 1751.4[a])

☐☐☐ 17.2 During the compounding of sterile drug preparations, access to the areas designated for compounding is limited to those individuals who are properly attired (CCR 1751.4[b])

☐☐☐ 17.3 All equipment used in the areas designated for compounding is made of a material that can be easily cleaned and disinfected. (CCR 1751.4[c])

☐☐☐ 17.4 Cleaning is done using a germicidal detergent and sterile water. A sporicidal agent is used at least monthly (CCR 1751.4[d][1-4])

17.4.1 All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor are cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent occurs on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

17.4.2 Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment are cleaned at least monthly.

17.4.3 Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

17.4.4 All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

☐☐☐ 17.5 Disinfection, using a suitable sterile agent, occurs on all surfaces in the ISO Class 5 PEC frequently, including: (CCR 1751.4[e])

17.5.1 At the beginning of each shift;

17.5.2 At least every 30 minutes when compounding involving human staff is occurring or before each lot;

17.5.3 After each spill; and

17.5.4 When surface contamination is known or suspected.

☐☐☐ 17.6 Pharmacies preparing sterile compounded preparations are using a PEC that provides ISO Class 5 air or better air quality (CCR 1751.4[f])

17.6.1 Certification and testing of primary and secondary engineering controls are performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed which would impact the device or area.

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17.6.2 Certification is completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

17.6.2.1 Certification records are retained for at least 3 years.

17.6.3 Unidirectional compounding aseptic isolators or compounding aseptic containment isolators used outside of an ISO Class 7 cleanroom if the isolators are certified to meet the following criteria: (CCR 1751.4[f][1-3])

17.6.3.1 Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

17.6.3.2 Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

17.6.3.3 Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

17.6.4 Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom are only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

☐☐☐ 17.7 Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC.

17.7.1 Additionally, each PEC used to compound hazardous agents shall be externally vented.

17.7.2 The negative pressure PEC is certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

17.7.3 Any drug preparation compounded in a PEC where hazardous drugs are prepared are labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. (CCR 1751.4[g])

17.7.4 During hazardous drug compounding performed in a compounding aseptic containment isolator, full hand hygiene and garbing occurs. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves. (CCR 1751.4[g][1])

☐☐☐ 17.8 If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals who use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again. (CCR 1751.4[h])

☐☐☐ 17.9 Compounding aseptic isolators and compounding aseptic containment isolators used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns. (CCR 1751.4[i])

☐☐☐ 17.10 Viable surface sampling is done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling is be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling are performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is performed under dynamic conditions which simulate actual production. Viable surface

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sampling is performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy identifies the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management. (CCR 1751.4[j])

☐☐☐ 17.11 The sterile compounding area in the pharmacy has a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. (CCR 1751.4[k])

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Sterile Compounding Attire (CCR 1751.5)

Yes No N/A

☐☐☐ 18.1. When compounding sterile drug preparations the following standards are met: (CCR 1751.5[a][1-6])

18.1.1 Personal protective equipment consisting of a low non-shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers are worn inside the designated area at all times. For hazardous compounding, double shoe covers are worn.

18.1.2 Personal protective equipment is donned and removed in an ante-area or immediately outside the segregated compounding area.

18.1.3 Personnel dons personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place which documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

18.1.4 Compounding personnel does not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.

18.1.5 Sterile gloves that have been tested for compatibility with disinfection by isopropyl alcohol are worn. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves are routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

18.1.6 Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails are excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

☐☐☐ 18.2. When preparing hazardous agents, appropriate gowns and personal protective equipment are worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator). (CCR 1751.5[b])

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19. Sterile Compounding Consultation; Training of Sterile Compounding Staff. (CCR 1751.6)

Yes No N/A

☐☐☐ 19.1 Consultation is available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy. (CCR 1751.6[a])

☐☐☐ 19.2 The pharmacist-in-charge ensures all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents. (CCR 1751.6[b])

☐☐☐ 19.3 Records of training and demonstrated competence are available for each individual and shall be retained for three years beyond the period of employment (CCR 1751.6[c])

☐☐☐ 19.4 The pharmacist-in-charge is responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations (CCR 1751.6[d])

☐☐☐ 19.5 The pharmacy complies with at least the following training requirements: (CCR 1751.6[e])

19.5.1 The pharmacy establishes and follows a written program of training and performance evaluation designed to ensure each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following: (CCR 1751.6[e][1][A-J])

19.5.1.1 Aseptic technique.
19.5.1.2 Pharmaceutical calculations and terminology.
19.5.1.3 Sterile preparation compounding documentation.
19.5.1.4 Quality assurance procedures.
19.5.1.5 Aseptic preparation procedures.
19.5.1.6 Proper hand hygiene, gowning and gloving technique.
19.5.1.7 General conduct in the controlled area (aseptic area practices).
19.5.1.8 Cleaning, sanitizing, and maintaining of the equipment and the controlled area.
19.5.1.9 Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.
19.5.1.10 Container, equipment, and closure system selection.

19.5.2 Each person engaged in sterile compounding has successfully completed practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Sterile Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

☐☐☐ 20.1 There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

20.1.1 The quality assurance program shall include at least the following (CCR 1751.7[a][1-3])

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20.1.1.1 Procedures for cleaning and sanitization of the sterile preparation area.
20.1.1.2 Actions to be taken in the event of a drug recall.
20.1.1.3 Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

☐☐☐ 20.2.1 The pharmacy and each individual involved in the compounding of sterile drug preparations successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. (CCR 1751.7[b][1])

20.2.2 Each individual's competency is revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients. (CCR 1751.7[b][2])

20.2.3 The pharmacy's validation process on aseptic technique and aseptic area practices is to be revalidated whenever: (CCR 1751.7[b][3][A-B])

20.2.3.1 The quality assurance program yields an unacceptable result.

20.2.3.2 There is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner affecting airflow or traffic patterns, or when improper aseptic techniques are observed.

20.2.4 The pharmacy must document the validation and revalidation process (CCR 1751.7[b][4]).

☐☐☐ 20.3 All sterile compounding personnel have successfully completed an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice has successfully completed a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations. (CCR 1751.7[c])

☐☐☐ 20.4 Re-evaluation of garbing and gloving competency occurs at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients. (CCR 1751.7[d])

☐☐☐ 20.5 Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing is performed per USP chapter 71 and pyrogen testing confirms acceptable levels of pyrogen per USP chapter 85 limits before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing applies regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients which were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparation. (CCR 1751.7[e][1])

20.5.1 The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens: (CCR 1751.7[e][2][A-B])

20.5.1.1 Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

20.5.1.2 Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

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21. Beyond Use Dating for Sterile Compounded Drug Preparations (CCR 1751.8)

Yes No N/A

☐☐☐ 21.1 Every sterile compounded drug preparation is given and labeled with a beyond use date incompliance with 1735.2 and does not exceed the shortest expiration date or beyond use date of any ingredient in sterile the compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and , in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia would justify an extended beyond use date, conforms to the following limitations:

☐☐☐ 21.2 The beyond use date states storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[a])

- 21.2.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; **and**
- 21.2.2 The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; **and**
- 21.2.3 Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

☐☐☐ 21.3 The beyond use date states storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[b])

- 21.3.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and
- 21.3.2 The compounding process involves complex aseptic manipulations other than the single-volume transfer; and
- 21.3.3 The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

☐☐☐ 21.4 The beyond use date states storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies: (CCR 1751.8[c])

- 21.4.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

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☐☐☐ 21.5 The beyond use date states storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[d])

21.5.1 The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

21.5.2 The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

21.5.3 The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

☐☐☐ 21.6 Any sterile compounded drug preparation which was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation is be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process.

21.6.1 Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time.

21.6.2 If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded.

21.6.3 "Immediate use" preparations are only compounded in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO Class 5 environment and where failure to administer could result in loss of life or intense suffering.

21.6.4 Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures. (CCR 1751.8[e])

☐☐☐ 21.7 The beyond use date for any compounded allergen extracts is the earliest manufacturer expiration date of the individual allergen extracts. (CCR 1751.8[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

22. Single-Dose and Multi-Dose Containers; Limitations on Use (CCR 1751.9)

Yes No N/A

☐☐☐ 22.1 Single-dose ampules are for immediate use only, and once opened are not stored for any time period. (CCR 1751.9[a])

☐☐☐ 22.2 Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within the following time limit, depending on the environment: (CCR 1751.9[b])

22.2.1 When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour.

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22.2.2 When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container remains within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

22.2.3 If the puncture time is not noted on the container, the container is immediately discarded.

☐☐☐ 22.3 Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications is discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container is immediately be discarded. (CCR 1751.9[c])

23. Sterile Compounding Reference Materials (CCR 1751.10)

☐☐☐ 23.1 The pharmacy has current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy. (CCR 1751.10)

24. Sterile Compounding License Renewal (B&PC 4127.1, 4127.2)

A license to compound sterile drug preparation will not be renewed until the following is met: (B&PC 4127.1, 4127.2)

Yes No N/A

☐☐☐ 24.1 The pharmacy has been inspected by the board and is in compliance with applicable laws and regulations.

☐☐☐ 24.2 The board reviews a current copy of the pharmacy's policies and procedures for sterile compounding.

☐☐☐ 24.3 The board is provided with copies of all inspection reports conducted of the pharmacy's premises in the prior 12 months documenting the pharmacy's operation.

☐☐☐ 24.4 The board is provided with copies of any reports from a private accrediting agency conducted in the prior 12 months documenting the pharmacy's operation.

☐☐☐ 24.5 The board receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

☐☐☐ 24.6 A nonresident pharmacy has reimbursed the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually. (B&PC 4127.2[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

25. Duties of a Pharmacy Issuing a Sterile Compounded Drug Recall (B&PC 4127.9)

Yes No N/A

☐☐☐ 25.1 The pharmacy contacts the recipient pharmacy, prescriber or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both (1) the use of or exposure to the recalled drug preparations may cause serious adverse health consequences or death; and (2) the recalled drug was dispensed or is intended for use in California. (B&PC 4127.9[a] B&PC 4127.1 and 4127.2)

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☐☐☐ 25.2 A recall notice is made to the patient if the recalled drug was dispensed directly to the patient. (B&PC 4127.9[b][1])

Yes No N/A

☐☐☐ 25.3 A recall notice is made to the prescriber if the recalled drug was dispensed directly to the prescriber. (B&PC 4127.9[b][2])

☐☐☐ 25.4 A recall notice is made to the recipient pharmacy who shall notify the prescriber or patient if the recalled drug was dispensed thereafter. (B&PC 4127.9[b][3])

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PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

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_____
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California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

To: Board Members

Subject: VI. Proposed Regulation to Amend 16 CCR 1793.5 Relating to the Pharmacy Technician Application form Incorporated by Reference

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Attachment 4

Relevant Law
Business and Professions Code Section 4202 establishes the requirements for licensure as a pharmacy technician.

Title 16 CCR Section 1793.5 establishes the application requirements for licensure as a pharmacy technician and incorporates by reference the application form.

Background
Earlier this year, Business and Professions Code section 4202 was amended to modify one of the pathways, specifically the certification pathway. This amendment takes effect January 1, 2017.

More recently, during the October 2016 board meeting, the board took action to accept either certification by the Pharmacy Technician Certification Board or certification by the ExCPT to satisfy the licensure requirement.

Because the board's application form requires updating to incorporate this change, a second regulation section must be amended.

Provided in **Attachment 4** is the draft regulation language and application form.

Staff Recommendation
Staff recommends that the board review the proposed amended language and application form and approve the proposal and initiate a rulemaking. Provided below is possible language that could be used as a motion to facilitate such action.

> Approve the draft regulation language to Section 1793.5 and the application incorporated by reference to initiate the rulemaking process. Delegate authority to the executive officer to make clarifying changes consistent with the board's policy direction upon recommendations by control agencies.

Attachment 4

Proposal to Amend Title 16 CCR § 1793.5

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" (Form 17A-5 (Rev. ~~10/15~~ 10/2016)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4402 and 4400, Business and Professions Code; and Section 11105, Penal Code.

California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

PHARMACY TECHNICIAN APPLICATION

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being considered incomplete ~~an incomplete application and a deficiency letter being mailed to you~~. An applicant for a pharmacy technician license, who fails to complete all the application requirements within 60 days after being notified by the board of deficiencies, may be deemed to have abandoned the application and may be required to file a new application, fee, and meet all the requirements which are in effect at the time of reapplication. ~~Please~~ Read all the application instructions before you complete the application.~~prior to completing this application.~~ ~~**Page 1, 2, and 3 of the application must be completed and signed by the applicant.**~~ All questions on this application must be answered. If not applicable indicate N/A. Attach additional sheets of paper if necessary.

Military Expedite ☐ **MILITARY** (Are you serving in the United States military?)
☐ **VETERAN** (Have you ever served in the United States military?)
☐ **ACTIVE DUTY MILITARY-Spouse or Partner (**~~Check here if you meet the requirements for expediting your application.)~~

Applicant Information - Please Type or Print

Applicant Information - Please Type or Print

Full Legal Name: Last Name: First Name: Middle Name:

Previous Names (AKA, Maiden Name, Alias, etc):

*Official Mailing/Public Address of Record (Street Address, PO Box #, etc):

City: State: Zip Code:

Residence Address (if different from above):

City: State: Zip Code:

Home#: ( ) Cell#: ( ) Work#: ( ) Email Address:

Date of Birth (Month/Day/Year): **Social Security # or Individual Tax ID #: Driver's License No: State:

Mandatory Education (check one box)

Please indicate how you satisfy the mandatory education requirement in Business and Professions Code Section 4202(a).

☐ High school graduate or foreign equivalent.
Attach an official embossed transcript or notarized copy of your high school transcript, or certificate of proficiency, or foreign secondary school diploma along with a certified translation of the diploma.

☐ Completed a general education development certificate equivalent.
Attach an official transcript of your test results or certificate of proficiency.

TAPE A COLOR PASSPORT STYLE PHOTOGRAPH (2"X2") TAKEN WITHIN 60 DAYS OF THE FILING OF THIS APPLICATION
NO POLAROID OR SCANNED IMAGES
PHOTO MUST BE ON PHOTO QUALITY PAPER

Pharmacy Technician Qualifying Method (check one box)

Please check one of the boxes below indicating how you qualify in order to apply for a pharmacy technician license pursuant to Section 4202(a)(1)(2)(3)(4) of the Business and Professions Code.

☐ Attached Affidavit of Completed Coursework or Graduation for: Associate degree in Pharmacy Technology, Training Course, or Graduate of a school of pharmacy

☐ Attached is a certified copy of PTCB certificate or ExCPT certificate – Date certified: _____

☐ Attached is a certified copy of your military training DD214

List all state(s) where you hold or held a license as a pharmacist, intern pharmacist and/or pharmacy technician and or another health care profession license, including California. Attach an additional sheet if necessary.

State	Registration Number	Active or Inactive	Issued Date	Expiration Date

Self-Query Report by the National Practitioner Data Bank (NPDB)

☐ Attached is the original sealed envelope containing my Self-Query Report from NPDB. (This must be submitted with your application.)

Photo ☐ Enf 1st Check ☐ Enf 2nd Check ☐ Qualify Code _____ Self-Query ☐	FP Cards/Live Scan ☐ FP Cards Sent _____ FP Fees ☐ DOJ Clear Date: _____ FBI Clear Date: _____	**FOR BOARD USE ONLY** License no. _____ Date issued _____ Date expires _____	App fee no. _____ Amount _____ Date cashiered _____

~~**You must provide a written explanation for all affirmative answers indicated below.**~~ **Please answer the following questions.**
Failure to do so may result in this application being deemed incomplete and being withdrawn.

1. Do you have a mental illness or physical illness that in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health or safety risks? **If "yes," attach a statement of explanation. If "no," proceed to #2.** Are the limitations caused by your mental illness or physical illness reduced or improved because you receive ongoing treatment or participate in a monitoring program? Yes ☐ No ☐ **If "yes," attach a statement of explanation.** If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing mental illness or physical illness to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether you are not eligible for license.	Yes ☐ No ☐
2. Have you previously engaged in the illegal use of controlled substances? If "yes," are you currently participating in a supervised substance abuse program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances? Yes ☐ No ☐ **Attach a statement of explanation.**	Yes ☐ No ☐
3. Do you currently participate in a substance abuse program or have previously participated in a substance abuse program in the past five years? If "yes," are you currently participating in a supervised substance abuse program or professional assistance program which monitors you to ensure you are maintaining sobriety? Yes ☐ No ☐ **Attach a statement of explanation.**	Yes ☐ No ☐
4. Has disciplinary action ever been taken against your designated representative, pharmacist, intern pharmacist and/or pharmacy technician license in this state or any other state? **If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.**	Yes ☐ No ☐
5. Have you ever had an application for a designated representative, pharmacist, intern pharmacist and/or pharmacy technician license denied in this state or any other state? **If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.**	Yes ☐ No ☐
6. Have you ever had a pharmacy license, or any professional or vocational license or registration denied, suspended, revoked, placed on probation or had other disciplinary action taken by this or any other government authority in California or any other state? **If "yes," provide the name of company, type of permit, type of action, year of action and state.** _____	Yes ☐ No ☐

7. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state? **If "yes," provide company name, type of permit, permit number and state where licensed.**	Yes ☐ No ☐
8. Have you ever been convicted of, or pleaded guilty or nolo contender/no contest to, any crime, in any state, the United States or its territories, a military court, or any foreign country? Include any felony or misdemeanor offense, and any infraction involving drugs or alcohol ~~with a fine of $500 or more~~. You must disclose a conviction even if it was: (1) later dismissed or expunged pursuant to Penal Code section 1203.4 et seq., or an equivalent release from penalties and disabilities provision from a non-California jurisdiction, or (2) later dismissed or expunged pursuant to Penal Code section 1210 et seq., or an equivalent post-conviction drug treatment diversion dismissal provision from a non-California jurisdiction. Failure to answer truthfully and completely may result in the denial of your application. NOTE: You may answer "NO" regarding, and need not disclose, any of the following: (1) criminal matters adjudicated in juvenile court; (2) criminal charges dismissed or expunged pursuant to Penal Code section 1000.4 or an equivalent deferred entry of judgment provision from a non-California jurisdiction; (3) convictions more than two years old on the date you submit your application for violations of California Health and Safety Code section 11357, subdivisions (b), (c), (d), or (e), or California Health and Safety Code section 11360, subdivision (b); and (4) infractions or traffic violations ~~with a fine of less than $500~~ that do not involve drugs or alcohol. ~~You may wish to provide the following information in order to assist in the processing of your application: descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident). If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required.~~ You may wish to provide the following information in order to assist in the processing of your application: 1) certified copies of the arresting agency report; 2) certified copies of the court documents; 3) and a descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required. **Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary.**	Yes ☐ No ☐

Arrest Date	Conviction Date	Violation(s)	Case #	Court of Jurisdiction (Full Name and Address)

APPLICANT AFFIDAVIT

~~You must provide a written explanation for all affirmative answers. Failure to do so will result in this application being deemed incomplete.~~ Falsification of the information on this application may constitute ground for denial or revocation of the license.

All items of information requested in this application are mandatory. Failure to provide any of the requested information may result in the application being rejected as incomplete.

Collection and Use of Personal Information. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form as authorized by Business and Professions Code sections 4200 and 4202 and Title 16 California Code of Regulations section 1793.5 and 1793.6. The California State Board of Pharmacy uses this information principally to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Mandatory Submission. Submission of the requested information is mandatory. The California State Board of Pharmacy cannot consider your application for licensure or renewal unless you provide all of the requested information.

Access to Personal Information. You may review the records maintained by the California State Board of Pharmacy that contain your personal information, as permitted by the Information Practices Act. The official responsible for maintaining records is the Executive Officer at the board's address listed on the application. Each individual has the right to review the files or records maintained by the board, unless confidential and exempt by law ~~Civil Code Section 1798.40~~.

Possible Disclosure of Personal Information. We make every effort to protect the personal information you provide us. The information you provide, however, may be disclosed in the following circumstances:

- In response to a Public Act request (Government Code section 6250 and following), as allowed by the Information Practices Act (Civil Code section 1798 and following);
- To another government agency as required or permitted by state or federal law; or
- In response to a court or administrative order, a subpoena, or a search warrant.

*Once you are licensed with the board, the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code section 6250 et seq.) and will be ~~placed~~ available on the Internet. This is where the board will mail all official correspondence. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is not your residence address, you must also provide your residence address to the board, in which case your residence will not be available to the public.

**Disclosure of your U.S. social security account number or individual taxpayer identification number is mandatory. Section 30 of the Business and Professions Code, Section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security account number. Your social security account number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security account number, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

MANDATORY REPORTER

Under California law, each person licensed by the California State Board of Pharmacy is a "mandated reporter" for both child and elder abuse or neglect ~~purposes~~ laws.

California Penal Code Section 11166 and Welfare and Institutions Code Section 15630 require that all mandated reporters make a report to an agency specified in Penal Code Section 11165.9 and Welfare and Institutions Code Section 15630(b)(1) [generally law enforcement, state and/or county adult protective services agencies, etc.] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child, elder and/or dependent adult whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or elder abuse or neglect. The mandated reporter must contact by telephone immediately or as soon as possible, to make a report to the appropriate agency(ies) or as soon as practicably possible. The mandated reporter must prepare and send a written report thereof within two working days or 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of ~~Section 11166 and Section 15630~~ the laws above is a misdemeanor, punishable by up to six months in a county jail, by a fine of one thousand dollars ($1,000), or by both that imprisonment and fine. For further details about these requirements, ~~consult~~ refer to Penal code section 11164 and Welfare and Institutions Code section 15630, and ~~subsequent~~ following sections.

APPLICANT AFFIDAVIT

(must be signed and dated by the applicant)

I, _____ , hereby attest to the fact that I am the applicant whose signature appears
(Print full Legal Name)

below. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. I understand that my application may be denied, or any license disciplined, for fraud or misrepresentation.

_____ _____

Original Signature of Applicant (signed and dated by the applicant within 60 days of filing the application) Date

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION FOR PHARMACY TECHNICIAN

Instructions: This form must be completed by the university, college, school, or pharmacist (The person who must complete this form will depend on how the applicant is qualifying). All dates must include the month, day, and year in order for the form to be accepted.

This is to certify that _____ has
Print Name of Applicant

☐ Completed a pharmacy technician training program accredited by the American Society of Health-System Pharmacists as specified in Title 16 California Code of Regulations Section 1793.6(a) on _____/_____/_____
(completion date must be included)

☐ Completed 240 hours of instruction as specified in Title 16 California Code of Regulations Section 1793.6(c) on _____/_____/_____
(completion date must be included)

☐ Completed an Associate Degree in Pharmacy Technology and was conferred on her/him on _____/_____/_____
(graduation date must be included)

☐ Graduated from a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE). The degree of Bachelor of Science in Pharmacy or the degree of PharmD was conferred on her/him on _____/_____/_____
(graduation date must be included)

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the above:

Signed: _____ Title: _____ Date: _____/_____/_____

Affix school seal here. **OR** **Attach a business card of the pharmacist who provided the training pursuant to Section 1793.6(c) of the California Code of Regulation here. The pharmacist's license number shall be listed.**	University, College, or School of Pharmacy Name: _____ Address: _____ _____ Print Name of Director, Registrar, or Pharmacist: _____ Phone Number: _____ Email: _____

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1625 N. Market Blvd, N219, Sacramento, CA 95834
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To: Board Members

Subject: VII. Stakeholder Summit Discussion on Implementation of Section 1557 of the Affordable Care Act (ACA) Regarding Nondiscrimination in Health Programs and Activities, Specifically Including Its Impact on Pharmacy Translations and Interpretations

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Attachment 5

a. Overview

The relevant provisions of the Section 1557 implementation rule require covered entities (e.g., pharmacies) to take reasonable steps to provide meaningful access to individuals with LEP. "Reasonable steps" may include providing language assistance services, such as oral language assistance or written translations. The rule specifically requires covered entities to post three types of publications:

- A notice of nondiscrimination
- A nondiscrimination statement
- Taglines - A tagline is a short statement written in a non-English language indicating that language assistance services are available at no cost. (A sample tagline in Spanish: *ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia linguística. Llame al 1-XXX-XXX-XXXX (TTY: 1-XXX-XXX-XXXX).)*

A cursory review indicates that the federal rule has a limited impact on existing California pharmacy laws and statutes.

The key issue for the board's concern would appear to be taglines, which resemble the "Point to your language" requirement in **CCR section 1707.6(c):**

- CCR section 1707.6(c) requires "point to your language" text to be printed in 12 specific languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog and Vietnamese.
- The Section 1557 rule requires that taglines be provided in the top 15 languages spoken in the state by people with LEP. In California, those languages are Spanish, Chinese, Vietnamese, Tagalog, Korean, Armenian, Persian (Farsi), Russian, Japanese, Arabic, Panjabi, Mon-Kher/Cambodian, Hmong, Hindi and Thai. (Sources: U.S. Department of Health and Human Services, Office for Civil Rights; CA Department of Finance.)

Two subsections of **CCR section 1707.5,** regarding patient-centered labels, include wording regarding languages on matters that does not appear in the federal rule:

- **1707.5(b)** requires the board to translate label directions into five languages but does not specify which languages. The new federal rule appears silent on this matter.
- **1707.5(d)** requires pharmacies to provide language assistance with label information for patients with LEP. However, 1707.5(d) does not specify which languages nor how many languages must be provided. The federal rule appears silent on this matter.

A copy of the Federal Rule and relevant pharmacy law is included in **Attachment 5**.

b. Presentations on Implementation

Stakeholders will be scheduled to advise the board on their respective action in response to the Final Rule on Section 1557 of the ACA regarding nondiscrimination in health programs and activities, specifically including its impact on pharmacy translations and interpretations.

c. Next Steps

Additionally for consideration included in **Attachment 5** is a summary of best practices for making prescription drug labels accessible to patients who are blind, visually impaired or elderly.

The board will have the opportunity to discuss next steps for the board to consider in response to the Final Rule on Section 1557 of the ACA and other areas to make prescription labels more accessible for consumers.

Attachment

FEDERAL REGISTER

Vol. 81 Wednesday,

No. 96 May 18, 2016

Part IV

Department of Health and Human Services

Office of the Secretary

45 CFR Part 92

Nondiscrimination in Health Programs and Activities; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 92

RIN 0945–AA02

Nondiscrimination in Health Programs and Activities

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule implements Section 1557 of the Affordable Care Act (ACA) (Section 1557). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. The final rule clarifies and codifies existing nondiscrimination requirements and sets forth new standards to implement Section 1557, particularly with respect to the prohibition of discrimination on the basis of sex in health programs other than those provided by educational institutions and the prohibition of various forms of discrimination in health programs administered by the Department of Health and Human Services (HHS or the Department) and entities established under Title I of the ACA. In addition, the Secretary is authorized to prescribe the Department's governance, conduct, and performance of its business, including, here, how HHS will apply the standards of Section 1557 to HHS-administered health programs and activities.

DATES: *Effective Date:* This rule is effective July 18, 2016.

Applicability Dates: The provisions of this rule are generally applicable on the date the rule is effective, except to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Eileen Hanrahan at (800) 368–1019 or (800) 537–7697 (TDD).

SUPPLEMENTARY INFORMATION:

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I. Background

Section 1557 of the ACA provides that an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. 2000d *et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972 (Title IX), 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975 (Age Act), 42 U.S.C. 6101 *et seq.* (age), or Section 504 of the Rehabilitation Act of 1973 (Section 504), 29 U.S.C. 794 (disability), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the Act or its amendments. Section 1557 states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of addressing violations of Section 1557.

Section 1557(c) of the ACA authorizes the Secretary of the Department to promulgate regulations to implement the nondiscrimination requirements of Section 1557. In addition, the Secretary is authorized to prescribe regulations for the Department's governance, conduct, and performance of its business, including how HHS applies the standards of Section 1557 to HHS-administered health programs and activities.[1]

A. Regulatory History

On August 1, 2013, the Office for Civil Rights of the Department (OCR) published a Request for Information (RFI) in the **Federal Register** to solicit information on issues arising under Section 1557. OCR received 402 comments; one-quarter (99) were from organizational commenters, with the remainder from individuals.

On September 8, 2015, OCR issued a proposed rule, ''Nondiscrimination in Health Programs and Activities,'' in the **Federal Register**, and invited comment on the proposed rule by all interested parties.[2] The comment period ended on November 9, 2015. In total, we received approximately 24,875 comments on the proposed rule. Comments came from a wide variety of stakeholders, including, but not limited to: Civil rights/advocacy groups, including language access organizations, disability rights organizations, women's organizations, and organizations serving lesbian, gay, bisexual, or transgender (LGBT) individuals; health care providers; consumer groups; religious organizations; academic and research institutions; reproductive health organizations; health plan organizations; health insurance issuers; State and local agencies; and tribal organizations. Of the total comments, 23,344 comments were from individuals. The great majority of those comments were letters from individuals that were part of mass mail campaigns organized by civil rights/advocacy groups.

B. Overview of the Final Rule

This final rule adopts the same structure and framework as the proposed rule: Subpart A sets forth the rule's general provisions; Subpart B contains the rule's nondiscrimination provisions; Subpart C describes specific applications of the prohibition on discrimination to health programs and activities; and Subpart D describes the procedures that apply to enforcement of the rule.

OCR has made some changes to the proposed rule's provisions, based on the comments we received. Among the significant changes are the following.

Section 92.4 now provides a definition of the term ''national origin.''

OCR decided against including a blanket religious exemption in the final rule; however, the final rule includes a provision noting that insofar as application of any requirement under the rule would violate applicable Federal statutory protections for religious freedom and conscience, such application would not be required.

OCR has modified the notice requirement in § 92.8 to exclude publications and significant communications that are small in size from the requirement to post all of the content specified in § 92.8; instead, covered entities will be required to post only a shorter nondiscrimination statement in such communications and publications, along with a limited number of taglines. OCR also is translating a sample nondiscrimination statement that covered entities may use in fulfilling this obligation. It will be available by the effective date of this rule.

In addition, with respect to the obligation in § 92.8 to post taglines in at least the top 15 languages spoken nationally by persons with limited English proficiency, OCR has replaced the national threshold with a threshold

[1] 5 U.S.C. 301.

[2] 80 FR 54172 (Sept. 8, 2015).

requiring taglines in at least the top 15 languages spoken by limited English proficient populations statewide.

OCR has changed § 92.101 to provide that sex-specific health programs or activities are allowable only where the covered entity can demonstrate an exceedingly persuasive justification, *i.e.,* that the sex-specific program is substantially related to the achievement of an important health-related or scientific objective.

OCR has changed § 92.201, addressing the obligation to take reasonable steps to provide meaningful access. That section now requires the Director to evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue to the individual with limited English proficiency, and to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan, appropriate to its particular circumstances. The final rule deletes the specific list of illustrative factors set out in the proposed rule.

Also, OCR has changed § 92.203, addressing accessibility of buildings and facilities for individuals with disabilities, to require covered entities that were covered by the 2010 Americans with Disabilities Act (ADA) Standards for Accessible Design prior to the effective date of this final rule to comply with those standards for new construction or alterations by the effective date of the final rule. The final rule also narrows § 92.203's safe harbor for building and facility accessibility so that compliance with the Uniform Federal Accessibility Standards (UFAS) will be deemed compliance with this part only if construction or alteration was commenced before the effective date of the final rule and the facility or part of the facility was not covered by standards under the ADA. As nearly all covered entities under the final rule are already covered by the ADA standards, these changes impose a de minimis cost.

Section 92.301 has been changed to clarify that compensatory damages for violations of Section 1557 are available in administrative and judicial actions to the extent they are available under the authorities referenced in Section 1557. Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision.

In responding to the comments it received on the proposed rule, OCR has provided a thorough explanation of each of these changes in the preamble. OCR has also clarified some of the nondiscrimination requirements of Section 1557 and made some technical changes to the rule's provisions. In addition, we have added some definitions to proposed § 92.4, as summarized in the preamble to this final rule.

II. Provisions of the Proposed Rule and Analysis and Responses to Public Comments

A. General Comments

OCR received a large number of comments asking that we categorically declare in the final rule that certain actions are or are not discriminatory. For example, some commenters asked that OCR state that a modification to add medically necessary care, or a prohibition on exclusions of medically necessary services, is never a fundamental alteration to a health plan. Similarly, other commenters asked that OCR include a statement in the final rule that an issuer's refusal to cover core services commonly needed by individuals with intellectual disabilities is discrimination on the basis of disability. Still other commenters asked that OCR state that limiting health care and gender transition services to transgender individuals over the age of 18 is discriminatory. Other commenters asked that OCR state that it is discriminatory to require individuals with psychiatric disabilities to see a mental health professional in order to continue receiving treatment for other conditions.

Many of these same commenters asked that OCR supplement the final rule with in-depth explanations and analyses of examples of discrimination. For example, several commenters asked that OCR add an example of discrimination in research trials. Similarly, many other commenters asked that OCR add an example of what they considered to be disability discrimination in health insurance practices, such as higher reimbursement rates for care in segregated settings.

OCR appreciates the commenters' desire for further information on the application of the rule to specific circumstances. OCR's intent in promulgating this rule is to provide consumers and covered entities with a set of standards that will help them understand and comply with the requirements of Section 1557. Covered entities should bear in mind the purposes of the ACA and Section 1557—to expand access to care and coverage and eliminate barriers to access—in interpreting requirements of the final rule. But we neither address every scenario that might arise in the application of these standards nor state that certain practices as a matter of law are ''always'' or ''never'' permissible. The determination of whether a certain practice is discriminatory typically requires a nuanced analysis that is fact-dependent. Nonetheless, OCR has included in the preamble a number of examples of issues and circumstances that may raise compliance concerns under the final rule.

OCR also received several comments, primarily from representatives of the insurance industry, recommending that where specific Centers for Medicare & Medicaid Services (CMS) or State requirements apply to covered entities, OCR should either (1) harmonize all standards with existing CMS rules, or (2) allow issuers to be deemed compliant with Section 1557 if they are compliant with existing Federal or State law. For example, some commenters requested that compliance with CMS regulations that pertain to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee, be deemed compliance with the final rule on Section 1557. These commenters were concerned that CMS or a State might approve a plan that OCR might later find discriminatory. The commenters sought clarification on how OCR will handle cases involving health plans regulated by multiple authorities, and suggested that a ''deeming'' approach would reduce confusion and avoid duplication of costs and administrative effort. Other commenters asked that compliance with language access standards promulgated by CMS or the States be deemed compliance with the final rule; those comments are discussed in more detail in the preamble at § 92.201.

OCR recognizes the efficiencies inherent in harmonizing regulations to which covered entities are subject under various laws. Indeed, entities covered under Section 1557 are likely also subject to a host of other laws and regulations, including CMS regulations, the Genetic Information Nondiscrimination Act of 2008,[3] the Family and Medical Leave Act, the ADA, Title VII of the Civil Rights Act of 1964, and State laws. OCR will coordinate as appropriate with other Federal agencies to avoid inconsistency and duplication in enforcement efforts.

That said, OCR declines to adopt a deeming approach whereby compliance with another set of laws or regulations automatically constitutes compliance with Section 1557. As to State laws, it

[3] Public Law 110–233, 122 Stat. 881 (2008).

is inappropriate to define requirements under Federal law based on what could be the varying, and potentially changing, requirements of different States' approaches. As to other Federal laws, OCR will give consideration to an entity's compliance with the requirements of other Federal laws where those requirements overlap with Section 1557. In such cases, OCR will work closely with covered entities where compliance with this final rule requires additional steps. But in the final analysis, OCR must, in its capacity as the lead enforcement agency for Section 1557, maintain the discretion to evaluate an entity's compliance with the standards set by the final rule. This is consistent with the approach taken by other agencies to civil rights obligations, in which compliance with one set of requirements, adopted under different laws or for different purposes, is not considered automatic compliance with civil rights obligations.

Subpart A—General Provisions

Purpose and Effective Date (§ 92.1)

In § 92.1, we proposed that the purpose of this part is to implement Section 1557 of the ACA, which prohibits discrimination in certain health programs and activities on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504, which together prohibit discrimination on the basis of race, color, national origin, sex, age, or disability.

We also proposed that the effective date of the Section 1557 implementing regulation shall be 60 days after the publication of the final rule in the **Federal Register**.

The comments and our responses regarding the proposed effective date are set forth below.

Comment: Some commenters asserted that 60 days after publication of the final rule did not allow sufficient time for entities to come into compliance with Section 1557 and requested that the effective date be one year after publication of the final rule. Similarly, one commenter stated that State agencies covered by Section 1557 need at least 150 days to come into compliance with Section 1557. The commenter stated that State agencies need additional time to assess the impacts, align nondiscrimination requirements from multiple Federal agencies, and make the required policy, operational, and system changes.

Response: OCR does not believe that extending the effective date beyond 60 days is warranted, except with regard to specific provisions for which there is a later applicability date, as set forth below. Most of the requirements of Section 1557 are not new to covered entities, and 60 days should be sufficient to come into compliance with any new requirements.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.1 with one modification. We recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year. Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Application (§ 92.2)

Section 92.2 of the proposed rule stated that Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal agency. It also stated that Section 1557 applies to all programs and activities that are administered by an Executive Agency or any entity established under Title I of the ACA.

In paragraph (a), we proposed to apply the proposed rule, except as otherwise provided in § 92.2, to: (1) All health programs and activities, any part of which receives Federal financial assistance administered by HHS; (2) health programs and activities administered by the Department, including the Federally-facilitated Marketplaces; and (3) health programs and activities administered by entities established under Title I of the ACA, including the State-based Marketplaces.

In paragraph (b), we proposed limitations to the application of the final rule. We proposed the adoption of the existing limitations and exceptions that already, under the statutes referenced in Section 1557, govern the health programs and activities subject to Section 1557. We noted that these limitations and exceptions are found in the Age Act and in the regulations implementing the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance.

In paragraph (b)(1), we proposed to incorporate the exclusions found in the Age Act, such that the provisions of the proposed rule would not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.[4] We requested comment on whether the exemptions found in Title IX and its implementing regulation should be incorporated into the final rule. We noted that unlike the Age Act, Section 504, and Title VI, which apply to all programs and activities that receive Federal financial assistance (including health programs and activities), Title IX applies only in the context of education programs and not to the majority of the health programs and activities subject to the proposed rule. In addition, we noted that many of Title IX's limitations and exceptions do not readily apply in a context that is grounded in health care, rather than education.

We invited comment on whether the regulation should include any specific exemptions for health service providers, health plans, or other covered entities with respect to requirements of the proposed rule related to sex discrimination. We stated that we wanted to ensure that the proposed rule had the proper scope and appropriately protected sincerely held religious beliefs to the extent that those beliefs may conflict with provisions of the proposed regulation. We noted that certain protections already exist with respect to religious beliefs, particularly with respect to the provision of certain health-related services; for example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,[5] the Religious Freedom Restoration Act (RFRA),[6] provisions in the ACA related to abortion services,[7] or regulations issued

[4] *See* 42 U.S.C. 6103(b).

[5] *See, e.g.,* 42 U.S.C. 300a–7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Public Law 114–53, Div. G, § 507(d) (Dec. 16, 2015).

[6] 42 U.S.C. 2000bb–1.

[7] *See, e.g.,* 42 U.S.C. 18023.

under the ACA related to preventive health services.[8] We invited comment on the extent to which these existing protections provide sufficient safeguards for any religious concerns in applying Section 1557.

We noted that a fundamental purpose of the ACA is to ensure that health services are available broadly on a nondiscriminatory basis to individuals throughout the country. Thus, we requested comment on any health care consequences that would ensue were the regulation to provide additional exemptions.

We also requested comment on the scope of additional exemptions, if any, that should be included and the processes for claiming them, including whether those processes should track those used under Title IX, at 45 CFR 86.12.

The comments and our responses regarding § 92.2 are set forth below.

Comment: Some commenters recommended that the final rule apply not only to health programs and activities receiving Federal financial assistance from the Department, but to health programs and activities receiving Federal financial assistance from other Departments. The commenters noted that in enacting Section 1557, Congress delegated rulemaking authority to the Department; they therefore maintained that the Department has the authority to promulgate rules that apply to other Departments. Commenters further noted that the Department has greater expertise in the application of civil rights laws to health programs and activities than do other Departments, and further urged that HHS regulations applicable to health programs and activities receiving Federal financial assistance from other Departments would be afforded deference under *Chevron U.S.A.* v. *NRDC, Inc.*[9]

In the alternative, commenters recommended that we collaborate with other Departments to effectuate the provisions of the final rule and ensure that other Departments enter into delegation agreements or Memoranda of Understanding that grant HHS interpretation and enforcement authority over health programs funded and administered by other Departments or that commit other Departments to move quickly to engage in their own rulemaking on Section 1557.

Response: While the rule recognizes that Section 1557 itself applies to health programs and activities receiving Federal financial assistance from other Departments, we decline to extend the scope of the rule to health programs and activities receiving Federal financial assistance from other Departments. Drafting a rule applicable to health programs and activities assisted by other Departments would pose numerous challenges, one of which is that the Department lacks the information and expertise necessary to apply the rule to those programs without further engagement and collaboration with those Departments. We agree that expeditious implementation of Section 1557 by other Departments is desirable, and hope that the Department's final rule will inform enforcement of Section 1557 by other Departments with respect to their federally assisted health programs and activities. To this end, the OCR Director sent a memorandum encouraging coordination of enforcement responsibilities under Section 1557 to all Federal agencies in November 2015.

Comment: Commenters recommended that the final rule apply not just to programs administered by HHS, but also to programs administered by other Departments.

Response: We decline to make the rule applicable to programs administered by other Departments. We will, however, continue to work with other Departments that administer health programs and activities to help those Departments ensure that their programs are nondiscriminatory.

Comment: Many commenters responded to the proposed rule's request for comment on whether the rule should include a religious exemption for health care providers, health plans, or other covered entities with respect to the requirements of the rule related to sex discrimination, or whether existing protections, including RFRA, ACA regulations for preventive health services, and Federal provider conscience laws provide sufficient safeguards for religious concerns.

Most of the organizations that commented on this issue, including professional medical associations and civil rights organizations, and the overwhelming majority of individual commenters, many of whom identified themselves as religious, opposed any religious exemption on the basis that it would potentially allow for discrimination on the bases prohibited by Section 1557 or for the denial of health services to women. Several religious organizations also opposed a religious exemption, asserting that RFRA, the Federal provider conscience statutes, and State RFRA statutes, which many States have enacted, provide sufficiently strong protections for religious providers and institutions. Many commenters said that mergers of religiously-affiliated hospitals with other hospitals have deepened concerns that would be raised by providing a religious exemption, as the mergers may leave individuals in many communities with fewer health care options offering the full range of women's health services. Many commenters also pointed to the language in the majority opinion in the Supreme Court's decision in *Hobby Lobby* v. *Burwell* that RFRA is not a shield that permits discrimination ''cloaked as religious practice to escape legal sanction.'' [10]

Some religious organizations that submitted comments strongly supported a religious exemption, arguing that faith-based health care providers and employers would be substantially burdened if required to provide or refer for, or purchase insurance covering, particular services such as gender transition services. Supporters of an exemption recommended that Section 1557 incorporate the religious exemption in Title IX, which exempts educational institutions controlled by religious organizations from the prohibition of sex discrimination if the application would be inconsistent with the religious tenets of the organization.[11] None of the commenters supporting a religious exemption asserted that there would be a religious basis for generally refusing to treat LGBT individuals for a medical condition, for example, refusing to treat a broken bone or cancer; rather, commenters asserted that the rule should exempt faith-based providers from providing particular services, such as services related to gender transition, that are inconsistent with their religious beliefs.

Response: As noted in the preamble to the proposed rule, certain protections already exist in Federal law with respect to religious beliefs, particularly with regard to the provision of certain health-related services. For example, we noted that the proposed rule would not displace the protections afforded by provider conscience laws,[12] RFRA,[13] provisions in the ACA related to abortion services,[14] or regulations issued under the ACA related to preventive health services.[15] Nothing in

[8] *See* 45 CFR 147.131.

[9] 467 U.S. 837 (1984).

[10] 132 S. Ct. 2751, 2783 (2014).

[11] 20 U.S.C. 1681(a)(3).

[12] *See, e.g.,* 42 U.S.C. 300a–7; 42 U.S.C. 238n; Consolidated and Further Continuing Appropriations Act 2015, Pub. L. 114–53, Div. G, § 507(d) (Dec. 16, 2015).

[13] 42 U.S.C. 2000bb–1.

[14] *See, e.g.,* 42 U.S.C. 18023.

[15] *See* 45 CFR 147.131.

this final rule displaces those protections.

Although some commenters urged us also to incorporate Title IX's blanket religious exemption into this final rule, we believe that applying the protections in the laws identified above offers the best and most appropriate approach for resolving any conflicts between religious beliefs and Section 1557 requirements. With regard to abortion, for example, specific ACA provisions concerning abortion will continue to control, including, but not limited to, provisions that bar qualified health plans offered through a Marketplace[SM] [16] from discriminating against an individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions,[17] and provisions that state that nothing in the ACA shall be construed to require a qualified health plan to provide coverage of abortion as an essential health benefit.[18]

In other cases, application of RFRA is the proper means to evaluate any religious concerns about the application of Section 1557 requirements. The RFRA analysis evaluates whether a legal requirement substantially burdens the exercise of religion; if so, the question becomes whether the legal requirement furthers a compelling interest and is the least restrictive means to further that interest.

We believe that the government has a compelling interest in ensuring that individuals have nondiscriminatory access to health care and health coverage and, under RFRA, would assess whether a particular application of Section 1557 substantially burdened a covered entity's exercise of religion and, if so, whether there were less restrictive alternatives available. Claims under RFRA are individualized and fact specific and we would make these determinations on a case-by-case basis, based on a thorough analysis and relying on the extensive case law interpreting RFRA standards.

We decline to adopt commenters' suggestion that we import Title IX's blanket religious exemption [19] into Section 1557. Section 1557 itself contains no religious exemption. In addition, Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and health care contexts that warrant different approaches.

First, students or parents selecting religious educational institutions typically do so as a matter of choice; a student can attend public school (if K–12) or choose a different college. In the health care context, by contrast, individuals may have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions. Moreover, the choice of providers may be even further circumscribed in emergency circumstances.

Second, a blanket religious exemption could result in a denial or delay in the provision of health care to individuals and in discouraging individuals from seeking necessary care, with serious and, in some cases, life threatening results. Thus, it is appropriate to adopt a more nuanced approach in the health care context, rather than the blanket religious exemption applied for educational institutions under Title IX.

Based on the foregoing, we have included a provision in this final regulation making clear that where application of this regulation would violate applicable Federal statutory protections for religious freedom and conscience, that application will not be required. The Department also retains the discretion to provide other accommodations or exemptions where permitted by Federal law and supported by sound public policy.

Comment: One commenter suggested that we clarify that the regulation applies only to a covered entity's health operations ''in the United States.''

Response: This regulation applies only to individuals who are subjected to discrimination, at least in part, in the United States and to the provision or administration of health-related services or health-related insurance coverage in the United States, consistent with the four statutes referenced in Section 1557.[20]

Consistent with the Department's Title VI regulation,[21] OCR interprets ''United States'' to include the U.S. territories. The definition of ''recipient'' of Federal financial assistance in the civil rights laws referenced in Section 1557 does not contain geographic limitations, and includes, in addition to States and political subdivisions, other ''public or private agenc[ies], institution[s], or organization[s].'' [22] Thus, health programs and activities of the U.S. Territories, and those provided or administered in the U.S. Territories, are covered by the final rule.[23]

Comment: One commenter requested that we clarify that expatriate health plans, plan sponsors of self-funded expatriate health plans, and issuers of fully-insured expatriate health plans are exempt from Section 1557 pursuant to the Expatriate Health Coverage Clarification Act of 2014 (EHCCA),[24] which provides generally that provisions of the ACA do not apply to expatriate health plans, employer plan sponsors of expatriate health plans, or expatriate health insurance issuers. The commenter noted that the EHCCA does not include any exceptions or special rules pertaining to Section 1557; thus, the commenter asserted, applying Section 1557 to expatriate health plans would be contrary to Congressional intent and would competitively disadvantage American health issuers in the global marketplace, resulting in consumers choosing offshore options and American issuers moving their plans offshore to compete.

Response: Section 3(a) [25] of the EHCCA specifies that the provisions of (including any amendment made by) the ACA and Title I and subtitle B of Title II of the Health Care and Education Reconciliation Act of 2010 shall not apply with respect to expatriate health plans; employers with respect to such plans, solely in their capacity as plan sponsors for such plans; or expatriate health insurance issuers with respect to coverage offered by such issuers under such plans, subject to the exceptions and special rules enumerated in Sections 3(B) and 3(C) of the EHCCA. Section 1557 is contained in Title I of the ACA; thus, pursuant to the EHCCA, Section 1557 does not apply with respect to expatriate health plans, expatriate health insurance issuers, or employer plan sponsors of expatriate plans, as defined in the EHCCA.

Comment: Tribes and tribal organizations submitted comments recommending that we make a number of changes throughout the rule and preamble to address the application of the rule to tribes and tribal health programs. Commenters objected to the characterization of 45 CFR 80.3(d), the exception in the Title VI regulation for

[16] Health Insurance Marketplace[SM] and Marketplace[SM] are service marks of the U.S. Department of Health and Human Services.

[17] 42 U.S.C. 18023(b)(4).

[18] 42 U.S.C. 18023(b)(1)(A).

[19] 42 U.S.C. 18116(a).

[20] 20 U.S.C. 1681(a); 29 U.S.C. 794(a); 42 U.S.C. 2000d; 42 U.S.C. 6102.

[21] 45 CFR 80.13(e).

[22] 45 CFR 80.13(i) (Title VI); 84.3(f) (Section 504); 86.2(i) (Title IX); 90.4 (Age Act).

[23] OCR notes that in contrast to Section 1557, which does not refer to the United States or to ''states,'' other ACA provisions refer to ''states'' and the Department has interpreted the meaning of ''state'' in the context of those statutory requirements. See 45 CFR 144.103.

[24] Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235, Div. M, § 3 (codified at 42 U.S.C. 18014).

[25] 42 U.S.C. 18014(f).

Indian health programs and other programs limited by Federal law to individuals of a particular race, color, or national origin, that has been incorporated into the Section 1557 rule, and recommended that we refer to 45 CFR 80.3(d) throughout and describe it rather than simply cite to it. Commenters asked us to exempt tribes and tribal health programs from § 92.207 and § 92.208 and make clear that tribal governments and health programs can limit insurance to their members. Commenters asserted that Purchased/Referred Care [26] programs should be permitted to limit coverage and be held harmless for discrimination on the basis of disability, age, or sex. One commenter recommended several additional changes to the rule to address its application to tribes, including excluding tribes and tribal health programs from the definitions of ''covered entity'' and ''health program or activity,'' and excluding assistance to tribes and tribal health programs from the definition of ''Federal financial assistance,'' along with other changes intended to achieve this purpose. Commenters stated that the changes proposed were necessary to reflect the full scope of protections in Federal law for tribal classifications and tribal sovereignty.

Response: 45 CFR 80.3(d) is not an exemption from coverage; it provides an exception to application of the prohibitions on race, color, and national origin discrimination when programs are authorized by Federal law to be restricted to a particular race, color, or national origin. The final rule incorporates that exception, and OCR will fully apply it, as well as other exemptions or defenses that may exist under Federal law. OCR intends to address any restrictions on application of the law to tribes in the context of individual complaints.

Comment: One tribal organization commented that tribal consultation on development of the rule was insufficient.

Response: We engaged in tribal consultation on the rule and, during that consultation, encouraged tribes and tribal organizations to submit comments on the proposed rule. Many did so. We believe that tribal consultation was sufficient.

Comment: One tribal organization stated that the reference to Indian Health Services (IHS) programs in the preamble was misleading, as some IHS programs are administered directly by tribes.

Response: We agree that the reference to IHS programs as an example of a federally administered program may be confusing, given that some IHS programs are administered directly by tribes. We have therefore changed the reference to ''IHS programs'' to ''IHS programs administered by IHS.''

Finally, we have added a severability clause to § 92.2, to indicate our intention that the rule be construed to give the maximum effect permitted by law to each provision. The rule provides that if a provision is held to be unenforceable in one set of circumstances, it should be construed to give maximum effect to the provision as applied to other persons or circumstances. Similarly, if a provision is held to be invalid or unenforceable, that provision should be severable from, and have no impact on the application of, the remainder of the rule. This provision is consistent with our interpretation of the Department's regulations implementing Title VI, Title IX, Section 504, and the Age Act.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.2, with two modifications. We are adding § 92.2(b)(2), which clarifies that if an application of Section 1557 requirements or this part would violate applicable Federal statutory protections for religious freedom and conscience, application of Section 1557 is not required. In addition, we have added § 92.2(c), containing a severability clause.

Relationship to Other Laws (§ 92.3)

In § 92.3 of the proposed rule, we proposed an explanation of the relationship of the rule to existing laws. Paragraph (a) proposed that Section 1557 is not intended to apply lesser standards for the protection of individuals from discrimination than the standards under Title VI, Title IX, Section 504, the Age Act, or the regulations issued pursuant to those laws. Consistent with the statute, paragraph (b) proposed that nothing in this part shall be interpreted to invalidate or limit the existing rights, remedies, procedures, or legal standards available to individuals aggrieved under other Federal civil rights laws or to supersede State or local laws that provide greater or equal protection against discrimination on the basis of race, color, national origin, sex, age, or disability. OCR explained that this intent is derived from Section 1557(b) of the ACA. In addition to the statutes that are cited directly in Section 1557(b), the proposed rule cited the Architectural Barriers Act of 1968,[27] the Americans with Disabilities Act of 1990 (ADA),[28] and Section 508 of the Rehabilitation Act of 1973 (Section 508).[29] We noted that these laws establish additional Federal civil rights protections for individuals with disabilities, and covered entities must be mindful that the obligations imposed by those laws apply to them independent of the application of Section 1557.

Summary of Regulatory Changes

OCR did not receive any comments on this provision. Therefore, for the reasons set forth in the proposed rule, we are finalizing the provisions as proposed in § 92.3 without modification.

Definitions (§ 92.4)

In § 92.4 of the proposed rule, we set out proposed definitions of various terms. The comments and our responses regarding § 92.4 are set forth below.

Disability. We proposed that the definition of ''disability'' be the same as the definition of this term in the Rehabilitation Act,[30] which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008.[31] In addition, we proposed to use the term ''disability'' in place of the term ''handicap,'' which is used in some previous civil rights statutes and regulations. We provided that when we cross-reference other regulatory provisions, regulatory language that uses the term ''handicap'' shall mean ''disability.'' We noted that this change in terminology does not reflect a change in the substance of the definition.

Comment: OCR received many comments related to the definition of disability. Several commenters asked OCR to provide additional guidance regarding the meaning of terms used within the definition of disability, including ''physical or mental impairment,'' ''major life activities,'' and ''substantially limits.'' Other commenters asked OCR to include the term ''chronic conditions'' in the definition of disability or to add

[26] Funds under the Purchased/Referred Care program (formerly the Contract Health Services program) are used to supplement and complement other health care resources available to eligible American Indians and Alaska Natives. *See https://www.ihs.gov/newsroom/index.cfm/factsheets/purchasedreferredcare* (last updated Jan. 2015).

[27] 42 U.S.C. 4151–4157 (2012).

[28] 42 U.S.C. 12101 *et seq.* (codified as amended by the Americans with Disabilities Amendments Act of 2008, Public Law 110–325, 122 Stat. 3553 (2008)).

[29] 29 U.S.C. 794d.

[30] 29 U.S.C. 705(9)(B).

[31] Public Law 110–325, 122 Stat. 3553, § 4 (Sept. 25, 2008) (codified at 42 U.S.C. 12102).

regulatory language to the definition of disability that creates a rebuttable presumption of disability for serious and chronic conditions. Still other commenters urged that OCR clarify that the definitions of disability and qualified individual with a disability are broad.

Response: As noted in the proposed rule, the definition of ''disability'' is the same as the definition of this term in the Rehabilitation Act, which incorporates the definition of disability in the ADA, as construed by the ADA Amendments Act of 2008. Thus, the proposed rule incorporates the definition of ''major life activities'' and the construction of all of the terms and standards in the definition of ''disability'' set forth in the ADA Amendments Act. We believe this definition is appropriate and that OCR's intent, consistent with the ADA Amendments Act, to broadly interpret the term ''disability'' is clear. Whether a chronic condition is a disability will depend on whether it falls within the definition of disability in the final rule.

Comment: A few commenters asked for a definition of the term ''reasonable modification.'' Other commenters asked for a definition of ''accessibility,'' especially as that term pertains to electronic and information technology. Both sets of commenters suggested that adding definitions to the final rule would provide greater clarity to covered entities.

Response: OCR believes that defining the terms ''reasonable modification'' and ''accessibility'' in this rule is unnecessary, given the meaning that these terms have acquired in the long history of enforcement of Section 504 and the ADA in the courts and administratively. We intend to interpret both terms consistent with the way that we have interpreted these terms in our enforcement of Section 504 and the ADA and so decline to add these definitions to the final rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition of ''disability'' as proposed without modification.

Electronic and information technology. We proposed to define ''electronic and information technology'' to be consistent with 36 CFR 1194.4, the regulation implementing Section 508.

Comment: A few commenters recommended that OCR amend the definition of ''electronic and information technology'' to state that ''electronic and information technology includes hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.'' These commenters asserted that this definition, which is based on the definition of ''health information technology'' in the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009,[32] is preferable to the definition OCR proposed, which is based on the regulations implementing Section 508 that were promulgated in 2000. According to these commenters, the Section 508 definition is outdated and unduly narrow.

Response: As OCR stated in the Notice of Proposed Rulemaking, the definition of ''electronic and information technology'' is based on 36 CFR 1194.4, the regulation implementing Section 508. OCR believes that a definition of ''electronic and information technology'' that is consistent with the regulations implementing Section 508 will reduce the possibility of confusing or conflicting standards for covered entities. Moreover, the definition used in the HITECH Act was created for use in another context and is narrower in some respects than would be appropriate for Section 1557. However, OCR also shares the commenters' concern that the current definition found at 36 CFR 1194.4 is outdated and unduly narrow. Accordingly, OCR notes the recent Access Board proposal to replace the term ''electronic and information technology'' with an updated term and definition.

Specifically, on February 27, 2015, the Access Board proposed to revise and update its standards for electronic and information technology developed, procured, maintained, or used by Federal agencies covered by Section 508.[33] As part of these proposed revisions and updates, the Access Board announced that it intends to replace the term ''electronic and information technology'' in 36 CFR 1194.4 with the term ''information and communication technology'' and revise the definition significantly to make it broader and more compatible with modern technology.[34] OCR believes that the changes proposed by the Access Board will address the commenters' concerns. Therefore, and in order to maintain consistency with Section 508 while also addressing commenters' concerns that the definition proposed by OCR is outdated and unduly narrow, OCR has decided to change the definition of ''electronic and information technology'' in this rule so that it means the same as ''electronic and information technology'' as defined at 36 CFR 1194.4 or any term that replaces ''electronic and information technology'' at 36 CFR 1194.4. By citing to the regulation, OCR's definition will update with the Access Board's finalized rule.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we have changed the definition of ''electronic and information technology'' as proposed in § 92.4 to state that it means the same as ''electronic and information technology,'' or any term that replaces it at 36 CFR 1194.4.

Employee health benefit program. We proposed that the term ''employee health benefit program'' means (1) health benefits coverage or health insurance provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to a health insurance issuer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA), at 29 U.S.C. 1191b(a)), a third party administrator, or an employer; (2) an employer-provided or -sponsored wellness program; (3) an employer-provided health clinic; or (4) long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer for a covered entity's employees.

Comment: One commenter requested that OCR clarify that wellness programs that are separate from the employee health benefit plan are still an ''employee health benefit program.''

Response: We agree that wellness programs separate from an employee health benefit plan fall within the definition of an employee health benefit program. For example, an employer providing a gift card to each employee who receives a flu shot would be a wellness program within the meaning of the regulation, regardless of whether the wellness program is part of the employer's group health plan. We believe that the definition of ''employee health benefit program'' in the

[32] 42 U.S.C. 300jj(5).

[33] Architectural and Transportation Barriers Compliance Board, Information and Communication Technology (ICT) Standards and Guidelines. 80 FR 10880 (proposed Feb. 27, 2015) (to be codified at 36 FR pt. 1194).

[34] *See* 80 FR at 10905.

regulation makes this clear and thus are not adopting any revisions.

Comment: Some commenters requested that the definition of ''employee health benefit program'' specifically include excepted benefits, as defined for purposes of section 2791(c) of the Public Health Service Act (codified at 42 U.S.C. 300gg–91(c)), such as limited scope vision and dental insurance, disease-specific insurance and fixed-indemnity plans.

Response: We do not believe it is necessary to include an exhaustive list of types of benefits that would be included as an ''employee health benefit program.'' The definition is broad enough to encompass any health benefit coverage or health insurance provided by an employer to its employees. Excepted benefits are further discussed infra under § 92.207.[35]

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 with minor technical revisions for clarity and for consistency with other parts of the final rule. We are making minor technical corrections to correct the ERISA citation to read ''29 U.S.C. 1191b(a)(1)''; to clarify that the term ''sponsored wellness program'' is an ''employer-sponsored'' wellness program; to add ''coverage'' to the term ''health insurance''; and to clarify that long term care coverage or insurance is provided or administered ''for the benefit of an employer's employees.''

Federal financial assistance. We proposed that the term ''Federal financial assistance'' includes grants, loans, and other types of assistance in accordance with the definition of ''Federal financial assistance'' in the regulations implementing Section 504 [36] and the Age Act,[37] and also specifically includes subsidies and contracts of insurance, in accordance with the statutory language of Section 1557. We also proposed that, consistent with OCR's enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B.

An additional clause was added to the proposed regulatory provision, modeled on the definition of ''Federal financial assistance'' in the regulation implementing Title IX, which clarifies that in the educational context, Federal financial assistance includes wages, loans, grants, scholarships and other monies that are given to any entity for payment to or on behalf of students who are admitted to that entity or that are given directly to these students for payment to that entity.[38] In the proposed rule, we noted that in the health care context, Federal funds are provided to or on behalf of eligible individuals for premium tax credits and advance payments of premium tax credits and cost sharing reductions to ensure the affordability of health insurance coverage purchased through the Health Insurance Marketplaces. Thus, we noted that an issuer participating in any Health Insurance Marketplace℠ is receiving Federal financial assistance when advance payments of premium tax credits and/or cost sharing reductions are provided to or on behalf of any of the issuer's enrollees. We noted that a health care provider that contracts with such an issuer does not become a recipient of Federal financial assistance by virtue of the contract, but would be a recipient if the provider otherwise receives Federal financial assistance.

Comment: Many commenters objected to the statement in the preamble to the proposed rule that, consistent with OCR's enforcement of other civil rights authorities, the definition of Federal financial assistance does not include Medicare Part B. These commenters urged us to reverse this position, asserting that the historical rationale for the Department's position that Medicare Part B payments are not Federal financial assistance is inapplicable to Section 1557, which explicitly covers ''contracts of insurance,'' and inconsistent with the current Medicare Part B payment scheme, in which providers are paid directly by the Medicare program instead of receiving payment from consumers who are then reimbursed by the Medicare program.

Response: OCR notes commenters' concerns, but does not believe that this rule is the appropriate vehicle to modify the Department's position.

Comment: We received many comments proposing that OCR revise the statement that a health care provider that contracts with an issuer does not become a recipient of Federal financial assistance by virtue of the contract. Commenters proposed that such a provider should become a recipient, and thus be covered by Section 1557, by virtue of the contract. The commenters expressed concern that under OCR's interpretation, such contractors would not be covered by the nondiscrimination requirements of Section 1557, thereby weakening the rule's effect.

Response: We do not believe the law supports the commenters' proposed across-the-board revision. Under the regulations implementing the statutes cited in Section 1557 and incorporated into this final rule, a recipient of Federal financial assistance is an entity to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient. To determine whether an entity is a recipient of such assistance, courts look to the entity that Congress intended to assist or subsidize with those funds.[39] In this context, the contractor that is providing health services is not the intended recipient of a premium tax credit or cost-sharing reduction that an issuer receives and is therefore not covered under Section 1557 by virtue of the contract.

That said, there are numerous ways in which health services providers are recipients in their own right, whether the Federal financial assistance they receive comes through certain Medicare payments, Medicaid payments, or other funds from the Department. Therefore, instead of falling outside of Section 1557's purview, many health care providers will be subject to Section 1557 irrespective of their relationship to issuers receiving Federal financial assistance.

Moreover, nothing in the rule authorizes qualified health plan issuers or other issuers that are covered entities to contract away their own nondiscrimination obligations. Issuers must ensure that enrollees have equal access to health services provided by their coverage without discrimination on the basis of a prohibited criterion. Thus, even if individual providers do not independently receive Federal financial assistance, an issuer maintains a duty to ensure compliance with civil rights laws with respect to the treatment of its enrollees who use its networks.

Comment: One comment inquired whether the rule applies to programs in which the Department is an employer or when the Department offers benefits to Department employees.

Response: The Department is not covered as a federally assisted program, although the Department is covered by the rule as an administrator of health programs and activities. As to programs for Department employees, HHS is covered by employment discrimination laws, including Section 504 and Title VII, protecting Federal employees.

[35] *See infra* discussion of excepted benefits under § 92.207.

[36] 45 CFR 84.3(h).

[37] 45 CFR 91.4.

[38] *See* 45 CFR 86.2(g)(1)(ii).

[39] *United States Dep't of Transport.* v. *Paralyzed Veterans of Amer.,* 477 U.S. 597, 604–06 (1986).

Comment: One commenter raised concerns over the applicability of the rule to doctors in solo medical practice, to doctors who practice in many settings, and to medical students receiving student loans. The commenter suggested that the health program or activity—not the solo practitioner as an individual—be required to comply with the rule, and requested that we clarify how a doctor can determine whether she is covered by the rule as she moves between practice settings. The commenter also expressed concern that a disproportionate number of younger doctors would be required to comply with the rule as recipients of Federal financial assistance in the form of student loans.

Response: We have not modified the final rule in response to these comments; however, we offer the following for clarification.

Section 1557 applies to a recipient of Federal financial assistance, whether a hospital, clinic, medical practice, or individual physician. Where, for example, a doctor is an employee of a hospital and the hospital receives Federal financial assistance, the hospital's program is the relevant health program or activity and it is the hospital that will be held accountable for discrimination under Section 1557. Where, similarly, a doctor contracts as an individual to provide health services at a free neighborhood clinic that receives Federal financial assistance, the clinic is the recipient of Federal financial assistance and liable for discrimination; the doctor is simply a contractor who is assisting the clinic in performing clinic services.

When a doctor has a private medical practice that receives Federal financial assistance, and the doctor, through her practice, works as an attending physician at a hospital, it is the medical practice that is providing the services at the hospital, and thus the practice that is liable for the discrimination.[40] Moreover, a solo medical practice (whether incorporated or not) that receives Federal financial assistance is a covered health program or activity.[41]

This approach is consistent with longstanding interpretations of civil rights law and the definition of a ''recipient'' of Federal financial assistance in the regulations implementing Section 504, Title VI, Title IX and the Age Act.

Finally, regarding receipt of student loan payments as Federal financial assistance, we clarify that the educational institution—not the student—is the recipient of the Federal financial assistance in that circumstance. Although the money is paid directly to the student, the university or other educational institution is the intended recipient. This is consistent with longstanding regulations implementing civil rights laws.

We made two clarifying changes to the definition of Federal financial assistance. In the proposed rule, we defined Federal financial assistance in subsection (1) as any type of arrangement in which the Federal government ''provides or makes available'' assistance. In subsection (2), we explained that Federal financial assistance ''provided or administered by the Department'' includes tax credits and other subsidies under Title I of the ACA and other funds providing health insurance coverage. Because our intention was to explain further the meaning of (1) as it applies to the Department in (2), we have changed (2) to use the same terms used in (1). Thus, (2) now refers to Federal financial assistance ''provided or made available'' by the Department.

In addition, in the proposed rule, subsection (2) provided that ''Federal financial assistance provided or administered by the Department includes all tax credits under Title I of the ACA,'' as well as other funds extended by the Department for providing health coverage. Because the Department plays a role in administering tax credits under Title I of ACA but does not have primary responsibility for administering that credit, and to ensure that tax credits under Title I of the ACA are understood to be included within the definition, we have modified this subsection to state that Federal financial assistance the Department provides or makes available includes Federal financial assistance that the Department plays a role in providing or administering.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 with two modifications. The language of Subsection (2) of the definition has been modified to state that Federal financial assistance the Department provides or makes available includes Federal financial assistance that the Department plays a role in providing or administering.

Gender identity. We proposed that the term ''gender identity'' means an individual's internal sense of gender, which may be different from an individual's sex assigned at birth. We noted that the way an individual expresses gender identity is frequently called ''gender expression,'' and may or may not conform to stereotypes associated with a particular gender. We also noted in the proposed rule that gender may be expressed through, for example, dress, grooming, mannerisms, speech patterns, and social interactions. For purposes of this part, we proposed that an individual has a transgender identity when the individual's gender identity is different from the sex assigned to that person at birth; an individual with a transgender identity is referred to in this part as a transgender individual. In the proposed rule, we noted that the approach taken in the proposed definition is consistent with the approach taken by the Federal government in similar matters.[42]

Comment: Several commenters suggested that we revise the definition of ''gender identity'' to reference non-binary identities in order to avoid ambiguity regarding application of the rule to individuals with non-binary gender identities. Some commenters noted that explicitly referencing non-binary identities in this definition would be important to avoid any doubt or misinterpretation given that gender has often been assumed to be binary, thus ignoring or marginalizing individuals with non-binary gender identities.

Response: OCR has made a slight change to the definition of ''gender identity'' to insert the clause ''which may be male, female, neither, or a combination of male and female.'' The insertion of this clause helps clarify that those individuals with non-binary gender identities are protected under the rule.

Comment: Some commenters suggested that, consistent with previous court and Federal agencies' interpretations, OCR add ''gender expression'' to the definition of ''gender identity'' in order to make explicit our

[40] The hospital may also be responsible for discrimination by the doctor's practice that occurs at the hospital.

[41] The rule defines a ''recipient'' of Federal financial assistance to include an individual. See § 92.4.

[42] *See, e.g.,* U.S. Office of Personnel Management, Guidance Regarding the Employment of Transgender Individuals in the Federal Workplace (May 27, 2011), *https://www.opm.gov/policy-data-oversight/diversity-and-inclusion/reference-materials/gender-identity-Guidance/;* U.S. Office of Personnel Management, U.S. Equal Employment Opportunity Commission, U.S. Office of Special Counsel, U.S. Merit Systems Protection Board. Addressing Sexual Orientation and Gender Identity Discrimination in Federal Civilian Employment: A Guide to Employment Rights, Protections, and Responsibilities, p. 2 (June 2015), *http://www.opm.gov/LGBTGuide.*

intention to protect individuals on this basis.

Response: In the proposed and final rules' definition of gender identity, we explain that the way an individual expresses gender identity is frequently called ''gender expression.'' OCR is clarifying that throughout this final rule, we interpret references to the term ''gender identity'' as encompassing ''gender expression'' and ''transgender status.'' This position is consistent with the position taken by courts and Federal agencies.[43] These bases of discrimination are protected under the rule.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with three modifications. The first sentence of the definition of gender identity has been revised to reference the application of the rule to individuals with non-binary gender identities. OCR also made a technical edit to the last sentence to delete reference to the term ''transgender identity.'' Finally, for clarity and consistency within the final rule, OCR has made a technical revision to the definition of gender identity to clarify that a transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Health program or activity. We proposed that the term ''health program or activity'' means the provision or administration of health-related services or health-related insurance coverage and the provision of assistance in obtaining health-related services or health-related insurance coverage. We also proposed that, similar to the approach of the Civil Rights Restoration Act of 1987 (CRRA)[44] and except as specifically set forth otherwise in this part,[45] the term further includes all of the operations of an entity principally engaged in providing or administering health services or health insurance coverage, such as a hospital, health clinic, community health center, group health plan, health insurance issuer, physician's practice, nursing facility, or residential or community-based treatment facility. We proposed that OCR interpret ''principally engaged'' in a manner consistent with civil rights laws that use this term.

In the proposed rule, OCR stated that we intended the plural ''health programs or activities'' used in this part to have the same meaning as the term ''health program or activity'' in the singular. Similarly, we noted that the proposed part's use of ''health programs and activities,'' a variation of ''health program or activity,'' does not reflect a change in the substance of the definition of ''health program or activity.''

We proposed to interpret ''health programs and activities'' to include programs such as health education and health research programs. Because Federal civil rights laws already prohibit discrimination on the basis of race, color, national origin, disability, or age in all health research programs and activities that receive Federal financial assistance and prohibit discrimination on the basis of sex in all health research programs conducted by colleges and universities, we determined that the application of Section 1557 to health research should impose limited additional burden on covered entities.

However, OCR recognized that health research is conducted to answer scientific questions and improve health through the advancement of knowledge; it is not designed to result in direct health benefits to participants. We also recognized that research projects are often limited in scope for many reasons, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other nondiscriminatory considerations. Thus, we noted that criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research.[46] OCR noted that we do not intend for inclusion of health research within the definition of health program or activity to alter the fundamental manner in which research projects are designed, conducted, or funded; nor did OCR propose to systematically review health research protocols.

We invited comment on programs and activities that should be considered health programs or activities.

Comment: We received comments requesting that we enumerate additional examples of a health program or activity, including but not limited to the Children's Health Insurance Program, all of the operations of Medicare, and student health plans.

Response: We agree that the Children's Health Insurance Program and other health programs operated by State and local governments are covered by the rule. We also agree that student health plans are a health program or activity covered by the rule, and note that all student health plans are covered by Title IX, as well as the other civil rights laws cited in Section 1557, if the institution receives Federal financial assistance.

Although the definition does not and could not specifically identify all health programs and activities covered by the rule (for example, we do not specifically mention programs that provide physical and/or behavioral health services, although they are health programs), we are adding the Children's Health Insurance Program and the Basic Health Program as additional examples, given their significance.

We decline to include ''all the operations of Medicare'' in the definition of health program or activity. While we agree that all parts of the Medicare program are a health program or activity, not all operations in the Medicare program constitute Federal financial assistance; as discussed above, Medicare Part B is excluded from the definition of Federal financial assistance under this rule and other HHS civil rights authorities.[47] Thus, we believe the proposed language could create confusion in determining the scope of the final rule.

Comment: Some commenters noted that OCR did not propose to define the term ''health'' in ''health program and activity,'' and recommended that OCR use the definition of ''health'' adopted by the World Health Organization, which includes an individual's or population's physical, mental, or social well-being.[48]

Response: OCR declines to add a definition of ''health,'' but interprets ''health'' to include physical and mental well-being.

Comment: Several commenters recommended that the rule apply only to the specific health program for which the entity receives Federal financial assistance, such as health insurance coverage sold through the Marketplace^{SM}, and not to other

[43] *See Rumble* v. *Fairview Heath Servs.,* Civ. No. 14–cv–2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (Section 1557); *Schroer* v. *Billington,* 577 F. Supp.2d 293, 303 (D.D.C. 2008)(Title VII); *Macy* v. *Holder,* EEOC Appeal No. 0120120821, Agency No. ATF–2011–00751, 2012 WL 1435995, at *7 (Apr. 20, 2012), *http://www.eeoc.gov/decisions/0120120821%20Macy%20v%20DOJ%20ATF.txt* (Title VII).

[44] Public Law 100–259, 102 Stat. 28 (1988).

[45] Employee health benefits programs are discussed elsewhere in rule. *See infra* discussion of § 92.208.

[46] We note that it is not permissible for clinical researchers to consider ''cost'' of accommodating participants with disabilities as a reason to exclude them from participation.

[47] Medicare Parts A, C, and D all constitute Federal financial assistance. See *www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-federal-financial-assistance/301/indeix.html.*

[48] *See http://www.who.int/about/definition/en/print.html.*(last visited Mar. 11, 2016).

products and services provided outside the Marketplace℠ by issuers participating in the Marketplace℠. These commenters stated that applying the rule to operations or products that are not the direct recipients of Federal financial assistance conflicts with the plain meaning of Section 1557.

Response: Section 1557 prohibits discrimination under ''any health program or activity, any part of which is receiving Federal financial assistance. . . .'' By applying the prohibition if ''any part'' of the health program or activity receives Federal financial assistance, the law provides that the term ''health program or activity'' must be interpreted in a manner that uniformly covers all of the operations of any entity that receives Federal financial assistance and that is principally engaged in health services, health insurance coverage, or other health coverage, even if only part of the health program or activity receives such assistance. This interpretation serves the central purposes of the ACA, and effectuates Congressional intent, by ensuring that entities principally engaged in health services, health insurance coverage, or other health coverage do not discriminate in any of their programs and activities, thereby enhancing access to services and coverage.

This approach is consistent with the approach Congress adopted in the CRRA, which amended the four civil rights laws referenced in Section 1557 and defines ''program or activity'' to mean ''all of the operations of . . . an entire corporation, partnership, or other private organization, or an entire sole proprietorship . . . which is principally engaged in the business of providing,'' among other things, a range of social and health services. The CRRA establishes that the entire program or activity is required to comply with the prohibitions on discrimination if any part of the program or activity receives Federal financial assistance. The CRRA has been consistently applied since its enactment in 1988, and we believe that Congress adopted a similar approach with respect to the scope of health programs and activities covered by Section 1557. If any part of a health care entity receives Federal financial assistance, then all of its programs and activities are subject to the discrimination prohibition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are modifying the definition as proposed in § 92.4 to include the Children's Health Insurance Program and the Basic Health Program as additional examples of a health program or activity.

Individual with limited English proficiency. We proposed that the term ''individual with limited English proficiency'' codify the Department's longstanding definition reflected in guidance interpreting Title VI's prohibition of national origin discrimination, entitled Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons [49] (HHS LEP Guidance). Under the proposed definition, an individual whose primary language for communication is not English is considered an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English. Accordingly, we proposed that an individual whose primary language for communication is not English, even if he or she has some ability to speak English, is an individual with limited English proficiency if the individual has a limited ability to read, write, speak or understand English.

Commenters addressing this definition overwhelmingly supported its codification from the HHS LEP Guidance to regulatory text. We did not receive suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4, without modification.

Language assistance services. OCR proposed that the term ''language assistance services'' identify types of well-established methods or services used to communicate with individuals with limited English proficiency, including (1) oral language assistance; (2) written translation of documents and Web sites; and (3) taglines. We noted that a covered entity has flexibility to provide language assistance services in-house or through commercially available options. We declined to offer an exhaustive list of available methods. However, we proposed that paragraph (1) identify the following as available methods to communicate orally with individuals with limited English proficiency: Oral interpretation (in-person or remotely) [50] and direct communication through the use of bilingual or multilingual staff competent to communicate directly, in non-English languages using any necessary specialized vocabulary, with individuals with limited English proficiency.

We did not receive suggested revisions to the wording of this definition. Comments we received on the specific types of language assistance services mentioned in the definition are addressed in the relevant portions of the preamble to § 92.4 for those respective terms.

For clarity and consistency within the final rule, we are replacing several phrases in this definition with other terms to conform to changes made in other provisions of the final rule. First, in paragraph (1) regarding oral language assistance, we are adding the words ''for an individual with limited English proficiency'' after ''qualified interpreter'' because § 92.4 now defines ''qualified interpreter for an individual with limited English proficiency'' separately from a ''qualified interpreter for an individual with a disability.'' Also, because § 92.4 defines ''qualified bilingual/multilingual staff,'' we are replacing ''bilingual or multilingual staff competent to communicate, in non-English languages using any necessary specialized vocabulary'' with ''the use of qualified bilingual/multilingual staff to communicate.'' In paragraph (2) regarding written translation, we are replacing the reference to written translation of ''documents and Web sites'' to ''written content in paper or electronic form.'' Finally, because § 92.4 defines ''qualified translator,'' we are adding ''performed by a qualified translator'' after ''written translation.''

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with technical revisions, as described in the preceding paragraph, to ensure consistency with other provisions of the final rule.

[49] 68 FR 47311, 47313 (Aug. 8, 2003).

[50] We use the terms ''oral interpretation'' and ''written translation'' for clarity. The term ''interpretation'' used without the preceding descriptor of ''oral'' refers to the communication of information orally and the term ''translation'' used without the preceding descriptor of ''written'' refers to the communication of information in writing. *See, e.g.*, U.S. Dep't of Justice, Commonly Asked Questions and Answers Regarding Limited English Proficient (LEP) Individuals, *http://www.lep.gov/faqs/faqs.html#OneQ11* (last visited Mar. 15, 2016) (differentiating between interpreters and translators in FAQ 11); Interpreters and Translators, U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Outlook Handbook, 2014–15, *http://www.bls.gov/ooh/media-and-communication/interpreters-andtranslators.htm* (explaining that interpreters convert information in a spoken language and translators convert information in written language).

National origin. The proposed rule did not define the term ''national origin.''

Comment: A few commenters recommended defining ''race, color, or national origin'' to include ''language'' and ''immigration status.'' Commenters asserted that ''language'' should be included to capture the application of national origin discrimination to individuals with limited English proficiency. As to immigration status, some commenters requested clarification that immigrants, and particularly non-U.S. citizens, are protected from discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 and this part.

Response: In response to comments, we are providing further clarification on the scope of ''national origin''; we determine it unnecessary to define ''race'' or ''color.'' Thus, this final rule defines ''national origin'' consistent with the well-established definition of the term that the Equal Employment Opportunity Commission (EEOC) uses in its interpretation of Title VII of the Civil Rights Act of 1964.[51] This definition clarifies that national origin includes not only an individual's place of origin, but also his or her ancestor's place of origin, which reflects our intent that individuals born in the United States but who have an ancestry outside the United States are protected. This definition also clarifies that national origin includes an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.[52]

By contrast, we decline to include the term ''immigration status'' in the definition of ''national origin.'' An individual's national origin is not the same as her citizenship or immigration status, and neither Title VI nor Section 1557 explicitly protects individuals against discrimination on the basis of citizenship or immigration status. However, as under Title VI, Section 1557 and this part protect individuals present in the United States, whether lawfully or not, who are subject to discrimination based on race, color, national origin, sex, age, or disability. Moreover, OCR considers an immigrant or noncitizen to state a cognizable national origin discrimination claim under Title VI,[53] Section 1557, and this part when the claim alleges that a covered entity's use of a facially neutral policy or practice related to citizenship or immigration status has a disparate impact on individuals of a particular national origin group.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term ''national origin'' in § 92.4 to include an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group as well as an individual's or her ancestor's place of origin.

On the basis of sex. We proposed that the term ''on the basis of sex'' includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.

We noted that Section 1557 extends the grounds for discrimination found in the nondiscrimination laws cited in the statute (*i.e.,* race, color, national origin, sex, age, or disability) to certain health programs and activities. We noted that the HHS Title IX regulation explicitly includes discrimination on the basis of pregnancy as a form of discrimination on the basis of sex, and we proposed that the definition in this section mirror that regulation.[54]

We noted that the proposed inclusion of sex stereotyping reflects the Supreme Court's holding in *Price Waterhouse* v. *Hopkins,*[55] and that discrimination based on stereotypical notions of appropriate behavior, appearance or mannerisms for each gender constitutes sex discrimination.

We proposed that discrimination on the basis of sex further includes discrimination on the basis of gender identity. We noted that like other Federal agencies,[56] HHS has previously interpreted sex discrimination to include discrimination on the basis of gender identity.[57] We also noted that courts, including in the context of Section 1557, have recognized that sex discrimination includes discrimination based on gender identity.[58] Thus, we proposed to adopt formally this well-

[51] 29 CFR 1606.1 (defining ''national origin discrimination'').

[52] In addition, courts have adopted this principle. *See, e.g., Bennun* v. *Rutgers State Univ.,* 941 F.2d 154, 173 (3d Cir. 1991), *cert. denied,* 502 U.S. 1066 (1992) (stating that an individual's birth in a foreign country where another culture predominates, immersion in that country's ways of life, and speaking the native language in one's home, are sufficient to identify the individual as part of a national origin group); *Fragante* v. *City and County of Honolulu,* 888 F.2d 591, 595–96 (9th Cir. 1989), *cert. denied,* 494 U.S. 1081 (1990) (stating that accent and national origin are inextricably intertwined in many cases); *Gutierrez* v. *Mun. Court of Southeast Jud. Dist., Los Angeles Cnty.,* 838 F.2d 1031, 1039 (9th Cir. 1988 *vac'd and rem,* 490 U.S. 1016 (1989)(stating that ''[b]ecause language and accents are identifying characteristics, ''rules which have a negative effect on bilinguals, individuals with accents, or non-English speakers, may be mere pretexts for intentional national origin discrimination''). A member of a religious group states a cognizable national origin discrimination claim under Title VI and Section 1557 and this part when that discrimination is based on a religious group's shared ancestry or its physical, cultural, and linguistic characteristics rather than its members' religious practice. *See* Letter from Thomas Perez, Assistant Attorney Gen., Civil Rights Div., U.S. Dep't of Justice to Russlynn Ali, Assistant Sec'y for Civil Rights, Office for Civil Rights, U.S. Dep't of Educ. Re: Title VI and Coverage of Religiously Identifiable Groups, at 2 (Sept. 8, 2010), *https://www.justice.gov/sites/default/files/crt/legacy/2011/05/04/090810_AAG_Perez_Letter_to_Ed_OCR_Title%20VI_and_Religiously_Identifiable_Groups.pdf.*

[53] *See* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Ariz. Health Care Cost Containment System & the Ariz. Dep't of Econ. Sec., OCR Transaction Nos. 10–117078 & 10–117875 (2015), *http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/Arizona/vra.pdf* [hereinafter HHS OCR VRA with AZ Agencies] (resolving cognizable complaints of national origin discrimination under Title VI following implementation of a State law requiring State employees, in the administration of public benefits programs, to report ''discovered violations of federal immigration law'' to U.S. Immigration and Customs Enforcement).

[54] *See* 45 CFR 86.40(b) (prohibiting discrimination on the basis of ''pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom'').

[55] 490 U.S. 228, 250–51 (1989).

[56] *See* 5 CFR 300.102(c), 300.103(c), 300.103(c), 315.806(d), 335.103(b)(1), 537.105(d), 900.603(e) (U.S. Office of Personnel Management regulations providing that discrimination on the basis of sex includes discrimination on the basis of gender identity); Directive 2014–02, U.S. Dep't of Labor, Office of Fed. Contract Compliance Programs, § 5 (Aug. 19, 2014), *http://www.dol.gov/ofccp/regs/compliance/directives/dir2014_02.html;* Statement of Interest of the United States, *Jamal* v. *SAKS & Co.,* No. 4:14–CV–2782 (S.D. Tex. Jan. 26, 2015) *https://www.justice.gov/sites/default/files/crt/legacy/2015/02/27/jamalsoi.pdf;* Statement of Interest of the United States, *Tooley* v. *Van Buren Pub. Sch.,* No. 2:14–cv–13466–AC–DRG (E.D. Mich. Feb. 24, 2015) *https://www.justice.gov/sites/default/files/crt/legacy/2015/02/27/tooleysoi.pdf;* Memo from Eric Holder, Att'y Gen., to U.S. Att'ys & Heads of Dep't Components (Dec. 18, 2014), *https://www.justice.gov/opa/pr/attorney-general-holder-directs-department-include-gender-identity-under-sex-discrimination;* U.S. Dep't of Educ., Questions and Answers on Title IX and Sexual Violence, p. B–2, *http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf; Macy,* 2012 WL 1435995, at *11.

[57] *See* Letter from Leon Rodriguez, Director, U.S. Dep't of Health & Human Servs., Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012), *https://www.nachc.com/client/OCRLetterJuly2012.pdf.*

[58] *See, e.g., Rumble* v. *Fairview Heath Servs.,* Civ. No. 14–cv–2037, 2015 WL 1197415, at *10 (D. Minn. Mar. 16, 2015) (Section 1557) (order denying motion to dismiss); *Barnes* v. *City of Cincinnati,* 401 F.3d 729, 737 (6th Cir.), *cert. denied,* 546 U.S. 1003 (2005)(Title VII); *Smith* v. *City of Salem, Ohio,* 378 F.3d 566, 575 (6th Cir. 2004) (Title VII); *Schroer* v. *Billington,* 577 F.Supp.2d 293, 304 (D.D.C. 2008) (Title VII). *But see Johnston* v. *Univ. of Pittsburgh,* 97 F.Supp.3d 657, 671 (W.D. Pa. 2015) (appeal docketed, No. 1502922) (3d Cir. Apr. 24, 2015) (holding that an individual treated in accordance with sex assigned at birth has not been discriminated against on the basis of sex under Title IX).

accepted interpretation of discrimination ''on the basis of sex.''

OCR stated that as a matter of policy, we also support banning discrimination in health programs and activities on the basis of sexual orientation. We noted that current law is mixed on whether existing Federal nondiscrimination laws prohibit discrimination on the basis of sexual orientation as a part of their prohibitions on sex discrimination. However, we further noted that a recent U.S. EEOC decision, *Baldwin* v. *Department of Transportation,*[59] concluded that Title VII's prohibition of discrimination ''on the basis of sex'' includes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations.

We proposed that the final rule reflect the current state of nondiscrimination law, and we sought comment on the best way of ensuring that this rule includes the most robust set of protections supported by the courts on an ongoing basis.

Comment: Several commenters commended OCR's inclusion of discrimination not only on the basis of pregnancy, but also on the basis of pregnancy-related procedures or conditions in the definition of ''on the basis of sex'' and noted that such a position is consistent with existing civil rights statutes. Other commenters noted concern that the inclusion of the phrase ''termination of pregnancy'' in the definition of ''on the basis of sex'' will be interpreted as requiring the provision or coverage of, or referral for, pregnancy termination, and urged OCR to state explicitly that neither Section 1557 nor the regulation imposes such a requirement.

Response: The definition of ''on the basis of sex'' established by this rule is based upon existing regulation and previous Federal agencies' and courts' interpretations that discrimination on the basis of sex includes discrimination on the basis of pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom.

Additionally, the final rule balances an individual's right to access health programs and activities free from discrimination with protections for religious beliefs and practices. As we explained in the preamble to the proposed rule and have reiterated here, this rule does not displace existing protections afforded by, for example, Federal provider conscience laws and RFRA. Again, with respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer to the discussion at § 92.2 in this preamble. With respect to abortion, moreover, nothing in Section 1557 displaces the ACA provisions regarding abortion, including but not limited to the provision that no qualified health plan offered through a Marketplace may discriminate against an individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions;[60] provisions that state that nothing in the ACA shall be construed to require a qualified health plan to provide coverage of abortion as an essential health benefit;[61] and the provision permitting States to prohibit abortion coverage in qualified health plans and restricting the use of Federal funding for abortion services.[62]

Comment: A significant number of commenters commended our inclusion of gender identity and sex stereotyping in the definition of ''on the basis of sex'' and noted that the inclusion is consistent with a growing body of legal precedent. Some commenters suggested OCR add transgender status and gender expression in the definition of ''on the basis of sex'' in order to make explicit our intention to protect individuals on these bases, consistent with previous court and Federal agency interpretations.

Conversely, a few commenters opined that the inclusion of gender identity discrimination as a form of discrimination on the basis of sex was based on erroneous interpretations of Title IX legislative history because Congressional intent to ban sex discrimination was based only on the biological classifications of males and females, not gender identity. A few commenters thought that OCR's reliance on previously adopted Federal agencies' interpretations was weak and unpersuasive and that the reliance on cases arising under Federal civil rights laws other than Title IX was misplaced, further pointing to a few recent court decisions under Title IX that rejected claims that discrimination on the basis of sex includes discrimination on the basis of gender identity.

A few commenters also suggested that the inclusion of ''gender identity'' as a prohibited basis of discrimination on the basis of sex may infringe upon individual patients' constitutional right to privacy by requiring those patients to participate in sex-specific programs or activities with a ''non-biological'' male or female and additionally contravenes employees' and faith-based organizations' religious beliefs by forcing them to participate in services affirming gender identity in violation of their religious convictions.

Response: The definition of ''on the basis of sex'' established by this rule is based upon existing regulation and previous Federal agencies' and courts' interpretations that discrimination on the basis of sex includes discrimination on the basis of gender identity and sex stereotyping. While OCR appreciates the commenters' request that we add transgender status and gender expression to the definition of ''on the basis of sex,'' we do not believe that it is necessary to add these terms to the definition. As previously stated, we encompass these bases in the definition of ''gender identity''; thus, references to ''gender identity'' include ''gender expression'' and ''transgender status.'' Because the definition of ''on the basis of sex'' includes gender identity, further reference to transgender status or gender expression here is superfluous.

OCR also believes that its inclusion of gender identity is well grounded in the law and disagrees with those commenters who argued to the contrary. As the Supreme Court made clear in *Price Waterhouse* v. *Hopkins,* in prohibiting sex discrimination, Congress intended to strike at the entire spectrum of discrimination against men and women resulting from sex stereotypes.[63] Courts after *Price Waterhouse* interpret Title VII's protections against discrimination on the basis of sex as encompassing not only ''sex,'' or biological differences between the sexes, but also ''gender'' and its manifestations.[64] In essence, *Price Waterhouse* thus rejects the reasoning, and vitiates the precedential value, of earlier Federal appellate court decisions that limited Title VII's coverage of ''sex'' to the anatomical and biological characteristics of sex. Moreover, courts frequently look to case law interpreting other civil rights provisions, including Title VII, for guidance in interpreting Title IX.[65]

OCR's approach accords with well-accepted legal interpretations adopted by other Federal agencies and courts.

[59] U.S. Equal Employment Opportunity Comm'n Appeal No. 0120133080, Agency No. 2012–24738–FAA–03 (July 15, 2015), *http://www.eeoc.gov/decisions/0120133080.txt.*

[60] 42 U.S.C. 18023(b)(4).

[61] 42 U.S.C. 18023(b)(1)(A).

[62] 42 U.S.C. 18023.

[63] 490 U.S. at 251 (citations omitted).

[64] *See, e.g., Smith* v. *City of Salem, Ohio,* 378 F.3d. 566, 573–74 (6th Cir. 2004).

[65] *See, e.g., Wolfe* v. *Fayetteville, Ark. Sch. Dist.,* 648 F.3d 860, 864 n.4 (8th Cir. 2011); *Weinstock* v. *Columbia Univ.,* 224 F.3d 33, 42 n.1 (2d Cir. 2000), *cert. denied,* 540 U.S. 811 (2003).

For example, Title IX Guidance issued by the U.S. Department of Education generally requires recipients of federal financial assistance to treat transgender students consistent with their gender identity.[66] The Fourth Circuit reversed a lower court decision dismissing the Title IX sex discrimination claim of a transgender student prohibited from using the school bathroom consistent with his gender identity, holding that the Department of Education's interpretation of its regulation was not plainly erroneous, and thus was entitled to controlling weight.[67]

The fact that there may be circumstances in which it is permissible to make sex-based distinctions is not a license to exclude individuals from health programs and activities for which they are otherwise eligible simply because their gender identity does not align with other aspects of their sex, or with the sex assigned to them at birth. The Department has a responsibility to ensure that health programs and activities of covered entities are carried out free from such discrimination.

To the extent that privacy considerations may be relevant in an anti-discrimination analysis, OCR will consider these interests in the context of individual complaints. We note, however, that at least one court has rejected a claim that an individual's legal right to privacy is violated simply by permitting another person access to a sex-specific program or facility that corresponds to their gender identity.[68] With respect to concerns about potential conflicts between provisions of the final rule and individuals' or organizations' sincerely held religious beliefs, we refer to the discussion at § 92.2 in this preamble.

Comment: A few commenters recommended that OCR clarify that the prohibition on sex discrimination extends to discrimination on the basis of the presence of atypical sex characteristics and intersex traits (*i.e.,* people born with variations in sex characteristics, including in chromosomal, reproductive, or anatomical sex characteristics that do not fit the typical characteristics of binary females or males). At least one commenter noted that this clarification is necessary because intersex people may face discrimination when medical providers or insurance companies follow policies which deem certain medical procedures available to only one sex, thereby excluding intersex people who may be registered under another sex.

Response: We agree with the commenters that the prohibition on sex discrimination extends to discrimination on the basis of intersex traits or atypical sex characteristics. OCR intends to apply its definition of ''on the basis of sex'' to discrimination on these bases.

Comment: Many commenters requested that OCR explicitly state in the rule that Section 1557's prohibition of discrimination on the basis of sex includes discrimination on the basis of sexual orientation. Other commenters asserted that Section 1557 did not intend to protect against sexual orientation discrimination and that OCR does not have authority to include this basis because no Federal appellate court has interpreted Title IX's or Title VII's ban on sex discrimination to protect same-sex relationships or conduct.

Response: As we noted in the preamble to the proposed rule, we support a prohibition on discrimination based on sexual orientation as a matter of policy. We believe that it is critical to meeting the goals of Section 1557 and, more broadly, the ACA, to ensure equal access to health care and health coverage. Indeed, these policy goals are reflected in the increasing number of actions taken by Federal agencies to ensure that lesbian, gay, and bisexual individuals are protected from discrimination. For example, CMS regulations bar discrimination on the basis of sexual orientation by Health Insurance Marketplaces and issuers offering qualified health plans;[69] Medicare regulations prohibit the restriction of visitation rights in hospitals based on sexual orientation (or gender identity);[70] and the Social Security Administration is now processing Medicare enrollments for same-sex spouses.[71] Court decisions have, moreover, repeatedly made clear that individuals and couples deserve equal rights regardless of their sexual orientation.[72]

The preamble to the proposed rule stated our policy position and noted that ''[t]he final rule should reflect the current state of nondiscrimination law, including with respect to prohibited bases of discrimination'' while seeking comment on the issue. While the preamble observed that no Federal appellate court has concluded to date ''that Title IX's prohibition of discrimination 'on the basis of sex'—or Federal laws prohibiting sex discrimination more generally—prohibits sexual orientation discrimination,'' it also noted recent court decisions that have prohibited discrimination in cases involving allegations of discrimination relating to an individual's sexual orientation on the grounds that such discrimination is discrimination on the basis of sex stereotyping.

Price Waterhouse v. *Hopkins*[73] is the foundational decision that underlies these legal developments. Though *Price Waterhouse* did not involve an allegation of discrimination based on an individual's sexual orientation, the Supreme Court recognized in that case that unlawful sex discrimination occurs where an individual is treated differently based on his or her failure to conform to gender-based stereotypes about how men or women should present themselves or behave. The Department of Justice has therefore taken the position that a well-pled complaint alleging discrimination against a gay employee because of his failure to conform to sex stereotypes states a viable sex discrimination claim under Title VII.[74] When a covered entity discriminates against an individual based on his or her sexual orientation, the entity may well rely on stereotypical notions or expectations of how members of a certain sex should act or behave. These stereotypes are precisely the type of gender-based assumptions prohibited by *Price Waterhouse.*[75]

[66] U.S. Dep't of Education, Office for Civil Rights, Questions and Answers in Title IX and Single Sex Elementary and Secondary Classes and Extra-Curricular Activities, (2014), *http://www2.ed.gov/about/offices/list/ocr/docs/faqs-title-ix-single-sex-201412.pdf.*

[67] *.G. ex rel. Grimm* v. *Gloucester Cty. Sch. Bd.,* No. 15–2056, 2016 WL 1567467 at * 6 (4th Cir. 2016).

[68] *See e.g., Crosby* v. *Reynolds,* 763 F. Supp. 666 (D. Me. 1991) (requiring female prisoner to share a cell with a transgender woman violated no clearly established constitutional right); *cf. Cruzan* v. *Special Sch. Dist., #1,* 294 F.3d 981 (8th Cir. 2002) (per curiam) (teacher's assertion that her personal privacy was invaded when school permitted a transgender woman to use women's restroom was not cognizable under employment discrimination law).

[69] 45 CFR 155.120(c)(1)(ii); 156.200(e).

[70] 42 CFR 482.13(h)(3).

[71] *http://www.medicare.gov/sign-up-change-plans/same-sex-marriage.html* (last visited Mar. 11, 2016).

[72] For example, in 1996, the Supreme Court struck down an amendment to the Colorado constitution that prohibited the State government from providing any legal protections to gay, lesbian, and bisexual individuals. *Romer* v. *Evans,* 517 U.S. 620 (1996). And, just last year, the Supreme Court ruled in *Obergefell* v. *Hodges,* 135 S. Ct. 2584 (2015), that states may not prohibit same-sex couples from marrying and must recognize the validity of same-sex couples' marriages.

[73] 490 U.S. 228 (1989).

[74] *See* Def.'s Renewed Mot. to Dismiss at 18–19, *Terveer* v. *Billington,* No. 1:12–cv–1290, ECF No. 27 (D.D.C. Mar. 21, 2013).

[75] *See, e.g., Deneffe* v. *SkyWest, Inc.,* No. 14–cv–00348, 2015 WL 2265373, at * (D. Colo. May 11, 2015); *Terveer* v. *Billington,* 34 F. Supp. 3d 100, 116 (D.D.C. 2014); *Boutillier* v. *Hartford Pub. Schs.,*

Continued

Based on this understanding, some courts have recognized in the wake of *Price Waterhouse* that discrimination ''because of sex'' includes discrimination based on sex stereotypes about sexual attraction and sexual behavior[76] or about deviations from ''heterosexually defined gender norms.''[77] For example, a recent district court decision in the Ninth Circuit held that the distinction between discrimination based on gender stereotyping and discrimination based on sexual orientation is artificial, and claims based on sexual orientation are covered by Title VII and Title IX, not as an independent category of claims separate from sex and gender stereotyping, but as sex or gender discrimination.[78]

In addition, in *Baldwin* v. *Department of Transportation* the EEOC concluded that Title VII's prohibition of discrimination ''because of sex'' includes sexual orientation discrimination because discrimination on the basis of sexual orientation necessarily involves sex-based considerations.[79] The EEOC relied on several theories to reach this conclusion: A plain reading of the term ''sex'' in the statutory language, an associational theory of discrimination based on ''sex,'' and the gender stereotype theory announced in *Price Waterhouse.*

For all of these reasons, OCR concludes that Section 1557's prohibition of discrimination on the basis of sex includes, at a minimum, sex discrimination related to an individual's sexual orientation where the evidence establishes that the discrimination is based on gender stereotypes. Accordingly, OCR will evaluate complaints alleging sex discrimination related to an individual's sexual orientation to determine whether they can be addressed under Section 1557.

OCR has decided not to resolve in this rule whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination under Section 1557. We anticipate that the law will continue to evolve on this issue, and we will continue to monitor legal developments in this area. We will enforce Section 1557 in light of those developments and will consider issuing further guidance on this subject as appropriate.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 without modification.

Qualified bilingual/multilingual staff. In the proposed rule, we proposed to define ''language assistance services'' to include, as a type of oral language assistance, the use of staff members who are ''competent to communicate, in non-English languages using any necessary specialized vocabulary, directly with individuals with limited English proficiency.''[80] The proposed rule did not define the term ''qualified bilingual/multilingual staff.''

Comment: Some commenters observed that as an alternative to providing oral interpretation, many covered entities rely on staff members to serve individuals with limited English proficiency in their respective primary languages. According to these commenters, covered entities mistakenly assume that staff members who possess a rudimentary familiarity with at least one non-English language are competent to provide oral language assistance for the covered entity's health program or activity. Commenters asked us to require covered entities to assess the proficiency of staff members who communicate directly with individuals with limited English proficiency in their respective primary languages.

Response: In response to commenters' observations, we have defined the term ''qualified bilingual/multilingual staff'' in § 92.4 to clarify the knowledge, skills, and abilities that a staff member must demonstrate for a covered entity to designate that staff member to provide effective oral language assistance.[81] Specifically, qualified bilingual/multilingual staff must demonstrate to the covered entity that they are proficient in English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and are able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary language. An individual who meets the definition of ''qualified bilingual/multilingual staff'' does not necessarily qualify to interpret or translate for individuals with limited English proficiency within the meaning of this rule.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term ''qualified bilingual/multilingual staff'' in § 92.4 to clarify that such an individual must be proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and must be able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified interpreter. We proposed that the term ''qualified interpreter'' means an individual who has the characteristics and skills necessary to interpret for an individual with a disability, for an individual with limited English proficiency, or for both. In the proposed rule, the language in paragraph (1), applicable for interpreting for an individual with a disability, is the same as language in the regulations implementing Titles II and III of the ADA, at 28 CFR 35.104 and 36.104, respectively. The language in paragraph (2) of the proposed rule, applicable for interpreting for an individual with limited English proficiency, reflects a synthesis of the attributes, described in the Department's LEP Guidance, that are necessary for an individual to interpret competently and effectively under the circumstances and thus to provide the effective oral language assistance services required under the law.[82] We noted that the fact

2014 WL 4794527 at *2 (D. Conn. 2014); *Koren* v. *The Ohio Bell Tel. Co.,* 894 F. Supp.2d 1032, 1037–38 (N.D. Ohio. 2012); *Heller* v. *Columbia Edgewater Country Club,* 195 F. Supp.2d 1212, 1224, *adopted,* 195 F. Supp.2d 1216 (D. Or. 2002); *Centola* v. *Potter,* 183 F. Supp.2d 403, 410 (D. Mass. 2002).

[76] *See Videckis and White* v. *Pepperdine Univ.,* No. 15–00298, 2015 WL 8916764 (C.D. Cal. Dec. 15, 2015) (denying motion to dismiss).

[77] *Isaacs* v. *Felder,* No. 2:13 cv 693, 2015 WL 6560655, at * 9 (M.D. Ala. Oct. 29, 2015) (internal quotation marks omitted).

[78] *Videckis,* 2015 WL 8916764. Prior circuit court decisions have drawn such distinctions. *See, e.g., Dawson* v. *Bumble & Bumble,* 398 F.3d 211, 218 (2d Cir. 2005); *Vickers* v. *Fairfield Med. Ctr.,* 453 F.3d 757, 763 (6th Cir. 2006).

[79] U.S. Equal Employment Opportunity Comm'n Appeal No. 0120133080, Agency No. 2012–24738–FAA–03 (July 15, 2015), *http://www.eeoc.gov/decisions/0120133080.txt* (finding that sexual orientation is inseparable from and inescapably linked to sex and thus that an allegation of discrimination based on sexual orientation is necessarily an allegation of sex discrimination).

[80] *See* 80 FR at 54176, 54216.

[81] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47317 (stating that the covered entity may provide oral language assistance through bilingual staff members that are ''competent to communicate directly with [limited English proficient] persons in their language'').

[82] *See* HHS LEP Guidance, 68 FR at 47311, 47316 (explaining that an individual's proficiency in another language, knowledge of specialized terminology, and adherence to interpreter ethics are considerations in determining competency to interpret); *id.* at 47317–18, 47323 (discussing why family members, friends, and ad hoc interpreters may not be competent to interpret); The language is also consistent with the approach we have taken in our Title VI enforcement efforts. *See, e.g.,* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Mee Memorial Hosp., OCR Transaction

that an individual has above average familiarity with speaking or understanding a language other than English does not suffice to make that individual a qualified interpreter for an individual with limited English proficiency.

We proposed that the definition of ''qualified interpreter'' includes criteria regarding interpreter ethics, including maintaining client confidentiality. As we stated in the proposed rule, bilingual or multilingual staff members may not possess competence in the skill of interpreting nor have knowledge of generally accepted principles of interpreter ethics. A qualified bilingual/multilingual nurse who is competent to communicate in Spanish directly with Spanish-speaking individuals may not be a qualified interpreter for an individual with limited English proficiency if serving as an interpreter would pose a conflict of interest with the nurse's treatment of the patient.

Comment: A few commenters suggested that OCR amend the definition of qualified interpreter to require interpreters to be licensed by State law in the State where the entity is providing services. Other commenters suggested that OCR require interpreters to be certified by a national nonprofit certification organization.

Response: We recognize the commenters' concerns regarding licensure and certification, but we decline to accept these recommendations. Although OCR considers licensure and certification as evidence that an interpreter is qualified, licensure and certification are neither necessary nor sufficient evidence of qualification for the following reasons.[83] First, OCR does not wish to unduly narrow the pool of qualified interpreters available to a covered entity by requiring certification or licensure; many interpreters who are currently unlicensed and uncertified are competent to translate at a level that would meet the requirements of Section 1557 and this part.

Second, there are several organizations, both for-profit and non-profit, that offer certification programs for interpreters. Even if the credentialing standards developed by those organizations currently satisfy Section 1557 requirements, the organizations' standards are subject to change and there is no assurance that such standards would consistently meet the standards of Section 1557. In addition, other national credentialing organizations could be established whose standards failed to meet the requirements of the law. Similar issues with respect to new and changing standards could also arise in the State licensing context.

Third, there are factors unrelated to credentials that could cause OCR to determine that an interpreter is unqualified. For example, if an interpreter has not practiced in a long time or is late to appointments, the interpreter might be unqualified regardless of the interpreter's State or non-profit credentials. For all of these reasons, we decline to amend the definition of qualified interpreter in the ways these commenters proposed.

Comment: We received many comments in support of the proposed rule's inclusion of a definition of ''qualified interpreter.'' Some commenters, however, requested that we define a qualified interpreter who interprets for individuals with limited English proficiency separately from a qualified interpreter who interprets for individuals with disabilities, noting that there are significant differences between the provision of oral interpretation services in these two contexts. Other commenters suggested broadening the lexicon an interpreter must possess to be a qualified interpreter for a particular covered entity's health program. Specifically, commenters suggested that an interpreter's required knowledge and abilities to be ''qualified'' should include not only knowledge of any necessary specialized vocabulary but also knowledge of terminology and phraseology.

Response: We have modified § 92.4 to provide separate definitions of ''qualified interpreter for an individual with limited English proficiency'' [84] and ''qualified interpreter for an individual with a disability.'' We agree that it is important to account for the qualifications necessary for interpreting for each set of individuals. In addition, we added the words ''terminology'' and ''phraseology'' in both definitions to align the final rule's description of the requisite knowledge, skills, and abilities an interpreter must possess with those recognized within the field.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we no longer define ''qualified interpreter'' as one term. We are using the content from proposed paragraphs (1), (1)(i), and (2) to create a separate definition for ''qualified interpreter for an individual with a disability'' and similarly use the content from proposed paragraphs (1) and (1)(ii) to create a separate definition for ''qualified interpreter for an individual with limited English proficiency.'' For both definitions, we added ''terminology and phraseology'' to the lexicon a qualified interpreter in both contexts must possess.

Qualified translator. The proposed rule did not use or define the term ''qualified translator.''

Comment: We received a significant number of comments recommending that the proposed rule define ''qualified translator.'' Commenters explained that bilingual individuals do not necessarily possess the skill of translating or the knowledge of specialized terminology to be able to translate written documents from English to another language. Similarly, a qualified interpreter for an individual with limited English proficiency may not possess the knowledge, skills, and abilities to translate, as the skill of interpreting is different from the skill of translating.[85]

Response: In response to commenters' recommendations, we are adding the term ''qualified translator'' to the final rule. The final rule defines qualified translator as someone who translates effectively, accurately, and impartially; adheres to generally accepted translator ethics principles; and is proficient in both written English and at least one other written non-English language, including any necessary specialized vocabulary, terminology and phraseology. We agree with commenters that even if an individual meets the definition of ''qualified bilingual/multilingual staff'' or ''qualified interpreter for an individual with

Nos. 12–143846, 13–1551016 & 13–153378, pt. II.J. (2014) [hereinafter HHS OCR VRA with Mee Memorial Hospital], *http://www.hhs.gov/ocr/civilrights/activities/agreements/mee.html* (defining qualified interpreter); Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Montgomery County Dep't of Soc. Servs., OCR Transaction No. 08–79992, pts. II.E (defining qualifications of an ''interpreter'' under the agreement), IV.H (requiring timely, competent language assistance); & IV.L (identifying interpreter standards) [hereinafter HHS OCR VRA with Montgomery County DSS], *http://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/examples/limited-english-proficiency/MCDSS-resolution-agreement/index.html.*

[83] *See* HHS LEP Guidance, 68 FR at 47316 (''Competency to interpret, however, does not necessarily mean formal certification as an interpreter, although certification is helpful.'').

[84] We note that this final rule uses the terms ''qualified interpreter for an individual with limited English proficiency'' interchangeably with ''qualified interpreter for the individual with limited English proficiency'' and ''qualified interpreter to an individual with limited English proficiency.'' The preposition and article used within the phrase do not represent a change in meaning.

[85] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47316; Int'l Medical Interpreters Assoc., Guide on Medical Translation 4 (Jan. 2009), *http://www.imiaweb.org/uploads/pages/438.pdf.*

limited English proficiency'' under this rule, that individual does not necessarily possess the knowledge, skills, or abilities to translate written content in paper or electronic form used in a covered entity's health programs or activities.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we are defining the term ''qualified translator'' in § 92.4 to set out the competencies an individual must have to translate written content in paper or electronic form in the covered entity's health programs or activities.

Sex stereotypes. We proposed that the term ''sex stereotypes'' refers to stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. We noted that these stereotypes can include expectations that gender can only be constructed within two distinct opposite and disconnected forms (masculinity and femininity), and that gender cannot be constructed outside of this gender construct.

Comment: Commenters suggested that OCR revise the definition of ''sex stereotypes'' because, while accurate in describing the types of assumptions that may motivate discrimination against non-binary individuals, the definition is cumbersome and may not be readily understood by persons not familiar with the issue. Several commenters expressed concern that the proposed language might be interpreted as limiting sex discrimination based on sex stereotyping to only include discrimination based on gender identity. Commenters suggested affirming in the final rule that any form of sex discrimination on the basis of sex stereotypes constitutes sex discrimination, whether or not it also constitutes discrimination on the basis of gender identity. Some commenters requested that OCR provide examples illustrating discrimination based on sex stereotypes that can form the basis of prohibited sex discrimination.

Several commenters suggested that OCR clarify the definition of ''sex stereotypes'' to address the relationship between sex stereotypes and sexual orientation. In this regard, commenters suggested that OCR revise the definition of ''sex stereotypes'' to add that ''sex-stereotypes also include gendered expectations related to the appropriate roles of men and women, such as the expectation that women are primary caregivers, and aspects of an individual's sexual orientation, such as the sex of an individual's sexual or romantic partners.''

Response: We have added a reference in the regulatory text to make clear that sex stereotypes include gendered expectations related to the appropriate roles of a certain sex.[86] With regard to sexual orientation, we refer commenters to the discussion in the preamble addressing the definition of ''on the basis of sex.'' [87]

Comment: Some commenters stated that the proposed definition of sex stereotypes is unprecedented in its breadth with no legal authority to support the proposition that individuals who claim to identify with non-binary genders constitute a protected class under Title IX or any other Federal law. Commenters suggested that it is impossible for an individual to have a non-binary gender identity.

Response: OCR has adopted the approach taken by the Federal government and numerous courts in similar matters—that sex stereotypes encompass not only stereotypes concerning the biological differences between the sexes, but also include stereotypes concerning gender norms.[88] As stated in the preamble to the proposed rule and clarified in the final rule, OCR recognizes that sex stereotypes can include the expectation that individuals consistently identify with only one of two genders (male or female), and that they act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes can also include a belief that gender can only be binary and thus that individuals cannot have a gender identity other than male or female. OCR recognizes that an individual's gender identity involves the interrelationship between an individual's biology, gender, internal sense of self and gender expression related to that perception; thus, the gender identity spectrum includes an array of possible gender identities beyond male and female.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the definition as proposed in § 92.4 with the following modifications: We have clarified that sex stereotypes can be based on expectations about gender roles.

Taglines. In the proposed rule, we defined taglines as short statements written in non-English languages to alert individuals with limited English proficiency to the availability of language assistance services, free of charge, and how the services can be obtained.[89] We did not receive comments with suggested revisions to the wording of this definition.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing this definition as proposed in § 92.4 without modification.

Assurances Required (§ 92.5)

In § 92.5, we proposed that each entity applying for Federal financial assistance, each issuer seeking certification to participate in a Health Insurance Marketplace SM, and each state seeking approval to operate a State-based Marketplace SM be required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557. We noted that the regulations implementing Title VI, Title IX, Section 504, and the Age Act all require similar assurances. We modeled the assurance, duration of obligation, and covenants language on the Section 504 regulation.[90] We also proposed to revise the Assurance of Compliance HHS–690 Form to include all civil rights laws, including Section 1557, with which covered entities must comply.

The comments and our responses regarding § 92.5 are set forth below.

Comment: Several commenters recommended that OCR require covered entities to collect data on race, ethnicity, language, sex, gender, gender identity, sexual orientation, disability, and age. These commenters suggested that covered entities should be required to assess the populations they serve so that the covered entities can better plan how to meet the needs of those populations.

[86] *See, e.g., Chadwick* v. *Wellpoint,* Inc., 561 F.3d 38, 45 (1st Cir. 2009) (adverse employment action based on assumption that women are responsible for family caregiving and will perform their jobs less well as a result of caregiving responsibilities is discrimination based on sexual stereotypes in violation of Title VII). *See also Glenn* v. *Brumby,* 663 F.3d 1312 (11th Cir. 2011) (''These instances of discrimination against plaintiffs because they fail to act according to socially prescribed gender roles constitute discrimination under Title VII according to the rationale of *Price Waterhouse.''*).

[87] *See* discussion § 92.4, *supra.*

[88] *See Price Waterhouse,* 490 U.S. at 251; *Smith,* 378 F.3d. at 573 (citations omitted).

[89] The HHS LEP Guidance, *supra* note 49, 68 FR at 47320, describes the practice of tagging non-English statements on the front of common documents, such as ''brochures, booklets, and in outreach and recruitment information'' informing individuals with limited English proficiency of the availability of language assistance services.

[90] 45 CFR 84.5.

The commenters also urged that OCR require annual submission of the data to OCR and develop standards to address training on data collection, privacy protections, safeguarding, voluntary reporting by patients, and supporting analyses based on multiple variables.

Response: OCR agrees that data collection is an important tool that can help covered entities to better serve their communities, and encourages covered entities to regularly evaluate the impact of the services they provide on different populations. However, OCR declines to require data collection as part of the assurances required under Section 1557. The Department collects data pursuant to Section 4302 of the ACA, and OCR has access to these data. In addition, OCR has the authority to require covered entities to collect data and to provide OCR access to information under §§ 92.302 and 92.303 of this part,[91] and will exercise this authority as needed and appropriate under particular circumstances in the future. With respect to recipients and State-based Marketplaces, §§ 92.302(a) and 92.302(b) incorporate the procedural provisions in the Title VI and the Age Act implementing regulations regarding enforcement actions under this part. Pursuant to these procedural provisions, when a recipient or State-based Marketplace SM fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law. OCR has inserted a new subsection (c) to § 92.302 to clarify that it has that it has this authority, and the text that was previously found at § 92.302(c) has been moved to the new § 92.302(d).

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.5 without modification.

Remedial Action and Voluntary Action (§ 92.6)

In § 92.6, we proposed provisions addressing remedial action and voluntary action by covered entities. In paragraph (a), we proposed that a recipient or State-based Marketplace SM that has been found to have discriminated on any of the bases prohibited by Section 1557 be required to take remedial action as required by the Director to overcome the effects of that discrimination. We proposed that similar to recipients and State-based Marketplaces, the Department, including the Federally-facilitated Marketplaces, is also obligated to address discrimination, but is subject to a different remedial process than recipients and State-based Marketplaces. In paragraph (b), we proposed to permit but not require all covered entities to take voluntary action in the absence of a finding of discrimination to overcome the effects of conditions that result or resulted in limited participation by persons based on race, color, national origin, sex, age, or disability. The provisions at §§ 92.6(a) and (b) are modeled after the Title VI, Title IX, Section 504, and Age Act regulations.

The comments and our responses regarding § 92.6 are set forth below.

Comment: One commenter requested that OCR specifically list the remedial actions available to OCR as well as the circumstances under which such remedial actions will be taken.

Response: In the discussion of enforcement mechanisms and procedures in the preamble to the proposed rule, OCR identified the range of enforcement tools available to OCR. However, it would not be feasible to specify the circumstances in which specific remedial actions would be taken. OCR evaluates each situation on a case-by-case basis and may use different remedial actions in different cases. In all cases, OCR attempts to achieve compliance and, in our experience, this approach has been successful.

Comment: One commenter requested clarification of the word ''control'' in the part of the regulation that states that where a recipient exercises ''control'' over a recipient that has discriminated, the Director may require both entities to take remedial action. Another commenter suggested that OCR only pursue remedial action against the entity actually found to have discriminated against an individual and not against the controlling entity.

Response: OCR declines to further define the word ''control'' as used in the regulation. This term has appeared in civil rights regulations enforced by OCR for many years, and its meaning has been established over time. OCR also declines to limit its authority to pursue remedial action with respect to an entity that exercises control over an entity that has discriminated. This too is longstanding authority under OCR's other authorities, and in OCR's experience, controlling entities that are recipients often play an important role in securing appropriate action to remedy discrimination.

Comment: One commenter suggested that there be limitations on the uses of remedial action. Specifically, the commenter stated that OCR should require remedial action only on behalf of individuals who either (1) applied to participate but were unable to participate due to alleged discrimination; or (2) had been participants and were subject to alleged discrimination. The commenter asserted that without such limitations, covered entities could be unfairly exposed to claims by individuals who would not have been participants notwithstanding any alleged discrimination.

Response: OCR does not believe that limiting the availability of remedial action as suggested is appropriate. It would not be consistent with Section 1557's and OCR's commitment to eliminating discrimination in all parts of a program or activity and remedying discrimination, where necessary, with respect to harmed individuals.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.6 without modification.

Designation of Responsible Employee and Adoption of Grievance Procedures (§ 92.7)

In § 92.7, we proposed requirements for each covered entity that employs 15 or more persons to designate a responsible employee to coordinate the entity's compliance with the rule and adopt a grievance procedure. Many entities covered by Section 1557 and this part are already required to designate a compliance coordinator and have a written process in place for handling grievances with respect to disability discrimination in all programs and activities or sex discrimination in education programs or activities.[92]

[91] Section 92.302 incorporates provisions of the Title VI implementing regulation with respect to enforcement actions concerning discrimination on the basis of race, color, national origin, sex, age, or disability. Those provisions authorize OCR to collect reports from recipients as necessary to determine compliance. Section 92.303 incorporates provisions in the Section 504 implementing regulation with respect to discrimination on the basis of prohibited criteria in health programs or activities administered by the Department. Those provisions authorize OCR to initiate actions as necessary to ensure compliance.

[92] Under Section 504, a recipient of Federal financial assistance with 15 or more employees must designate at least one individual to coordinate the covered entity's compliance with Section 504's

Continued

In paragraph (a), we proposed that a covered entity that employs 15 or more persons be required to designate at least one employee to coordinate compliance with the requirements of the rule. We noted that a covered entity that has already designated a responsible employee pursuant to the regulations implementing Section 504 or Title IX may use that individual to coordinate its efforts to comply with Section 1557.

In paragraph (b), we proposed that a covered entity that employs 15 or more persons be required to adopt a grievance procedure that incorporates appropriate due process standards and allows for the prompt and equitable resolution of complaints concerning actions prohibited by Section 1557 and this part. We noted that a covered entity that already has a grievance procedure addressing claims of disability discrimination that meets the standards established under the Section 504 regulation may use that procedure to address disability claims under Section 1557. In addition, we noted that covered entities may use that procedure to address all other Section 1557 claims, provided that the entity modifies the procedure to apply to race, color, national origin, sex, and age discrimination claims.

We proposed that for the Department, including Federally-facilitated Marketplaces, OCR will be deemed the responsible employee. In addition, we proposed that OCR's procedures for addressing complaints of discrimination on the grounds protected under Section 1557 will be deemed grievance procedures for the Department, including for the Federally-facilitated Marketplaces.

In the proposed rule, OCR invited comment on whether all covered entities, not only those that employ 15 or more persons, should be required to designate responsible employees and establish grievance procedures.

The comments and our responses regarding § 92.7 are set forth below.

Comment: Some commenters opposed inclusion of proposed § 92.7, arguing that it is unnecessary and costly and has few benefits because discrimination in health programs and activities does not exist. Other commenters urged that Federal regulation in this area constrains covered entities' flexibility to decide how to address individuals' complaints of discrimination. Specifically, these commenters encouraged OCR to allow covered entities to retain existing internal grievance processes, leverage grievance processes within State agencies or within other entities, or develop new grievance procedures.

Response: We recognize commenters' concerns, but we disagree with commenters regarding the necessity of proposed § 92.7. To promote the effective and efficient implementation of Section 1557 and this part, it is necessary for covered entities with 15 or more employees to identify at least one individual accountable for coordinating the covered entity's compliance and to have a written process in place for handling grievances. We recognize that not all covered entities are organized and operate in the same way. Thus, we do not prescribe who in the covered entity must serve as the responsible employee—nor do we prohibit combining this function with other duties so long as there is no conflict of interest.

In addition, we disagree with commenters that proposed § 92.7 is costly, limits covered entities' flexibility, or conflicts with existing internal or State-mandated grievance procedures. As we stated in the proposed rule, recipients of Federal financial assistance with 15 or more employees, as well as the State-based Marketplaces, could increase the responsibilities of an already-designated coordinator to include the coordination of compliance with Section 1557 and this part.[93] These entities could also increase the scope of the existing grievance procedures required under Section 504 and the ADA to accommodate complaints of discrimination addressing all bases prohibited under Section 1557. Moreover, nothing in the rule bars a covered entity from combining the grievance procedure required under Section 1557 with procedures it uses to address other grievances, including those unrelated to individuals' civil rights. As described in the Regulatory Impact Analysis of the proposed rule[94] and reiterated in the Regulatory Impact Analysis to this final rule, the costs associated with these requirements are estimated to be minimal.

Comment: Some commenters stated that the final rule should specify minimum regulatory requirements for the grievance procedure required in § 92.7(b). Such minimum requirements would include, for instance: Timeframes for filing, resolving, and issuing written decisions regarding complaints; an appeal process; notice regarding retaliation protections; and clarification that no person needs to exhaust a covered entity's grievance procedure prior to filing a Section 1557 complaint with OCR. These commenters urged OCR to adopt regulatory requirements, instead of a model grievance procedure only, stating that a model policy alone is insufficient to ensure that an entity's grievance procedure provides meaningful rights and protections.

Response: We understand the commenters' concerns, but we decline to promulgate minimum standards for the content of the grievance procedure required in § 92.7(b); such an approach would be too prescriptive. Because Section 1557 and this part cover a variety of types of entities, we want to preserve flexibility for entities to adapt the rule's requirements to their own health programs and operational capacity, so long as the rules result in the prompt and equitable resolution of complaints. However, to provide covered entities an example of how to structure a grievance procedure that affords individuals appropriate procedural safeguards and provides for the prompt and equitable resolution of complaints, we have included a sample procedure as Appendix C. We disagree with commenters that a sample grievance procedure is insufficient; rather, a sample grievance procedure provides guidance to covered entities while also preserving their flexibility. In response to commenters' suggestion that we note that an individual need not exhaust a covered entity's grievance procedure prior to filing a Section 1557 complaint, we clarify that no such exhaustion requirement exists, as reflected in the sample grievance procedure included as Appendix C to the final rule.

Comment: Many commenters supported the alternate approach that would require covered entities with fewer than 15 employees to comply with § 92.7. These commenters reasoned that requiring all covered entities to designate a coordinator and establish a grievance procedure would give each entity the internal mechanisms to resolve compliance issues earlier and informally, allowing them to potentially avoid a formal investigation by OCR. Accordingly, these commenters asserted that the importance of extending

prohibition of disability discrimination and must have a written process in place for handling grievances. 45 CFR 84.7(a). Under Title IX, a recipient of Federal financial assistance must designate at least one individual to coordinate the recipient's compliance with Title IX's prohibition of sex discrimination with respect to the recipient's education program or activity and must have a written process in place for handling grievances. 45 CFR 86.8(a). Under Title II of the ADA, an entity with 50 or more employees must designate at least one individual to coordinate the covered entity's compliance with Title II's prohibition of disability discrimination and must have a written process in place for handling grievances. 28 CFR 35.107(a).

[93] *See* 80 FR 54172, 54202 (Sept. 8, 2015).

[94] *Id.*

required compliance with § 92.7 to covered entities with fewer than 15 employees justified the anticipated additional expense of compliance.

Some commenters observed that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule already requires many entities covered by Section 1557 and this part to implement grievance policies and identify compliance coordinators, regardless of the number of employees of the entity.[95] The commenters suggested that the implementation of these requirements under the HIPAA Privacy Rule has given entities with fewer than 15 employees covered by both the HIPAA Privacy Rule and Section 1557 and this part the experience necessary to implement the similar requirements of § 92.7. Because many of the covered entities with fewer than 15 employees, such as most health care providers receiving Federal financial assistance, are subject to the HIPAA Privacy Rule, commenters asserted that extending the requirements of § 92.7 to covered entities with fewer than 15 employees would impose a limited burden.

Conversely, some commenters suggested that compliance with § 92.7 would be too time consuming and costly for covered entities with fewer than 15 employees. These commenters explained that due to the small number of employees, small covered entities may have difficulty identifying an unbiased third-party employee to investigate and respond to grievances. For instance, commenters noted that it is not uncommon for the chief physician or other professional to serve as the compliance coordinator for a small covered entity, but that such a role would be inappropriate if that individual was the subject of a grievance. These commenters also observed that requiring a covered entity to handle internal grievances under Section 1557 might expose the entity to the risk of civil liability, because Section 1557 allows for private enforcement. These commenters recommended that OCR allow small covered entities flexibility in determining when to defer to outside counsel or other independent, unbiased third parties to address grievances and thus mitigate their liability risk.

Response: We decline to extend the requirements of § 92.7 to covered entities with fewer than 15 employees. Although we recognize the benefits that extension of the requirements of § 92.7 would generate, we conclude that the costs, which would be borne by small entities, likely outweigh the benefits. Although many covered entities with fewer than 15 employees may have already identified a compliance coordinator and implemented a grievance policy to comply with the HIPAA Privacy Rule, extending the requirements of § 92.7 to such entities would create additional costs, as entities would need to revise their existing policies and retrain compliance coordinators.

Although we decline to extend the requirement of § 92.7 to covered entities with fewer than 15 employees, nothing in the final rule bars a covered entity with fewer than 15 employees from designating an employee to coordinate compliance with Section 1557 and this part or from adopting and implementing a grievance procedure. As we stated in the proposed rule, in OCR's experience, the presence of a coordinator and grievance procedure enhances the covered entity's accountability and helps bring concerns to prompt resolution, oftentimes prior to an individual bringing a private right of action.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.7 with one technical modification in § 92.7(a): We replaced the reference to the ''Office for Civil Rights'' with ''Director,'' as § 92.4 defines ''Director'' to mean the Director of the Department's OCR. We have also added a sample grievance procedure as Appendix C to the final rule to provide covered entities an example of a grievance procedure that meets the requirements of § 92.7(b).

Notice Requirement (§ 92.8)

In § 92.8, OCR proposed that each covered entity take initial and continuing steps to notify beneficiaries, enrollees, applicants, or members of the public of individuals' rights under Section 1557 and this part and of covered entities' nondiscrimination obligations with respect to their health programs and activities. We modeled this section generally after the notice requirements found in regulations implementing Title VI, Title IX, Section 504, and the Age Act, which require covered entities to have a notice in place.[96]

Paragraphs (a)(1)–(7) of proposed § 92.8 identify the components of the notice. Specifically, paragraph (a)(1) proposed that the notice include that the covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability.

Paragraph (a)(2) proposed that the notice include a statement that the covered entity provides auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities, when such aids and services are necessary to provide an individual with a disability an equal opportunity to benefit from the entity's health programs or activities. Paragraph (a)(3) proposed that the notice state that the covered entity provides language assistance services, free of charge, in a timely manner, to individuals with limited English proficiency, when those services are necessary to provide an individual with limited English proficiency meaningful access to a covered entity's health programs or activities.

Paragraph (a)(4) proposed that the notice include information on how an individual can access the aids and services referenced in (a)(2) and (a)(3).

Paragraph (a)(5) proposed that the notice provide contact information for the responsible employee coordinating compliance with Section 1557 and this part, where such a responsible employee is required by § 92.7(a).

Paragraph (a)(6) proposed that the notice state that the covered entity has a grievance procedure where such a grievance procedure is required by § 92.7(b), and information on how to file a grievance.

Paragraph (a)(7) proposed that the notice provide information on how to file a complaint with OCR. We noted that inclusion of this requirement ensures that covered entities inform individuals about the enforcement mechanisms outside of the covered entity's internal process.

Proposed paragraph (b) stated that within 90 days of the effective date of this part, each covered entity shall post the notice required in § 92.8(a) in English, consistent with paragraph (f) of this section.

Paragraph (c) proposed that the Director shall make available a sample notice. We provided that covered

[95] *See* 45 CFR 164.520(b)(1)(vi) and § 164.530(a)(1)(ii) (requires designation of ''contact person or office who is responsible for receiving complaints under this subsection'' and the provision of a notice ''that contains a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint,'' respectively.)

[96] 45 CFR 80.6(d) (requiring recipients to provide notice of individuals' rights under Title VI), 84.8(a)–(b) (requiring recipients to provide notice of individuals' rights under Section 504), 86.9(a)–(c) (requiring notice of individuals' rights under Title IX), 91.32 (requiring recipients to provide notice of individuals' rights under the Age Act).

entities may use this sample notice or may develop their own notices that convey the information in paragraphs (a)(1) through (7).

OCR invited comment on whether the proposed rule should permit covered entities to combine the content of the notice with the content of other notices that covered entities may be required to disseminate or post under Federal laws. OCR further invited comment on what steps covered entities may or should take to ensure that notices that combine the content required in § 92.8(a)(1)–(7) with other required notices do so without compromising the intent of § 92.8 to inform individuals of their civil rights under Section 1557 and this part. OCR also invited comment on whether the final rule should allow the notice to be modified for publications and other communication vehicles that may not have sufficient space to accommodate the full notice.

Paragraph (c) also proposed that the Director shall translate the sample notice into the top 15 languages spoken by individuals with limited English proficiency nationally and make the translated notices available to covered entities electronically and in any other manner the Director determines appropriate. We encouraged covered entities to post one or more of the translated notices that the Director provides and to make the notice available in non-English languages other than those provided by the Director. OCR sought comments on requiring, rather than merely encouraging, covered entities to post one or more of the notices in the most prevalent non-English languages frequently encountered by covered entities in their geographic service areas.

With regard to the proposal that the Director provide translations of the sample notice, we described that we selected the top 15 languages spoken by individuals with limited English proficiency nationally as a data driven policy.[97] We noted that we plan to review U.S. Census Bureau data as newer data become available to determine if and when the top 15 languages spoken nationally by individuals with limited English proficiency change, warranting the Director to make available notices in additional non-English languages.

Paragraph (d) proposed that within 90 days of the effective date of this part, each covered entity shall post, consistent with paragraph (f) of this section, taglines in at least the top 15 languages spoken nationally by individuals with limited English proficiency. We requested comment on a sample tagline in Appendix B to the proposed rule.

Paragraph (e) proposed that the Director shall make available taglines in the top 15 languages spoken nationally by individuals with limited English proficiency for use by covered entities. OCR proposed this approach to maximize efficiency and economies of scale by enabling covered entities to receive the benefits of having multi-language taglines available without incurring the associated translation costs.

In paragraph (f), we proposed that covered entities must post the English-language notice required in § 92.8(a) and taglines required in § 92.8(d) in a conspicuously-visible font size in: Significant publications or significant communications targeted to beneficiaries, enrollees, applicants, or members of the public, which may include patient handbooks, outreach publications, or written notices pertaining to rights or benefits or requiring a response from an individual; in conspicuous physical locations; and in a conspicuous location on the home page of a covered entity's Web site. We sought comment on the scope of significant publications and significant communications.

We noted that covered entities that distribute significant publications or significant communications will need to update these publications to include the notice required in § 92.8(a) and taglines required in § 92.8(d). However, we proposed allowing entities to exhaust their current stock of hard copy publications rather than requiring a special printing of the publications to include the new notice.

We stated that covered entities may satisfy the requirement to post the notice on the covered entity's home page by including a link in a conspicuous location on the covered entity's home page that immediately directs the individual to the content of the notice elsewhere on the Web site. Similarly, we stated with regard to the requirement to post taglines that covered entities can comply by posting ''in language'' Web links, which are links written in each of the 15 non-English languages posted conspicuously on the home page that direct the individual to the full text of the tagline indicating how the individual may obtain language assistance services. For instance, a tagline directing an individual to a Web site with the full text of a tagline written in Haitian Creole should appear as ''Kreyòl Ayisien'' rather than ''Haitian Creole.''

In the proposed rule, we invited comment on a State-based methodology for identifying the languages in which covered entities would be required to post taglines and for which the OCR Director would be required to translate the notice. We explained that the top 15 languages spoken by individuals with limited English proficiency nationally can differ from the languages spoken most frequently by individuals within the areas served by covered entities' health programs and activities. Thus, we invited comment on a requirement for entities to make taglines available in the top 15 languages spoken State-wide, rather than nationwide, by individuals with limited English proficiency. This threshold aligns with Federal regulations governing the Health Insurance Marketplaces and qualified health plan issuers.[98]

To reduce the burden on covered entities, proposed subsection (g) of this section stated that a covered entity's compliance with § 92.8 satisfies the notice requirements under HHS's Title VI, Section 504, Title IX, and Age Act regulations. We requested comment on this proposal.

The comments and our responses regarding § 92.8 are set forth below.

Comment: Some commenters suggested that we revise the information required in § 92.8(a)(1)–(7) regarding the notice of individuals' rights. For instance, some commenters suggested that we specify that Section 1557 prohibits discrimination on the basis of ''national origin, including primary language and immigration status'' and ''sex, including pregnancy, gender identity, sex stereotypes, or sexual orientation. . . .'' These commenters asserted that the addition of these terms would more completely reflect the scope of protected classes under Section 1557. A few commenters recommended that the notice inform individuals of any religious accommodations or exemptions that the covered entity has received from compliance with civil rights laws and explain the services that

[97] *See* 80 FR 54179 (describing the methodology used in the proposed rule).

[98] *See* 45 CFR 155.205(c)(2)(iii)(A). This regulation, which requires taglines on certain documents and Web site content in at least the top 15 languages spoken State-wide by individuals with limited English proficiency is not the only tagline requirement with which qualified health plan issuers must comply. Qualified health plan issuers must comply with another tagline requirement applicable to group health plans and health insurance issuers, which requires taglines, on certain notices and on a health plan's summary of benefits and coverage, in languages in which 10% of individuals with limited English proficiency county-wide are exclusively literate. *See, e.g.,* 45 CFR 147.136(e)(2)(iii), (e)(3) (HHS regulations); 29 CFR 2590.715–2719(e)(2)(iii), (3) (DOL regulations for group health plans and health insurance issuers that are not grandfathered health plans).

the covered entity will and will not provide as a result of any religious exemptions or accommodations. Finally, a few commenters recommended revising §§ 92.8(a)(2) and (a)(3) to more closely parallel each other. For example, these commenters recommended that we list examples of language assistance services in paragraph (a)(3) and add a reference to providing meaningful access for persons with disabilities in paragraph (a)(2) of § 92.8.

Response: We decline to incorporate the suggestions made with regard to § 92.8(a)(1). The final rule defines the terms ''on the basis of sex'' and ''national origin'' in § 92.4, which is sufficient to define the scope of these protected classes as used in § 92.8(a)(1) and in Appendix A.[99] We are concerned that replicating the regulatory definitions of ''on the basis of sex'' and ''national origin'' in § 92.8(a)(1) and across-the-board in the final rule would dilute the concise, targeted message of the nondiscrimination statement and reduce the value of identifying the core bases on which discrimination is prohibited. Further, replicating the definitional text of these bases in § 92.8(a)(1) but not throughout the final rule may cause unnecessary confusion regarding the scope of discrimination prohibited by Section 1557 and this part. Accordingly, we decline to make the suggested revisions and are removing the terms ''including sex stereotypes and gender identity'' from the sample notice in Appendix A. OCR intended the nondiscrimination statement in § 92.8(a)(1) to convey covered entities' overarching nondiscrimination obligations in a simple and streamlined manner, as the notice requirements do in regulations implementing Title VI, Title IX, Section 504, and the Age Act.[100] The notice requirement of the Title IX implementing regulations does not require recipients of Federal financial assistance to identify exclusions from Title IX's application or exceptions to discrimination prohibited under Title IX.[101] Moreover, under the final rule, the availability of a religious exemption will depend on an analysis of the particular situation; thus, it would be difficult for an entity to state that it was exempt for all purposes. Accordingly, this final rule preserves the simplicity of the nondiscrimination statement consistent with other Federal civil rights laws.

We have revised § 92.8(a)(3) to list examples of language assistance services to parallel § 92.8(a)(2), which lists examples of auxiliary aids and services. We decline to modify the standards in paragraphs (a)(2) and (a)(3) because ''meaningful access'' is not the proper standard used in Section 504 for ensuring effective communication for individuals with disabilities.

Finally, as we stated in the proposed rule, Appendix A to part 92 is a sample notice. Covered entities are free to draft their own notices that convey the content in § 92.8(a)(1)–(7).

Comment: We received many comments addressing practical concerns about the size and length of required notices and taglines. Some commenters supported giving covered entities the flexibility to combine the content of the notice in § 92.8(a)(1)–(7) with other notices required under other Federal laws. For instance, a few comments stated that the State-based Marketplaces should be allowed to combine the content of the notice in § 92.8(a) with disclosures required by Federal regulations governing the Health Insurance Marketplaces at 45 CFR 155.230. Conversely, some commenters strongly opposed the idea of combining the content of the notice required in § 92.8(a) with other notices, reasoning that the combination, and likely modification, of the notice's content would diminish the clear message of the notice.

Some commenters expressed concern that posting the notice and the taglines in a ''conspicuously-visible font size'' as proposed in § 92.8(f)(1) and a ''conspicuous physical location'' as proposed in § 92.8(f)(1)(ii) would occupy prohibitive amounts of space for covered entities operating in small physical spaces, such as pharmacies. These commenters suggested that OCR permit covered entities operating in smaller physical spaces to post taglines in fewer than 15 non-English languages. Other commenters requested clarification from OCR on what constitutes a ''conspicuous physical location'' in § 92.8(f)(ii) and ''conspicuously visible font size'' in § 92.8(f)(1).

A number of commenters recommended that the final rule require covered entities to post the notice of individuals' rights—and not just taglines—in non-English languages.

Response: We intend to provide covered entities some flexibility to implement the requirements of § 92.8 in the manner that they determine meets the standards of this section while also reducing burden.

For instance, we will permit covered entities to combine the content of the notice in § 92.8(a)(1)–(7) with the content of other notices, such as notices required under other Federal civil rights laws. The content of the combined notice still must clearly convey the information required in § 92.8 (a)(1)–(7) and must separately meet any applicable notice requirements under relevant legal authorities. For instance, the regulations implementing Title IX and Section 504 require that a recipient provide a notice of individuals' rights to employees and applicants for employment.[102] Because this final rule is limited in its application to employment, it may not be sufficient for an entity covered by Title IX, Section 504, and Section 1557 and this part to rely on a notice conveying the content required in § 92.8(a)(1)–(7) as meeting its notice obligations under the regulations implementing Section 504 and Title IX. Accordingly, proposed paragraph (g), which is now re-designated as paragraph (h) of this final rule, no longer treats an entity's compliance with particular paragraphs of § 92.8 as constituting compliance with the notice provisions of other Federal civil rights authorities.

Specifically, § 92.8(h) now clarifies that covered entities may combine the content of the notice in § 92.8(a)(1)–(7) with the content of other notices as long as the combined notice clearly informs individuals of their civil rights under Section 1557 and this part. In addition to having flexibility with respect to combining notices, covered entities also have flexibility in determining the exact size and location of notices and taglines within their facilities as long as they do not compromise the intent of § 92.8 to clearly inform individuals of their civil rights under Section 1557 and this part.

The touchstone by which we will assess whether a covered entity's provision of notice and taglines is effective is whether the content is sufficiently conspicuous and visible that individuals seeking services from, or participating in, the health program or activity could reasonably be expected to see and be able to read the information.

[99] An individual's national origin is not the same as her citizenship or immigration status, and neither Title VI nor Section 1557 explicitly protects individuals against discrimination on the basis of citizenship or immigration status. However, as under Title VI, Section 1557 and this part protect individuals present in the United States, whether lawfully or not, who are subject to discrimination based on race, color, national origin, sex, age, or disability. *See* discussion *supra* note 53.

[100] *Supra* note 96.

[101] 45 CFR 86.9(a).

[102] *See* 45 CFR 86.9(a)(1) (requiring a recipient to provide a notice of individuals' rights to applicants for employment and to employees, among other groups of individuals); *id.* 84.8(a) (requiring a recipient to provide a notice of individuals' rights requiring notice to employees, among other groups of individuals).

Although we encourage covered entities to post the notice of individuals' rights in one or more of the most prevalent non-English languages frequently encountered by covered entities in their geographic service areas, we decline to require such posting in the final rule because of the resource burdens and opportunity costs to covered entities. Posted taglines sufficiently alert individuals to the language assistance services available and appropriately balance the educational value of the notices with the burdens to covered entities.

Given that we are not requiring covered entities to post notices in non-English languages, having taglines available in multiple languages is even more important to provide notice to individuals with limited English proficiency of the availability of language assistance services. Thus, we decline to reduce the number of languages in which taglines are required to appear, even for covered entities operating in smaller physical spaces. Covered entities have flexibility in determining the exact size and location of notices and taglines as long as they meet the requirements of this section.

Comment: We received many comments recommending alternative approaches to the proposed rule's requirement for taglines. A few commenters opposed the requirement in proposed § 92.8(d) as unnecessary because oral interpretation is generally available through the customer service telephone line listed on many consumers' health insurance cards. Some commenters suggested that the final rule should permit covered entities to include taglines on the inside of an envelope that a covered entity's health program or activity uses to mail a significant publication or a significant communication. A few commenters suggested replacing tagline text with an icon that would symbolize the availability of oral interpretation services. These commenters suggested that the icon would likely reach more language groups than taglines, and would also occupy substantially less space on significant publications and significant communications.

Response: We decline to eliminate the tagline requirement because such an approach would not provide adequate notice of language assistance services. We appreciate that many health insurance issuers provide telephonic oral interpretation services through their customer service lines/call centers—a number that usually appears on an insured individual's health insurance identification card. We do not, however, regard the mere availability of this information as adequate notice to individuals with limited English proficiency of the availability of language assistance services, much less as notice of each of the components of paragraphs (a)(1)–(7) of § 92.8. Moreover, this approach is not appropriate in all instances because not all covered entities rely on the use of an individual identification card.

In addition, we decline to authorize placement of taglines on the inside of an envelope. Such a placement would diminish the visibility of the taglines, downgrade their importance, and fail to adequately notify individuals because envelopes are generally torn open and then discarded.

With respect to use of an icon, we appreciate the commenters' suggestion and believe that it may hold promise in the future. However, we also decline to require the use of an icon in the final rule. At this point in time, use of an icon alone would not provide consumers with sufficient notice of the availability of language assistance services, which is the intent of § 92.8(d).

Comment: A small number of commenters provided feedback on the application of the requirement to post the notice and taglines in significant publications and significant communications that are small in size, such as brochures, postcards, targeted fliers, small posters, and those that are communicated through social media platforms. Some commenters recommended that the final rule exempt such communications and publications from the posting requirement in § 92.8(f)(1)(i); others recommended that the final rule provide covered entities latitude to substantially shorten the notice and taglines for these publications and communications. Commenters advocating for either of these two positions stated that the limited amount of space in such publications and communications makes them an impractical medium for disclosures of civil rights.

Other commenters opposed any exceptions for significant publications and significant communications that are small-sized, given the importance of notifying individuals about their rights under Section 1557, such as how to obtain auxiliary aids and services for individuals with disabilities and how to obtain language assistance services for individuals with limited English proficiency.

Response: We agree that the notice and tagline requirements for small-sized significant publications and communications should be distinguished from the requirements for significant publications and significant communications that are not small-sized. We also agree with commenters who suggested that small-sized significant publications and significant communications are not well-suited to extensive civil rights disclosures and that they function to drive consumers to other sources of information, such as a covered entity's Web site, where the full civil rights notice and taglines are required by § 92.8(f)(iii). Furthermore, posting the full notice and all 15 taglines to small-sized publications and communications may obscure the content and message of the document, thus undermining the value of such publication or communication. As a result, we are modifying § 92.8(f)(1)(i) to exclude small-sized significant publications and communications from requirements to have a notice and at least 15 taglines.

We disagree, however, with fully exempting significant publications and significant communications that are small-sized from the notice and tagline requirements because these documents, such as tri-fold brochures, pamphlets, and postcards, often serve as a gateway for an individual to apply for, or participate in, a particular health program or activity. To this end, the final rule establishes a separate requirement for small-sized significant publications and significant communications: A covered entity must include a nondiscrimination statement in lieu of the full notice, and taglines in two non-English languages in lieu of all 15 taglines, on small-size significant publications and significant communications.

Specifically, we moved most of the text from proposed paragraph (b) into a new paragraph (b)(1) and added paragraph (b)(2), which addresses the obligation to post a nondiscrimination statement that conveys the information in § 92.8(a)(1) on small-sized significant publications and significant communications. Similarly, we moved most of the text from proposed paragraph (d) into a new paragraph (d)(1) and added paragraph (d)(2), which addresses the obligation to post taglines in at least the top two languages spoken by individuals with limited English proficiency in the relevant State or States on small-size significant publications and significant communications. Finally, we re-designated proposed paragraph (g) as paragraph (h) and we added new paragraphs (g)(1)–(2) to address the posting standards applicable to small-sized significant publications and significant communications.

In choosing a lower threshold than at least the top 15 languages spoken by

individuals with limited English proficiency, we chose a concrete number of languages, rather than a threshold formulated as a percentage, because on average about two-thirds of the limited English proficient population in each State [103] is reached by the top two languages spoken by individuals with limited English proficiency in that State. Moreover, requiring a specific number of taglines makes the impact of the requirement predictable for all covered entities in planning how these two taglines, along with the nondiscrimination statement, will fit on their significant communications and significant publications that are small-sized. In almost all States, the top two languages spoken by individuals with limited English proficiency captures Spanish and the other most prevalent non-English language. This approach in paragraphs (b)(2), (d)(2), and (g)(1)–(2) of § 92.8 is more streamlined than requiring the full notice and all 15 taglines but still will inform the majority of individuals with limited English proficiency of their rights to be protected from discrimination under Section 1557 and this part.

In addition, we have added a sample nondiscrimination statement in Appendix A that conveys the information in § 92.8(a)(1), for which the Director will also provide translations. Accordingly, we have modified paragraph (c) of § 92.8 to state that the Director will provide translations of the sample nondiscrimination statement. The translations of the sample notice and sample nondiscrimination statement are for covered entities' discretionary use only—the final rule does not require the posting of the notice or nondiscrimination statement in non-English languages.

Comment: A substantial majority of commenters on § 92.8 provided feedback on the methodology for determining the number of languages in which covered entities will be required to post taglines. Some commenters supported the proposed rule's national methodology because of its simplicity, particularly for covered entities that operate in multiple States. Conversely, other commenters expressed concern that the national standard fails to account for concentrations of particular limited English proficient communities within areas served by covered entities' health programs and activities, including Native American languages spoken by those served in Tribal health programs. One commenter recommended that if the final rule includes a national standard, OCR should require taglines in the top 25 languages spoken nationally by individuals with limited English proficiency. This commenter further recommended that when calculating the top 25 languages, OCR should rely on a data set that ''unbundles'' bundled language groups, such as ''other Asian languages,'' because some languages represented in bundled categories may be highly prevalent in the service area of a particular covered entity's health program or activity.[104]

Most commenters disfavoring a national methodology recommended that the languages in which covered entities must post taglines should be the top 15 languages spoken State-wide by individuals with limited English proficiency. Commenters explained that the State-wide threshold would be more attuned to the diversity of languages spoken by individuals with limited English proficiency in each State and would align with Federal regulations governing the Marketplaces and qualified health plan issuers.[105] Some of these commenters also recommended that the final rule should require covered entities that serve individuals in multiple States to post more than 15 taglines if the composite list of each State's list aggregates to a total of more than 15 languages. These commenters reasoned that such an interpretation is necessary to further the purpose of addressing the diversity of languages spoken by individuals with limited English proficiency served by a particular covered entity.

Other commenters recommended other approaches, such as requiring taglines in languages in which at least 10% of individuals with limited English proficiency county-wide are exclusively literate,[106] or, in languages spoken by at least 5% of individuals with limited English proficiency or 500 individuals with limited English proficiency in the covered entity's service area, whichever yielded the greater number of languages. Still other commenters recommended that the rule allow covered entities to choose between a State-wide and a national methodology in determining the languages in which to post taglines, depending on the geographic scope of the intended audience for the ''significant publication or significant communication'' to which the taglines are posted. These commenters explained that a covered entity that operates nationally may choose to post on the covered entity's Web site taglines in languages based on a nationwide threshold but may choose to include on a significant communication to an individual taglines in languages based on a State-wide threshold for the State in which the individual resides.

Response: In response to commenters' recommendations, § 92.8(d)(1) of the final rule requires covered entities to post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States. Accordingly, paragraphs (d)(1)–(2) of § 92.8 refer to this State-based methodology rather than a national methodology. This threshold captures, on average, 90% of each State's LEP population.

We adopt a State-based approach for three main reasons. First, a State-based methodology is more attuned to the diversity of languages spoken by individuals with limited English proficiency and thus provides notice to more individuals with limited English proficiency.

Second, this State-wide approach better harmonizes with the number of languages in which taglines must be provided by Marketplaces and qualified health plan issuers under 45 CFR

[103] In estimating this percentage, we used the same data sources, *infra* notes 109 and 110, and the same methodology described in the discussion, *infra,* that we used to identify the languages under the State-based approach in which the Director will translate the sample notice and taglines, as required by § 92.8(c) and (e) of the final rule.

[104] In October 2015, for the second time since the U.S. Census Bureau's American Community Survey (ACS) began, the Census Bureau released detailed tables that unbundle the 39 languages and language groups that ACS publishes annually through its American Factfinder data set. U.S. Dep't of Commerce, U.S. Census Bureau, Data, Detailed Languages Spoken at Home and Ability to Speak English for the Population 5 Years and Over: 2009–2013, *http://www.census.gov/data/tables/2013/demo/2009-2013-lang-tables.html* [hereinafter U.S. Census Bureau, ACS 2009–2013 Detailed Languages] (last visited May 3, 2016). The unbundled data includes 380 possible languages or language groups spoken by individuals who speak English less than ''very well.'' In the proposed rule, HHS explained that it calculated the top 15 languages spoken nationally by individuals with limited English proficiency by relying on the American Factfinder data set that bundles languages. *See* 80 FR 54172, 54179 n.30 (Sept. 8, 2015) (describing the tagline methodology).

[105] 45 CFR 155.205(c)(iii)(A) (beginning no later than November 1, 2016, requiring taglines on Web site content and documents that are critical for obtaining coverage or access to health care services through a qualified health plan for certain individuals in at least the top 15 languages spoken by individuals with limited English proficiency in the relevant State; documents are deemed to be critical for obtaining health insurance coverage or access to health care services through a qualified health plan if they are required to be provided by law or regulation to certain individuals); *see infra* note 107 (describing other tagline requirements applicable to qualified health plan issuers as a result of market-wide regulations).

[106] This 10% county-level threshold for taglines applies to group health plans and health insurance issuers. *See, e.g.,* 45 CFR 147.136(e)(2)(iii), (e)(3) (HHS regulations); 29 CFR 2590.715–2719(e)(2)(iii), (3) (DOL regulations).

155.205(c)(2)(iii)(A).[107] Section 92.8 of this final rule applies to all entities covered by Section 1557, but for Marketplaces and qualified health plan issuers that are subject to the tagline requirements at 45 CFR 155.205(c)(2)(iii)(A) and § 92.8 of this final rule, our State-wide methodology lessens the burden to which Marketplaces and qualified health plan issuers might otherwise be subject.

Third, a county-level approach is impractical because detailed language data are not available for counties with populations of less than 100,000. For counties with populations of at least 100,000 for which detailed language data are available, there are limited data for individuals who speak English less than ''very well'' and speak a non-English language other than Spanish.[108] For county-level data that are available, moreover, we are concerned that sampling error would render many estimates of small language populations unreliable when assessed within the small geographic area of a county.

With regard to the data used to identify the languages under the State-based methodology in which the Director will translate the sample notice, sample nondiscrimination statement, and taglines, as required by § 92.8(c) and (e) of the final rule, we rely on the most recent bundled and unbundled five-year[109] data available from the U.S. Census Bureau. We rely on the data set that estimates the prevalence of foreign-language speakers who speak English less than ''very well,''[110] and we made technical adjustments, such as to remove any spoken languages that do not have a written equivalent in which the Director could translate a tagline.

We intend the threshold's application in § 92.8(d)(1)–(2), which applies to the ''relevant State or States,'' to permit covered entities that serve individuals in more than one State[111] to aggregate the number of individuals with limited English proficiency in those States to determine the top 15 languages required by § 92.8(d)(1), or the top 2 languages required by § 92.8(d)(2) where each respective provision applies.[112] The languages produced from this aggregation are static with respect to the posting requirement in § 92.8(f). Using one of the three posting methods as an example—the posting of the taglines in a covered entity's physical locations required by § 92.8(f)(1)(ii)—a covered entity that operates multiple health programs serving individuals within various States, or that operates a health program with a multi-State service area, complies with § 92.8(f)(1)(ii) when it posts, in its physical locations across the States it serves, taglines in at least the top 15 languages spoken by the aggregate limited English proficient populations of those States, rather than of each individual State. We do not intend to require a covered entity that operates health programs in multiple States (or in States nationwide), or that administers a health program with a multi-State service area (or even a nationwide service area), to tailor the taglines for the specific State in which the entity is physically located or in which an individual with limited English proficiency, with whom the entity communicates, lives. This interpretation best balances the burden on covered entities with the notification of language assistance services to individuals required by § 92.8(d).[113]

We reiterate, however, that the requirements of § 92.8(d)(1)–(2) establish a floor; covered entities are free to include taglines in additional languages beyond 15 languages. For instance, a covered entity that has chosen to aggregate languages may choose to post taglines in all languages on the aggregated list rather than posting just the top 15 languages. Moreover, a covered entity that that operates health programs in multiple States or that administers a health program with a multi-State service area may decide not to aggregate. Instead, the entity may choose to tailor the taglines posted in its physical locations for the specific State in which the physical location exists; similarly, the entity may choose to tailor the taglines on a certain significant communication based on the State in which an individual with limited English proficiency, with whom the entity communicates, lives.

In addition, we note that complying with § 92.8(d)(1)–(2) is not a substitute for complying with the prohibition of national origin discrimination as it affects individuals with limited English proficiency under Section 1557 or this part, including the general nondiscrimination provisions in § 92.101 and the meaningful access provisions in § 92.201 of this final rule. Thus, although this section identifies the languages in which covered entities must post taglines, it does not relieve those entities of the separate obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency who communicate in other languages.

Comment: One commenter recommended including American Sign

[107] Qualified health plan issuers are also bound by the tagline requirement in market-wide regulations at 45 CFR 147.136(e). Under § 147.136(e), taglines must appear on certain notices and on a health plan or issuer's summary of benefits and coverage, in languages in which 10% of individuals with limited English proficiency county-wide are exclusively literate. *See, e.g.,* 45 CFR 147.136(e)(2)(iii), (e)(3). This methodology applies to a narrower set of documents than those to which the tagline requirement applies in Federal regulations governing Marketplaces and qualified health plan issuers. *Compare* 45 CFR 147.136(e)(2)(iii) (requiring taglines on internal claims and appeals notices) *and* 45 CFR 147.200(a)(5) (requiring taglines on summaries of benefits and coverage) *with* 45 CFR 155.205(c)(2)(iii)(A) (requiring taglines on Web site content and documents that are critical for obtaining health insurance coverage or access to health care services through a qualified health plan). For CMS's most recent technical guidance on the tagline requirement at 45 CFR 155.205(c)(2)(iii)(A), *see* Guidance and Population Data for Exchanges, Qualified Health Plan Issuers, and Web-Brokers to Ensure Meaningful Access by Limited-English Proficient Speakers Under 45 CFR 155.205(c) and 156.250 (Mar. 30, 2016), *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.html#*, Language Access Guide for Exchanges, Qualified Health Plan (QHP) Issuers, and Web-Brokers (last visited May 3, 2016).

[108] U.S. Census Bureau, ACS 2009–2013 Detailed Languages, *supra* note 104 (detailing data parameters in the user notes). At least 25,000 individuals who speak English less than ''very well'' must speak the same language for the ACS county-level data to identify such language speakers. *Id.*

[109] We rely on the American Community Survey (ACS) 5-year data set because its stability is superior to the 1-year data set, especially when analyzing small populations. U.S. Census Bureau, American Community Survey, When to Use 1-year, 3-year, or 5-year Estimates, *http://www.census.gov/programs-surveys/acs/guidance/estimates.html* (last visited May 3, 2016). The U.S. Census Bureau has discontinued the ACS 3-year data set, which is the data set on which we relied in the proposed rule. U.S. Census Bureau, Census Bureau Statement on the 3-Year American Community Survey Statistical Product (Feb. 2, 2015), *http://content.govdelivery.com/accounts/USCENSUS/bulletins/eeb4af* (last visited May 3, 2016).

[110] U.S. Dep't of Commerce, U.S. Census Bureau, American FactFinder, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Older, ACS Estimates by State: 2010–2014 (released Dec. 2015); U.S. Census Bureau, ACS 2009–2013 Detailed Languages, *supra* note 104. We are not aware of a public data source providing as robust data as the ACS that estimates the languages in which individuals with limited English proficiency read, understand, or speak. Thus, we are relying on a data set identifying individuals who have a limited ability to speak English as a proxy for limited English proficiency population.

[111] This categorization includes covered entities that operate multiple health programs serving individuals within various States or that operate a health program with a multi-State service area.

[112] For a similar approach, *see* HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750, 10788 (Feb. 27, 2015) (describing the Department's interpretation of 45 CFR 155.205(c)(2)(iii)(A) and (B) for entities with multi-State service areas).

[113] As newer ACS data become available with respect to the data sets on which we base our methodology, we will determine if and when the at least top 15 languages spoken by individuals with limited English proficiency State-wide change, warranting the Director to make available notices and taglines translated in additional non-English languages.

Language as a language for which a posted tagline be required in § 92.8(d). This commenter stated that taglines denoting the availability of American Sign Language Interpretation could communicate this message by displaying still images, rather than a written language.

Response: We decline to include American Sign Language as a language for which a tagline is required in § 92.8(d)(1)–(2) because the notice of individuals' rights in § 92.8(a)(2), which must be posted in a conspicuously-visible font size and location just like taglines, addresses this issue. Specifically, paragraph (a)(2) requires that the notice of individuals' rights state that the covered entity provides auxiliary aids and services, which include sign language interpreters, to individuals with disabilities when necessary to provide such individuals an equal opportunity to benefit from the entity's health programs or activities.

Comment: A few commenters recommended that the final rule prescribe the location of taglines at or near the beginning of significant publications and significant communications. These commenters provided anecdotal evidence that individuals with limited English proficiency who received multi-page English notices requiring time-sensitive responses failed to see taglines appearing on the last page. Commenters explained that to the individuals' detriment, they discarded the notices without responding, resulting in termination of health insurance coverage and other negative outcomes. A number of commenters recommended that covered entities be required to include the text of all required taglines, not just the in-language link, conspicuously on the homepage of their Web sites.

Response: Although we encourage covered entities to include notices and taglines at the beginning of significant publications and significant communications to ensure that they are meaningfully accessible to the consumer, we decline to require this prescriptive approach as part of the final rule. In some circumstances, such as lengthy publications, it may be necessary to include the notice and taglines at the beginning of a document to meet the requirements of § 92.8(f)(1)(i) and (g)(1)–(2); in others, posting elsewhere, including on a separate insert [114] accompanying the English-language significant publication or significant communication, may be adequate. Furthermore, in today's increasingly electronic and digital age where covered entities may make their first impressions through Web content (often on small mobile devices), we are sensitive to covered entities' need for autonomy in designing and managing the appearance of their public internet home pages.

Although the law requires that individuals receive sufficient notice of language assistance services available to assist individuals with limited English proficiency in understanding the content of a covered entity's Web site, we believe that the use of in-language links permitted under this provision of the proposed rule is the approach that best balances notice to individuals against burden to covered entities.

Comment: Some commenters described the proposed requirement to post the notice in ''significant publications and significant communications'' as onerous. One commenter recommended that health plans provide the notice to individuals on an annual basis, along with individuals' annual enrollment package, instead of on each ''significant publication and significant communication.'' Some commenters requested that OCR include, in regulation text, the examples of ''significant publications and significant communications'' we provided in the preamble to the proposed rule, specifically outreach publications and patient handbooks. A few commenters requested that OCR consult with other Federal agencies on the scope of ''significant publications and significant communications'' to establish a common understanding of this term so that covered entities whose publications and communications are regulated by more than one Federal agency are not subject to conflicting standards.

Other commenters were concerned about OCR's statement in the preamble of the proposed rule that OCR intended the scope of ''significant publications and significant communications'' to include not only documents meant for the public but also individual letters or notices to an individual, such as a letter to a consumer notifying the individual of a change in benefits. These commenters observed that, pursuant to existing Federal and State law, many letters already include disclosures and other legally mandated information; consequently, the requirement to post both the notice and taglines required in proposed § 92.8(a) and (d), respectively, might dilute the primary message of the letter and confuse or frustrate consumers. Some commenters requested clarification on how ''vital documents'' as used in the Department's LEP Guidance relates to ''significant publications and significant communications'' in § 92.8(f)(1)(i) of the proposed rule.

Response: We disagree with commenters' characterization of § 92.8(f)(1)(iii) as ''onerous.'' We acknowledge that compliance with this subsection may impose some limited burdens on covered entities. However, these burdens are outweighed by the benefits that § 92.8(f)(1)(iii) will generate for individuals with limited English proficiency by making them aware, in their own languages, of the availability of language assistance services. Notifying individuals of their rights under Section 1557 and this part, including the availability of language assistance services for individuals with limited English proficiency and the availability of auxiliary aids and services for persons with disabilities, is critical to providing an equal opportunity to access health care and health coverage. For these reasons, OCR intends to interpret ''significant communications and significant publications'' broadly, which is consistent with the notice provisions of other Federal civil rights authorities, such as Section 504 [115] and Title IX.[116]

We decline to limit the posting requirement in § 92.8(f)(iii) to an annual frequency. The notice requirements in other Federal civil rights laws on which we modeled § 92.8 do not contain a similar limitation. Moreover we also note that not every covered entity sends annual notices.

[114] For instance, Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, and Medicare Prescription Drug Plans must include a ''CMS Multi-Language Insert'' in the text of certain documents or as a separate page included with certain documents. U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Medicare Marketing Guidelines, § 30.5.1, 7–8 (Jul. 2, 2015), *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html.*

[115] 45 CFR 84.8(a)–(b) (indicating that methods of notifying individuals' of their rights under Section 504 may include ''publication in newspapers and magazines, placement of notices in [Federal financial assistance] recipients' publication[s], and distribution of memoranda or other written communications'' as well as ''recruitment materials or publications containing general information that . . .[the recipient] makes available to participants, beneficiaries, [and] applicants. . . .'').

[116] 45 CFR 86.9(a)(2)(i) (requiring initial notice of individuals' rights to appear in local newspapers, newspapers and magazines published by the recipient of Federal financial assistance, and ''memoranda or other written communications distributed to every student . . . of such recipient'') and 86.9(b)(1) (requiring each recipient of Federal financial assistance to ''prominently include a statement of . . . [the recipient's nondiscrimination policy] in each announcement, bulletin, catalog, or application form which it makes available . . .'').

We also decline to enshrine a list of examples of ''significant publications and significant communications'' in regulation for two main reasons. First, the final rule applies to such a diverse range of covered entities that codifying examples likely would not provide meaningful guidance to the full spectrum of covered entities regulated. Second, we intend to maximize covered entities' flexibility, and each covered entity is in the best position to determine which of its communications and publications with respect to its health programs and activities are significant.

In response to commenters who requested that ''significant publications and significant communications'' be limited to documents intended for the public, rather than those intended for specific individuals, we decline to limit the intended scope of such documents to those aimed only at the public at-large. We intend the scope of significant publications and significant communications to include not only documents intended for the public, such as outreach, education, and marketing materials, but also written notices requiring a response from an individual and written notices to an individual, such as those pertaining to rights or benefits. We have no reasoned basis to distinguish and exempt significant publications and significant communications intended for specific individuals from significant publications and significant communications intended for the public at-large. Indeed, in some situations, a written notice with information tailored to a specific individual's benefits or participation may be even more important to that individual than a significant publication or significant communication conveying information to the public. Accordingly, an individual's awareness of his or her rights under Section 1557, such as the availability of auxiliary aids and services for persons with disabilities (required in § 92.8(a)(2) to be in the nondiscrimination notice) is just as important as information communicated to the public at-large.[117]

The HHS LEP Guidance uses the term ''vital documents'' to refer to the documents for which covered entities should prioritize written translations for individuals with limited English proficiency.[118] The HHS LEP Guidance does not define vital documents. Rather, the Guidance states that ''[w]hether or not a document (or the information it solicits) is 'vital' may depend upon the importance of the program, information, encounter, or service involved, and the consequence to the LEP person if the information in question is not provided accurately or in a timely manner.'' [119] The HHS LEP Guidance also provides examples of documents likely to be ''vital,'' such as ''consent and complaint forms, . . . [ ] written notices of eligibility criteria, rights, denial, loss, or decreases in benefits or services . . . [ ] [and] [a]pplications to participate in a recipient's program or activity or to receive recipient benefits or services.'' [120]

OCR intends for ''vital documents'' to represent a subset of ''significant communications and significant publications'''' in which covered entities must post the notice (or nondiscrimination statement in § 92.8(b), where applicable) and taglines required by § 92.8(d) and (f), among other electronic and physical locations. In clarifying this point, we emphasize that the HHS LEP Guidance uses the term ''vital documents'' to address how a covered entity should meet its Title VI obligations to translate entire documents. By contrast, we refer to ''significant communications and significant publications'' in this rule to identify the documents in which covered entities are required to post the notice of individuals' rights (or nondiscrimination statement, where applicable) and taglines. We are not adopting an across-the-board requirement for covered entities to translate certain written documents into a threshold number of languages.

Comment: Some commenters recommended that OCR provide funding and other resources to non-profit organizations for the purpose of creating a national social media campaign to publicize the requirements of Section 1557.

Response: It is beyond scope of the final rule for OCR to fund organizations' education and outreach efforts. OCR continues, however, to conduct outreach and provide technical assistance to inform covered entities of their obligations and individuals of their rights under Federal civil rights laws, including Section 1557 and this part. OCR will continue to disseminate, via web and social media platforms, fact sheets and other useful materials to covered entities and individuals.

Comment: OCR received a number of comments suggesting revisions to the sample notice in Appendix A and the sample tagline in Appendix B to the proposed rule, such as revisions to improve adherence to plain language writing principles. For example, with respect to the sample notice, a few commenters recommended revisions with respect to the provision of language assistance services: Adding the word ''qualified'' prior to the word ''interpreters,'' which is listed as a type of language assistance service; replacing ''first language'' with ''primary language''; replacing ''translated into other languages'' with ''written in other languages''; and deleting ''when needed to communicate effectively with us.''

One commenter objected to the conditional tense of the sample tagline in Appendix B, which stated that ''[i]f you speak [insert language], language assistance services may be available to you . . . ,'' expressing concern that it might deter an individual from asking for or about language assistance services. In addition, commenters suggested that the conditional phrasing of ''may be available'' is inconsistent with covered entities' obligations under § 92.201 to take reasonable steps to provide meaningful access to each individual with limited English proficiency.

A few commenters recommended that the sample tagline in Appendix B be shortened but offered no specific recommendations on shorter language. Some commenters suggested that OCR consumer test the sample notice in Appendix A of the proposed rule before providing it as a sample in the final rule.

Response: We share commenters' views that the sample notice should clearly convey civil rights information, which can often be complex. We agree with the specific revisions from commenters to improve the sample notice's statement about a covered entity's provision of language assistance services. We have modified Appendix A to the final rule to reflect these

[117] For comparison, the meaningful access requirements of other Federal regulations governing qualified health plan issuers apply to all information that is critical for obtaining health insurance coverage or access to health services through the qualified health plan, including ''applications, forms, and notices'' and information is deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer is ''required by law or regulation'' to provide the document to certain individuals. *See* 45 CFR 156.250. CMS's annual guidance to qualified health plan issuers lists examples of documents to which CMS interprets § 156.250 to apply, such as certain correspondence and notifications, summary of benefits and coverage disclosures, formulary drug lists, provider directories, and a plan's explanation of benefits or similar claim processing information. U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Final 2017 Letter to Issuers in the Federally-facilitated Marketplaces, 80–81 (Feb. 29, 2016), *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf.*

[118] HHS LEP Guidance, *supra* note 49, 68 FR at 47318–19.

[119] *Id.* at 47318.

[120] *Id.* at 47319.

revisions, and have made technical revisions to include OCR's contact information for filing a complaint. In our view, the sample notice, with these modifications, adequately apprises individuals of their civil rights under Section 1557 and this part without providing irrelevant or confusing information. We remind covered entities that nothing in the final rule prohibits covered entities from drafting their own notices to meet the requirements of § 92.8(a)(1)–(7), which covered entities are free to consumer test.

In addition, we have added a nondiscrimination statement to Appendix A that covered entities can post on significant publications and significant communications that are small-sized.

We appreciate commenters' attention to the details of the sample tagline's phrasing. We have modified Appendix B to the final rule to address commenters' concerns that the tagline's conditional wording might deter an individual from asking for or about language assistance services. With technological advancements in language assistance services, we are confident that covered entities have the ability, at a minimum, to obtain qualified oral interpretation services in the languages in which covered entities will provide taglines, consistent with § 92.8(d)(1)–(2); thus, the sample tagline as modified states that language services ''are'' available. In addition, we replaced the word ''contact'' with ''call'' to simplify the vocabulary used for average literacy levels. The modifications we have made amplify taglines' function as a critical gateway to language assistance services. Taglines derive value not only from informing individuals with limited English proficiency of language assistance services but also from prompting individuals to contact the covered entity to obtain language assistance. We decline to shorten the sample tagline because we are concerned that doing so would compromise the tagline's message and intent. We remind covered entities that Appendix B is a sample; covered entities are free to develop their own taglines as long as they provide taglines consistent with § 92.8(d)(1)–(2) of this part.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we have modified § 92.8 and Appendices A and B to part 92 as follows:

In § 92.8(a), we made technical modifications to paragraph (a) and paragraphs (a)(1)–(3). In paragraph (a) we replaced the conjunction ''or'' with ''and.'' In paragraph (a)(1), we clarified that the nondiscrimination statement of the notice applies to the health programs and activities of a covered entity. In paragraph (a)(2), we inserted the phrase ''for individuals with disabilities'' after ''qualified interpreters'' because the final rule now defines qualified interpreters for individuals with disabilities separately from qualified interpreters for individuals with limited English proficiency. In paragraph (a)(3), we added examples of language assistance services to promote alignment with paragraph (a)(2), which provides examples of auxiliary aids and services.

Most of the text in proposed § 92.8(b) is now reflected in new paragraph (b)(1). We added paragraph (b)(2) that requires a covered entity to post a nondiscrimination statement consistent with newly-designated paragraph (g)(1), which applies to significant publications and significant communications that are small-sized. In newly-designated paragraph (b)(1) and (f)(1), we eliminated ''English-language'' before ''notice'' to avoid the incongruous result that a significant publication or significant communication written in a non-English language must include a notice written in English.

In § 92.8(c), we added language to convey OCR's plans to translate the sample nondiscrimination statement for covered entities to use at their discretion.

In paragraph (d) of § 92.8, we added paragraph designations (1) and (2) to distinguish the final rule's tagline requirements for significant publications and significant communications that are not small-sized from those that are small-sized. Most of the text in proposed paragraph (d) is now reflected in paragraph (d)(1). In newly-designated (d)(1), we replaced the national threshold with a threshold requiring taglines in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States. In addition, we added a reference to the posting requirement in paragraph (f)(1) of § 92.8 for clarity. Paragraph (d)(2) identifies the tagline requirement for significant publications and significant communications that are small-sized. In paragraphs (c) and (e) of § 92.8, we replaced the national threshold with a reference to the languages triggered by the State-wide methodology described in paragraph (d)(1).

In § 92.8(f), we revised paragraph (f)(1) and paragraphs (f)(1)(i) and (iii). Specifically, in paragraph (f)(1), we made a technical revision to remove an errant reference to paragraph (b) and we replaced the reference to paragraph (d) with (d)(1) to conform to the new paragraph designations of the final rule. In § 92.8(f)(1)(i), we replaced the conjunction ''or'' with ''and'' as a technical revision to align the text with the same technical revision in § 92.8(a). In addition, we excluded publications and significant communications that are small-sized from the requirement to post the notice conveying all content in § 92.8(a)(1)–(7) and from the requirement to post all 15 taglines. In paragraph (f)(1)(iii), we clarified the location of the tagline when posted to the covered entity's Web site.

We re-designated paragraph (g) in the proposed rule as paragraph (h) in this final rule. In the final rule, paragraph (g) addresses covered entities' requirements to post a nondiscrimination statement and taglines in significant publications and significant communications that are small-sized. Specifically, paragraph (g)(1) addresses the requirement to post a nondiscrimination statement and paragraph (g)(2) addresses the requirement to post taglines.

Newly re-designated paragraph (h) no longer treats an entity's compliance with particular paragraphs of § 92.8 as constituting compliance with the notice provisions of other Federal civil rights authorities. We revised the paragraph to address a covered entity's permissive authority to combine the content of the notice in paragraphs (a)(1)–(7) of this section with the content of other notices.

In Appendix A to the final rule, we made the following changes to improve the plain language reading of the sample notice and to streamline the sample notice's messaging:

- Deleted ''sex stereotypes and gender identity'' from the end of the first sentence;
- Replaced ''worse'' with ''differently,'' and deleted the pronoun ''their'' prior to listing the bases on which the covered entity does not discriminate;
- Replaced ''first language'' with ''primary language'';
- Deleted ''when needed to communicate effectively with us'';
- Added ''qualified'' to modify ''interpreters'' with respect to serving individuals with limited English proficiency;
- Replaced ''translated into other languages'' with ''written in other languages'';
- Added placeholders for a covered entity to provide not only the name of its civil rights coordinator but also the individual's title; and

• Added contact information for filing a complaint with OCR.

In addition, we added a sample nondiscrimination statement in Appendix A for covered entities to post in significant publications and significant communications that are small-sized and accordingly broadened the title of Appendix A to reflect its revised scope.

In Appendix B to the final rule, we modified the language by replacing ''may be available'' with ''are available'' and by adding language to improve the plain language reading of the sample tagline, by replacing ''[c]ontact'' with ''call.''

Subpart B—Nondiscrimination Provisions

Subpart B of the final rule incorporates regulatory provisions implementing the application of the civil rights statutes referenced in Section 1557(a): Title VI, Title IX, the Age Act, and Section 504.

Discrimination Prohibited (§ 92.101)

We proposed that § 92.101 of subpart B prohibit discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity to which Section 1557 or this part applies. We proposed that paragraphs (a) and (b) follow the structure of the implementing regulations for Title VI, Section 504, Title IX, and the Age Act by including a general nondiscrimination provision in paragraph (a) followed by a provision identifying specific discrimination prohibited in paragraph (b). In paragraph (c), we proposed to address exceptions to discrimination prohibited under the Title VI, Section 504, and Age Act regulations. We proposed that paragraph (d) effectuate technical changes in terminology to apply the provisions incorporated from other regulations to the covered entities obligated to comply with this proposed rule.

In paragraph (a)(1) of § 92.101 of the proposed rule, we restated the core objective of Section 1557(a), which prohibits discrimination on the grounds prohibited under Title VI (race, color, or national origin), Title IX (sex), the Age Act (age), or Section 504 (disability) in any health program or activity to which this part applies.

In paragraph (a)(2), we proposed to limit the ways in which the proposed rule applies to employment. We noted that except as provided in § 92.208, which addresses employee health benefit programs, the proposed rule does not generally apply to discrimination by a covered entity against its own employees. Thus, the proposed rule would not extend to hiring, firing, promotions, or terms and conditions of employment outside of those identified in § 92.208; such claims could continue to be brought under other laws, including Title VII, Title IX, Section 504, the ADA and the Age Discrimination in Employment Act,[121] as appropriate. We invited comment on our proposal to exclude these forms of employment discrimination from the scope of the proposed rule.

We proposed that paragraph (b) incorporate into the regulation the specific discriminatory actions prohibited by each civil rights statute which Section 1557 references. We considered harmonizing each of the specific discriminatory actions prohibited across each civil rights law addressed by Section 1557. We noted that although harmonization could reduce redundancy in the specific discriminatory actions incorporated that are similar to one another, harmonization would likely lead to confusion and unintended differences in interpretation that are subtle yet significant. We therefore proposed that paragraphs (b)(1)–(4) incorporate the specific discriminatory actions prohibited under each civil rights law on which Section 1557 is grounded. We sought comment on this proposed approach.

We proposed that paragraph (b)(1) adopt the specific discriminatory actions prohibited by the Title VI implementing regulation, which appear at 45 CFR 80.3(b)(1)–(6).

In paragraph (b)(2)(i), we proposed to address the specific prohibition of discrimination on the basis of disability with which recipients and State-based Marketplaces must comply. In paragraph (b)(2)(i), we proposed to adopt relevant provisions in the Section 504 implementing regulation for federally assisted programs and activities at 45 CFR part 84. We provided that the provisions incorporated are the specific discriminatory actions prohibited at § 84.4(b); the program accessibility provisions at §§ 84.21 through 84.23(b); and the provisions governing education, health, welfare, and social services at §§ 84.31, 84.34, 84.37, 84.38, and 84.41–84.55.

We proposed that paragraph (b)(2)(ii) address the specific prohibitions of discrimination on the basis of disability with which the Department, including the Federally-facilitated Marketplaces, must comply. We proposed that this paragraph adopt relevant provisions in the Section 504 implementing regulation for federally administered programs and activities at 45 CFR part 85. We provided that the provisions adopted are the specific discriminatory actions prohibited at § 85.21(b) and the program accessibility provisions at §§ 85.41 through 85.42 and 84.44 through 84.51.

We proposed that paragraph (b)(3) adopt the specific discriminatory actions prohibited by the Title IX implementing regulation, which appear at 45 CFR 86.3(b)(1) through (8).

We also proposed that paragraph (b)(4) adopt the specific discriminatory actions prohibited by the Age Act implementing regulation, which appear at 45 CFR 91.11(b).

In paragraph (b)(5), we proposed that the specific discriminatory actions prohibited in § 92.101(b)(1) through (4) do not limit the general prohibition of discrimination in § 92.101(a). We noted that this statement is consistent with regulatory provisions in the implementing regulations for Title VI at 45 CFR 80.3(b)(5) and the Age Act at 45 CFR 91.11(c).

In paragraph (c), we proposed to incorporate the exceptions to the general prohibition of discrimination that appear in the implementing regulations for Title VI, Section 504, and the Age Act, as these exceptions have applied to health programs and activities for nearly 40 years. We noted that, generally, the exceptions in the Title VI, Section 504, and Age Act implementing regulations provide that it is not discriminatory to exclude a person from the benefits of a program that Federal law limits to a protected class. We did not address the sex-based distinctions authorized in Title IX and its implementing regulation in the context of education programs or activities. We noted that these distinctions do not necessarily apply in the health care context. However, we also noted that Title IX and the Department of Education's Title IX regulations allow some single-sex education programs when certain requirements are met.[122] We did not propose to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex, but sought comment on what other sex-based distinctions, if any, should be permitted in the context of health programs and activities and the standards for permitting the distinctions.

Finally, we proposed that paragraph (d) effectuate technical changes to apply

[121] 29 U.S.C. 621–634.

[122] 34 CFR 106.34.

the provisions incorporated in § 92.101(b) and (c) to covered entities obligated to comply with the proposed rule by, among other things, replacing references to ''recipient'' in the incorporated provisions with ''covered entity.''

The comments and our responses regarding § 92.101 of subpart B are set forth below.

Comment: A few commenters recommended that OCR add the words ''or deterred'' to the general prohibition of discrimination, so that it would read as follows: ''Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded or deterred from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies.''

Response: We believe the regulatory text, as it is currently written, conveys the intent to prohibit discriminatory deterrence from participation in a health program or activity. As OCR noted in the preamble to the proposed rule, paragraph (a)(1) of § 92.101 prohibits discrimination on the grounds prohibited under Title VI, Title IX, the Age Act, and Section 504 in any health program or activity to which this part applies. It is well established under these and other civil rights law that deterrence on the basis of a prohibited criterion is a form of discrimination. Similarly, discrimination on the basis of perceived race, color, national origin, sex, age, or disability is prohibited discrimination under the final rule, as it is under the authorities referenced in Section 1557.

Comment: One commenter asked for clarification that, when scientific evidence supports differential treatment to ensure safe, high-quality care, such treatment would not be considered discriminatory. This commenter pointed out that the risks and benefits of treatments may differ due to characteristics such as age, gender, physical stature, and genetics. For example, based on the best available science, experts have judged that, for men and younger women, absent a known family history, the risks associated with radiation exposure from routine mammograms outweigh the benefits. Thus, practice guidelines suggest not administering screening mammograms to women under a certain age or to men.

Response: Scientific or medical reasons can justify distinctions based on the grounds enumerated in Section 1557. We affirm this understanding of the final rule and believe that the regulatory text encompasses that approach.

Comment: A few commenters asked that OCR prohibit discrimination in health programs or activities on the basis of ''health status, claims experience, medical history, or genetic information'' in addition to race, color, national origin, sex, age, and disability.

Response: This rule implements Section 1557 of the ACA, which prohibits discrimination on the bases of race, color, national origin, sex, age, and disability. Accordingly, the commenters' request is beyond the scope of this rule. However, OCR recognizes that discrimination based on health status, claims experience, medical history, or genetic information can, depending on the facts, have a disparate impact that results in discrimination on a basis prohibited by Section 1557 and will process complaints alleging such discrimination accordingly. In addition, such discrimination also may violate other laws, such as other provisions of the ACA or the Genetic Information Nondiscrimination Act of 2008.[123]

Comment: Many commenters disagreed with the approach taken in the proposed rule to exclude discrimination in employment in areas other than employee health benefits. Commenters stated that the text of Section 1557 does not exclude employment discrimination; that Section 1557 protects ''individuals,'' similar to Title IX's protection of ''person[s];'' and that Title IX has been interpreted to protect not just students but employees of educational institutions. They also noted that Section 504 covers employment without exception and that Title VI covers employment discrimination when it affects beneficiaries of the covered program.[124]

Response: For the reasons stated in the preamble to the proposed rule, OCR declines to interpret Section 1557 to grant itself jurisdiction (outside the context of employee health benefit plans under circumstances set out in § 92.208) over claims of employment discrimination brought by employees against their employers that are covered entities. In holding that both Title IX and Section 504 broadly prohibit discrimination in employment, the Supreme Court relied heavily on the legislative history and underlying purpose of these statutes.[125] By contrast, there is no indication that broadly prohibiting employment discrimination was a chief purpose of Section 1557, which is focused on discrimination against participants in health programs and activities. To the extent that employees who are subject to discrimination are employed by entities that are covered under other employment discrimination laws, their complaints can be brought under those other laws. And as to employees of small employers, we do not believe that Congress in Section 1557 intended to alter, across the board, the longstanding exclusion of small employers from most employment discrimination laws. That said, nothing in this rule is intended to alter the established principles underlying the unlimited coverage of employment discrimination under both Title IX and Section 504, and OCR will process such claims brought under these statutes under its longstanding procedures.[126]

Comment: Some commenters asked that OCR clarify that Section 1557's prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability includes intersectional discrimination that might affect persons who are part of multiple protected classes. For example, discrimination against an African-American woman could be discrimination on the basis of both race and sex.

Response: OCR is clarifying here that Section 1557's prohibition of discrimination reaches intersectional discrimination. We believe that the regulatory text encompasses this approach.

Comment: Commenters noted that various forms of harassment in health care can discourage individuals from seeking care and suggested that OCR include a separate provision that explicitly prohibits all forms of harassment based on protected characteristics, including sexual harassment and other forms of sex-based harassment.

Response: OCR recognizes that various forms of harassment can impede an individual's ability to participate in

[123] *Supra* note 3.

[124] *See North Haven Bd. of Educ.* v. *Bell*, 456 U.S. 512 (1982).

[125] *Id.* at 522–30; *Consolidated Rail* v. *Darrone*, 465 U.S. 624, 626 (1984).

[126] Moreover, nothing in this rule is intended to affect OCR's ability to address discrimination against patients on a prohibited basis, even where that discrimination is effectuated through actions against a covered entity's employee. If, for example, a medical practice that receives Federal financial assistance fired a Hispanic doctor because the practice no longer wished to serve the doctor's predominantly Hispanic, limited English proficient patients, OCR could pursue relief on behalf of affected patients to ensure that their access to the practice was not discriminatorily denied. *Cf.* 45 CFR 80.3(c)(3) (Title VI applies where discrimination in employment tends to exclude individuals, on the basis of race, color, or national origin, from participation in a covered program).

or benefit from a health program or activity and can thus constitute unlawful discrimination under Section 1557 and this part. Under Title IX, harassing conduct creates a hostile environment if the conduct is sufficiently serious to interfere with or limit an individual's ability to participate in or benefit from a program.[127] For example, a provider's persistent and intentional refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth constitutes illegal sex discrimination if such conduct is sufficiently serious to create a hostile environment. Similarly, a provider using derogatory language because an individual is an unmarried sexually active or pregnant woman constitutes illegal sex-based harassment if such conduct is sufficiently serious to create a hostile environment. Consistent with the well-established interpretation of existing civil rights laws, OCR interprets the final rule to prohibit all forms of unlawful harassment based on a protected characteristic. Because it has been long-established that harassment is a form of prohibited discrimination under each of the laws cited in Section 1557 and this part, OCR does not believe a separate harassment provision is necessary and therefore declines to revise the proposed rule to include one.

Comment: Many commenters recommended that OCR add regulation text stating that the Tri-Agency Guidance[128] imposes legally enforceable obligations on entities covered by Section 1557 and that OCR has direct authority to enforce the Tri-Agency Guidance as well as the statutory and regulatory provisions therein articulated.[129] The Tri-Agency Guidance describes how States can structure their application and enrollment processes in compliance with Title VI and program authorities to ensure that State agencies do not administer federally assisted public benefit programs in a manner that delays or denies services to eligible individuals, including children, living in mixed-immigration status households.

Commenters asked for such regulatory language based on concerns that some covered entities administer their programs in a manner that discriminates based on national origin by delaying or denying access to public benefits based on practices such as: Erecting onerous documentation requirements; denying eligible applicants the opportunity to prove eligible income, identity, citizenship status, or immigration status; or making generalized assumptions about applicants' eligibility based on the actual or perceived immigration status or national origin of any family member.[130] Commenters also expressed concern that some covered entities fail to understand the eligibility differences between various immigrant visa statuses and length of residency requirements, fail to distinguish between applicants and non-applicants in requests for Social Security numbers (SSNs), or require the disclosure of SSNs or immigration status without first explaining the use or confidentiality of this information.

Response: OCR appreciates hearing from commenters on this important issue. However, we decline to explicitly reference, in regulation, the Tri-Agency Guidance and the authorities therein articulated for two main reasons. First, it is beyond the scope of this final rule to address program authorities over which OCR does not have enforcement authority.

Second, regulatory modifications to the proposed rule are unnecessary to allow OCR to address a covered entity's policy or practice, such as requiring the disclosure of SSNs or certain citizenship or immigration status information, that raises compliance concerns under Section 1557's prohibition of national origin discrimination. OCR addresses such issues under Title VI.[131] We similarly have authority to address such issues under Section 1557 and this part when, for example, an individual's complaint alleges that a covered entity has implemented a facially-neutral policy, such as requiring the disclosure of immigration status from applicants and non-applicants, that has a disparate impact on individuals of a particular national origin group.

Thus, to the extent that the Tri-Agency Guidance identifies situations that may raise Title VI compliance concerns and offers best practices for resolving those concerns, this information is equally applicable to health programs and activities covered under Section 1557 as it is to the health and human service programs addressed in the Tri-Agency Guidance. The Department continues to adhere to the principles set forth in the Tri-Agency Guidance in the implementation of the Department's programs[132] and through OCR's enforcement of Title VI. OCR intends to apply these principles in our enforcement of Section 1557 and this part and will continue to accept complaints alleging that covered entities' actions deter eligible individuals from applying for benefits offered by health programs and activities on the basis of their national origin. Section 1557 and this part, however, do not alter programmatic laws and regulations that restrict eligibility for particular health programs to persons of certain immigration or

[127] *See, e.g.,* U.S. Dep't of Educ., Office for Civil Rights, Questions and Answers on Title IX and Sexual Violence (2014) at A–2, available at *http://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf.*

[128] U.S. Dep't of Health & Human Servs. and U.S. Dep't of Agriculture, Policy Guidance Regarding Inquiries into Citizenship, Immigration Status and Social Security Numbers in State Applications for Medicaid, State Children's Health Insurance Program (SCHIP), Temporary Assistance for Needy Families (TANF), and Food Stamp Benefits (2000) [hereinafter Tri-Agency Guidance], *http://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/tri-agency/index.html* (describing how States can structure their facially-neutral policies and practices to enroll eligible children and families of all national origins to reduce and eliminate access barriers).

[129] In addition to Title VI, the Tri-Agency Guidance addresses the Privacy Act of 1974 and program authorities authorizing and implementing Medicaid, CHIP, Temporary Assistance for Needy Families, and the Food Stamp Program. *Id.* at 1–2, Q2.

[130] The Tri-Agency Guidance addresses the circumstances under which a State may not deny benefits when a non-applicant applying on behalf of a child, or a non-applicant household member, does not provide information regarding his or her citizenship status, immigration status or a Social Security number. The Guidance recommends that public benefits applications allow non-applicants to declare early in the process whether they are seeking benefits only on behalf of an eligible child or family member so that further inquiry is limited to factors necessary for determining the child's or family member's eligibility. *Id.* at 206, Q3–Q7.

[131] *See* HHS OCR VRA with AZ Agencies, *supra* note 53, (resolving cognizable complaints of national origin discrimination under Title VI following implementation of an Arizona State law requiring State employees, in the administration of public benefits programs, to report ''discovered violations of federal immigration law'' to U.S. Immigrations and Customs Enforcement).

[132] *See, e.g.,* 77 FR 18310, 18355 (Mar. 27, 2012) (applying the principles of the Tri-Agency Guidance to Marketplace℠ regulations on the health insurance application process); U.S. Dep't of Health & Human Servs., Office of Community Servs., Admin. on Children & Families, HHS Guidance on the Use of Social Security Numbers and Citizenship Status Verification for Assistance by LIHEAP Grantees' Programs, A6 (2014), *http://www.acf.hhs.gov/programs/ocs/resource/liheap-im-hhs-guidance-on-the-use-of-social-security-numbers-ssns-and-citizenship-status-verification* (strongly encouraging LIHEAP Grantees to structure their eligibility processes to avoid the delay or denial of benefits to eligible persons in mixed-immigration status households); U.S. Dep't of Health & Human Servs., Admin. on Children & Families, Office of Child Care, Clarifying Policy Regarding Limits On The Use Of Social Security Numbers Under the Child Care and Development Fund and the Privacy Act Of 1974, Program Instr. No. ACYF–PI–CC–00–04 (2000), *http://www.acf.hhs.gov/programs/occ/law/guidance/current/pi0004/pi0004.htm* (requiring States to make clear that the provision of a SSN is voluntary and child care benefits will not be denied or withheld for failure to provide a SSN).

citizenship statuses, and thus allow covered entities to make requests for that information when required by such authorities.[133]

Comment: A few commenters recommended that HHS clarify its longstanding position that the regulations implementing Section 504 require health care entities with fewer than 15 employees to provide auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question. These commenters pointed out that while 45 CFR 84.52(d)(1) requires the provision of auxiliary aids only by covered entities with 15 or more employees, 45 CFR 84.52(d)(2) provides that the Director may require recipients with fewer than 15 employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services. The commenters recognized that in 2000, HHS issued a notice in the **Federal Register** announcing that the Director had decided to require recipients with fewer than 15 employees to provide appropriate auxiliary aids pursuant to 42 CFR 84.52(d)(2).[134] However, the commenters also asserted that some judicial decisions have questioned whether the Director's notice constitutes a binding legislative rule or merely a policy statement by HHS.[135] Accordingly, these commenters were concerned that the proposed rule's incorporation of 45 CFR 84.52(d) might not be clear enough to also incorporate the Director's notice that health care entities with fewer than 15 employees must provide auxiliary aids and services on the same basis as health care entities with 15 or more employees.

Response: To ensure clarity as to our intent, we have revised the language in § 92.101(b)(2)(i) to delete the reference to 45 CFR 84.52(d) and have added new language to that section requiring covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills where necessary to afford such persons an equal opportunity to benefit from the service in question.

As explained in the Director's original notice adopting this policy, OCR believes that Section 504's auxiliary aids and services requirement should be applied to covered entities with fewer than 15 employees in the interest of uniformity and consistent administration of law. Under Title III of the ADA, privately operated public accommodations are obligated to provide appropriate auxiliary aids and services, regardless of their size, where necessary to ensure effective communication with individuals with disabilities, unless they can demonstrate that taking such steps would fundamentally alter the nature of their program, services or activities, or would result in undue financial and administrative burdens.[136] OCR's decision to require all entities, regardless of size, to provide auxiliary aids and services under Section 1557 and this part thus furthers consistency among disability discrimination laws; importantly, it also furthers the ACA's goal of improving access to health coverage and health care because requiring all entities to provide auxiliary aids and services will result in enhanced services for people with disabilities. Moreover, because this requirement has been OCR's policy for more than a decade, covered entities are familiar with the obligations it imposes.

Comment: A few commenters asked that OCR add language to the rule declaring that medical treatment for individuals with disabilities must be as effective as treatment for individuals without disabilities.

Response: At § 92.101(b)(2)(i), the final rule incorporates 45 CFR 84.4(b)(1)(iii) of the Section 504 implementing regulation, which states that recipients may not provide qualified individuals with disabilities ''with an aid, benefit, or service that is not as effective as that provided to others. . . .'' Such benefits include medical treatment, though recipients cannot, and are not required under the rule to, ensure equally effective outcomes.

Comment: A number of commenters urged that OCR make clear that, consistent with the requirements of Title II of the ADA and Section 504,[137] disability-based discrimination under Section 1557 encompasses the needless segregation of individuals with disabilities. They pointed, in particular, to the need to make clear that covered entities must make coverage and reimbursement decisions that support serving individuals with disabilities in integrated settings unless doing so would fundamentally alter the entities' service systems, citing to the HHS Guidance on Medicaid Managed Care.[138]

Response: We agree that since Section 1557 explicitly incorporates Section 504's prohibitions against disability-based discrimination, it therefore encompasses a ban on the unnecessary segregation of individuals with disabilities. As such, and as required by Title II of the ADA and Section 504 and interpreted in *Olmstead* v. *L.C.*[139] and its progeny, public entities (State and local governments) must administer services to individuals with disabilities in the most integrated setting appropriate to their needs unless doing so is a fundamental alteration of the public entity's service delivery system. The ''most integrated setting'' mandate applies to the full spectrum of the public entity's service delivery system, including coverage and reimbursement decisions, when the entity ''(1) directly or indirectly operates facilities and or/programs that segregate individuals with disabilities; (2) finances the segregation of individuals with disabilities in private facilities; and/or (3) through its planning, service system design, funding choices, or service implementation practices, promotes or relies upon the segregation of individuals with disabilities in private facilities or programs.'' [140] OCR will continue its ongoing *Olmstead* enforcement efforts under Section 504 and Title II of the ADA, as well as Section 1557 and this part, where appropriate.

Comment: Several commenters recommended that OCR specify that age-related distinctions are prohibited, apart from exclusions in the Age Act for (1) age distinctions contained in a

[133] *See, e.g.,* 45 CFR 155.305(f)(6) (in some cases, a Marketplace[SM] must require the SSN of an individual who is not requesting coverage for himself or herself, but whose SSN could be used to verify eligibility information for a household member who is requesting Marketplace[SM] coverage and financial assistance, such as a child).

[134] *See* U.S. Dep't of Health & Human Servs., Office for Civil Rights; Section 504 of the Rehabilitation Act of 1973; Notice of Exercise of Authority Under 45 CFR 84.52(d)(2) Regarding Recipients With Fewer Than Fifteen Employees, 65 FR 79368 (Dec. 19, 2000).

[135] *See, e.g., Columbia* v. *Gregory,* Civ. No. 08–cv–98, 2008 WL 4192437, *4 (D.N.H. Sep. 9, 2008).

[136] *See* 42 U.S.C. 12182(b)(2)(A)(iii).

[137] *See* 28 CFR 35.130(b)(7) (requiring public entities to administer services to individuals with disabilities in the most integrated setting appropriate to their needs); 45 CFR 84.4(b)(2); *Olmstead* v. *L.C.*, 527 U.S. 581 (1999).

[138] U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Services, Guidance to States Using 1115 Demonstrations or 1915(b) Waivers for Managed Long Term Services and Supports Programs 3 (May 20, 2013), *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/downloads/1115-and-1915b-mltss-guidance.pdf.*

[139] *527 U.S. 581 (1999).*

[140] U.S. Dep't of Justice, Statement of the Department of Justice on Enforcement of the Integration Mandate of Title II of the Americans with Disabilities Act and *Olmstead* v. *L.C.*, (June 21, 2011), *http://www.ada.gov/olmstead/q&a_olmstead.htm.*

Federal, State or local statute or ordinance that provide benefits based on age, establish criteria for participation in age-related terms, or describe intended beneficiaries to target groups in age-related terms, and (2) actions that reasonably take into account age as a factor necessary to the normal operation or the achievement of any statutory objective of such program or activity. Under these comments, for example, a decision to limit coverage of a service to individuals in a particular age range, even though that service is also effective for individuals of other ages, would violate Section 1557 if the age limitation is not based on a statute or ordinance and is not necessary for the normal operation or achievement of the goals of the service.

Response: OCR declines to adopt the standard recommended by the commenters. As noted elsewhere, the rule permits actions based on age to overcome the effects of conditions that resulted in limited participation in the covered entity's health program or activity based on age.[141] We also note that other provisions of the rule incorporate provisions in the regulation implementing the Age Act that permit age distinctions in HHS regulations and a recipient's provision of special benefits to the elderly or children.[142]

Comment: A few commenters asked that OCR clarify that State mandates that have age limits are exempt and that States are allowed to create new State mandates that have age distinctions if that is clinically appropriate.

Response: As reflected in the provision of the final rule at § 92.2(b)(1), age distinctions contained in Federal, State, or local statutes or ordinances adopted by an elected, general purpose legislative body are not covered by the final rule. States may adopt new laws that contain age distinctions; those distinctions would not violate the final rule.[143]

Comment: One commenter asked us to clarify the application of Section 1557 with respect to age rating in health insurance plans and related employer contributions.

Response: As we noted above, OCR is incorporating in the final rule the exclusions found in the Age Act, such that the provisions of the proposed rule would not apply to any age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which provides any benefits or assistance to persons based on age, establishes criteria for participation in age-related terms, or describes intended beneficiaries to target groups in age-related terms.[144] For instance, age rating in premium rates within a 3:1 ratio in Marketplace℠ plans would not violate Section 1557 because it is permitted under the ACA.[145] Further, this rule would not prohibit a covered entity from establishing and applying, or offering a plan on a Marketplace℠ that establishes or applies, in a nondiscriminatory manner, neutral rules related to employer contribution amounts, such as contributing a fixed percentage or dollar amount of each employee's premium or placing a cap on the total amount of employer contributions, even though the dollar amount of the contribution or the employee's share of the premium may be smaller or greater for some employees than for others based on the permissible age rating of the employee's premium.

Comment: One commenter recommended that OCR clarify that in order to operate in a nondiscriminatory manner, issuers must ensure that their plans do not impose arbitrary age, visit, or coverage limits. This commenter pointed out that children often need more frequent preventive and supportive services than adults, including immunizations, developmental assessments and screenings, and nutritional counseling, to enable them to maintain or improve their health into adulthood. Furthermore, children with special health needs may need additional services, such as speech or physical therapy, on a more frequent basis than adults to enable them to develop specific skills or meet their developmental potential. Similarly, children will also require replacement of durable medical equipment or devices on a much more frequent schedule than is provided in an adult benefit package.

Response: OCR agrees that arbitrary age, visit, or coverage limitations could constitute discrimination, including discrimination based on age, in certain cases, for example where consideration of age is not necessary to the normal operation of a health program. In addition, as noted above, where differential treatment is justified by scientific or medical evidence, such treatment will not be considered discriminatory. The general prohibition of discrimination in the rule applies to these issues.

Comment: Commenters noted that due to the educational context for which they were created, Title IX regulations do not reach the full breadth of discriminatory actions on the basis of sex that are prohibited by Section 1557; these commenters recommended that the final regulation incorporate prohibitions from Title VI, Section 504, and the Age Act to more fully address discrimination on the basis of sex in health programs and activities. In addition, commenters stated that the final rule should make clear that in the absence of a finding of discrimination, a covered entity may take affirmative action to overcome the effects of conditions which resulted in limited participation by persons on the basis of sex.

Response: OCR appreciates the concern raised by the commenters that, due to the fact that Title IX applies only to educational programs, the full range of specific discriminatory actions prohibited under other laws is not explicitly included in Title IX's regulations. OCR has revised the final regulation to incorporate additional language in § 92.101(b)(3) to help clarify the full breadth of discriminatory actions that can constitute sex discrimination under Section 1557. Additionally, both the proposed and the final rule make clear in § 92.6 (Remedial Action and Voluntary Action) that covered entities are permitted, but not required, to take voluntary action in the absence of a finding of discrimination to overcome the effects of conditions that result or resulted in limited participation by persons based on any prohibited ground covered under the regulation.

Comment: Several commenters noted that although sex-specific programs may be clinically necessary in some instances, for example, in clinical trials that aim to determine whether sex differences exist in the manifestation or recommended treatment of certain diseases, the Department should clarify that sex-specific programs—*i.e.*, those in which participation is limited to members of one sex only—are permissible only when they are narrowly tailored and necessary to accomplish an essential health purpose.

Response: OCR agrees with commenters that sex-specific programs (programs limited exclusively to one sex) should be permitted only under limited circumstances. OCR believes that the constitutional standard established by the Supreme Court in

[141] *See* § 92.101(c).

[142] *See* § 92.101(c) (incorporating 45 CFR 91.17).

[143] We note that age limits may violate CMS regulations under the ACA and covered entities are responsible for ensuring compliance with all applicable CMS regulations and other Federal laws.

[144] *See* 42 U.S.C. 6103(b).

[145] 42 U.S.C. 300gg(a)(1)(A)(iii). *See also* 45 CFR 147.102.

United States v. *Virginia* [146] provides the most appropriate level of protection and thus has chosen to adapt this standard for application in evaluating the lawfulness of sex-specific health programs or activities under Section 1557 and this part. In *Virginia*, the Court stated that a governmental entity attempting to justify a sex-specific program must demonstrate an ''exceedingly persuasive justification'' for a sex-based classification in accordance with the U.S. Constitution's Equal Protection Clause.[147] As the Court explained, this means that the governmental entity must show ''at least that the [challenged] classification serves important governmental objectives and that the discriminatory means employed are substantially related to the achievement of those objectives.'' [148] In *Virginia*, which challenged Virginia Military Institute's male-only admissions policy, the Court found that the governmental entity had fallen ''far short of establishing the exceedingly persuasive justification'' necessary to sustain a sex-based classification.[149] The Court made clear that proffered justifications cannot rely on overbroad generalizations and cannot be hypothesized or invented post hoc in response to litigation.[150]

Under this demanding standard, as adapted in this rule, a sex-specific health program or activity classification is unlawful unless the covered entity can show an exceedingly persuasive justification for it, that is, that the sex-based classification is substantially related to the achievement of an important health-related or scientific objective. In evaluating a complaint of discrimination challenging a covered entity's sex-specific health program or activity, OCR may consider a variety of factors relevant to the particular program or activity. In all cases, however, OCR will expect a covered entity to supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex. In no case will OCR accept a justification that relies on overly broad generalizations about the sexes.

Under this standard, OCR anticipates that most health researchers will be able to justify sex-specific clinical trials, such as those that test treatments for sex-specific conditions or that evaluate differences in responses to treatment regimens among the sexes, based upon the scientific purposes of the study. Where there is no clinical or scientific rationale for making a program sex-specific, by contrast, a covered entity that offers such a program would need to demonstrate, through such means as research literature, empirical data, accepted professional standards, and/or facts specific to participants in the program, that maintaining the sex segregation of the program is necessary for the program to achieve its purpose. Overly broad generalizations would not be sufficient.

No commenters asked OCR to adopt the sex-specific standards authorized in Title IX or the Department of Education's Title IX regulations. OCR has chosen to apply an adapted constitutional standard under Section 1557 rather than the standard authorized in Title IX and the Department of Education's Title IX regulations because, as noted in the proposed rule, and by several commenters, the single-sex educational exceptions found in Title IX and the Department of Education's Title IX regulations—such as exceptions for some single-sex education programs (*e.g.*, contact sports in physical education classes; classes on human sexuality; and choruses) when certain requirements are met—do not readily apply in a context grounded in health care.

In addition, we note that OCR's adaptation of the constitutional standard as the standard to be applied to sex-specific health programs or activities under Section 1557 is consistent with the constitutional standard that already applies to sex-specific public health programs and activities, which are covered entities under this rule if they receive Federal financial assistance. OCR has adapted the standard to use the term ''important health-related or scientific objective,'' in recognition of the fact that the rule's provision on sex-specific programs or activities applies to both private and public covered entities in the context of health programs and activities. The same Section 1557 nondiscrimination standards, including this adapted standard, apply to health programs or activities subject to this rule whether public or private covered entities operate them.

Finally, as we initially noted in the proposed rule, we do not intend to prohibit separate toilet, locker room, and shower facilities where comparable facilities are provided to individuals, regardless of sex. OCR recognizes that under some existing Federal, State and local laws, rules or regulations, certain types of sex-specific facilities such as restrooms may be permitted. The approach taken by OCR is consistent with the long standing approach taken to these types of facilities.

However as previously stated in the discussion of the definition of ''on the basis of sex'' in § 92.4, even where it is permissible to make sex-based distinctions, individuals may not be excluded from health programs and activities for which they are otherwise eligible based on their gender identity.[151] Courts have rejected claims that any legal right to privacy is violated and that one person suffers any cognizable harm simply by permitting another person access to a sex-specific program or facility which corresponds to their gender identity.[152]

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions as proposed in § 92.101 with the following modifications:

We have re-designated § 92.101(b)(1) as § 92.101(b)(1)(i), and added a new section § 92.101(b)(1)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of race, color, or national origin against beneficiaries of the covered entity's health program or activity. Similarly, we have re-designated § 92.101(b)(4) as § 92.101(b)(4)(i), and added a new section § 92.101(b)(4)(ii), which prohibits aiding or perpetuating discrimination against an individual by providing significant assistance to an entity or person that discriminates on the basis of age against health program or activity beneficiaries. These provisions complement similar provisions incorporated in the final rule with respect to disability and sex discrimination and are included to ensure that we are providing the same protections from race, color, national origin, and age discrimination as are provided with respect to sex and disability discrimination.

In addition, we have changed the language in § 92.101(b)(2)(i) to exclude reference to 45 CFR 84.52(d). We are re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a

[146] 518 U.S. 515 (1996).

[147] *Id.* at 531–32.

[148] *Id.* at 532–33 (internal citations omitted).

[149] *Id.* at 533–34.

[150] *Id.* at 533.

[151] *See Lusardi* v. *McHugh*, U.S. Equal Employment Opportunity Comm'n Appeal No. 0120133395, Agency No. ARREDSTON11SEP05574, 2015 WL 1607756 (April 1, 2015) (finding Agency's denial of Complainant's access to the common women's restroom on account of her gender identity violated Title VII), *http://www.eeoc.gov/decisions/0120133395.txt.*

[152] *See, e.g.*, *Crosby*, 763 F. Supp. 666; *cf Cruzan*, 294 F.3d 981.

new subsection, § 92.202(b) that requires covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

We have re-designated the existing regulation text at § 92.101(b)(3) as § 92.101(b)(3)(i). We have added new subsections, § 92.101(b)(3)(ii) and § 92.101(b)(3)(iii) to clarify the full breadth of discriminatory actions prohibited by Section 1557 on the basis of sex. Last, we have added a new subsection, § 92.101(b)(3)(iv) to clarify when covered entities may provide a sex-specific health program or activity.

Subpart C—Specific Applications to Health Programs and Activities

Section 1557 is unique among Federal civil rights laws in that it specifically addresses discrimination in health programs and activities. To provide additional specificity regarding nondiscrimination requirements in this setting, Subpart C builds upon pre-existing civil rights regulations referenced in Subpart B.

Meaningful Access for Individuals With Limited English Proficiency (§ 92.201)

Overview of § 92.201

In § 92.201, OCR proposed to effectuate Section 1557's prohibition on national origin discrimination as it affects individuals with limited English proficiency in health programs and activities of covered entities.

We explained that for individuals with limited English proficiency, lack of proficiency in English—and the use of non-English languages—is a direct outgrowth of, and is integrally tied to, their national origins.[153] It is well-established under Title VI and its implementing regulation that a prohibition on national origin discrimination requires covered entities to take reasonable steps to provide meaningful access to individuals with limited English proficiency.[154] The U.S. Supreme Court has held that the provision of language assistance services is essential to ensure the equality of opportunity promised by nondiscrimination laws.[155] As we stated in the Department's 2000 LEP Policy Guidance:

> The key to providing meaningful access for LEP persons is to ensure that the recipient/covered entity and LEP person can communicate effectively. The steps taken by a covered entity must ensure that the LEP person is given adequate information, is able to understand the services and benefits available, and is able to receive those for which he or she is eligible. The covered entity must also ensure that the LEP person can effectively communicate the relevant circumstances of his or her situation to the service provider.[156]

General Requirements § 92.201(a), (b) and (c)

In § 92.201(a), we proposed to adopt the well-established principle that covered entities must take reasonable steps to provide meaningful access to health programs and activities for all individuals with limited English proficiency whom the covered entities serve or encounter.[157] We provided that, consistent with our longstanding enforcement of Title VI, we intended the general obligation in paragraph (a) to be a context-specific standard that the Director considers in light of the particular facts.[158]

We stated that the proposed standard balances two core principles critical in effectuating Section 1557's prohibition of national origin discrimination. First, the Department must ''ensure that [health programs and activities] aimed at the American public do not leave some behind simply because they face challenges communicating in English.'' [159] We noted that provider-patient communication is essential to the concept of patient centeredness, which is a core component of quality health care and has been shown to improve patients' health and health care.[160] Second, we stated that the level, type and manner of language assistance services required under paragraph (a) should be assessed based on the relevant facts, which may include the operations and capacity of the covered entity.

For these reasons, proposed paragraph (b) identified how the Director will evaluate whether a covered entity has met the requirement in paragraph (a).[161] In paragraph (b)(1), we proposed to require the Director to consider, and give substantial weight to, the nature and importance of the health program or activity, including the particular communication at issue. In paragraph (b)(2), we proposed to require the Director to take other relevant factors into account and identified some of those that might be relevant.

In paragraphs (b)(2)(i) and (ii), OCR proposed to identify the length, complexity, and context of the

[153] *See, e.g.,* 80 FR at 54182.

[154] *See, e.g., Lau* v. *Nichols,* 414 U.S. 563, 566 (1974) (interpreting Title VI and its implementing regulations to require a school district with students with limited English proficiency of Chinese origin to take affirmative steps to provide the students with a meaningful opportunity to participate in Federally funded educational programs); HHS LEP Guidance, *supra* note 49, 68 FR at 47313 (''[T]he failure of a recipient of [F]ederal financial assistance from HHS to take reasonable steps to provide LEP persons with [a] meaningful opportunity to participate in HHS funded programs may constitute a violation of Title VI and HHS's implementing regulations''); U.S. Dep't of Health & Human Servs., Office for Civil Rights, Policy Guidance, Title VI Prohibition against National Origin Discrimination As It Affects Persons with Limited English Proficiency, 65 FR 52762, 52765 (August 30, 2000) (''The most important step in meeting this [meaningful access] obligation is for recipients of Federal financial assistance such as a grants, contracts, and subcontracts to provide the language assistance necessary to ensure such access, at no cost to the LEP person.''). *See also* Exec. Order No. 13166, *Improving Access to Services for Persons with Limited English Proficiency,* 65 FR 50121 (Aug. 11, 2000) (requiring each Federal Department to improve access to Federally assisted programs and activities by persons with limited English proficiency and to implement a system by which individuals with limited English proficiency can meaningfully access the Departments' Federally conducted programs and activities).

[155] 80 FR at 54182 (citing *Lau,* 414 U.S. at 566) (reasoning that a federally funded educational program's failure to take affirmative steps to rectify the language deficiency of limited English proficient students of Chinese ancestry denies them a meaningful opportunity to participate in the educational program on the basis of their national origin).

[156] 65 FR at 52765.

[157] The Department's LEP Guidance provides an in-depth explanation of Title VI's prohibition against national origin discrimination as it affects limited English proficient populations and how recipients can determine what steps are reasonable to provide all individuals with limited English proficiency meaningful access. HHS LEP Guidance, *supra* note 49.

[158] Under Title VI, OCR investigates each complaint and conducts its compliance reviews on a case-by-case basis and tailors each case resolution to the particular facts of each case. For highlights of OCR's Title VI enforcement specific to the prohibition of national origin discrimination as it affects individuals with limited English proficiency, see Enforcement Success Stories Involving Individuals with Limited English Proficiency, U.S. Dep't of Health & Human Servs., Office for Civil Rights, *http://www.hhs.gov/ocr/civilrights/activities/examples/LEP/index.html* (last visited May 4, 2016).

[159] 80 FR 54172, 54183 (quoting HHS LEP Guidance, *supra* note 49, 68 FR at 47312).

[160] *Id.* (citing U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, Chapter 6, Patient Centeredness, National Healthcare Quality Report (2013), *http://www.ahrq.gov/research/findings/nhqrdr/nhqr13/chap6.html*). Person-centered and family centered care is one of the six priorities of the National Quality Strategy. Dep't. of Health & Human Servs., Agency for Health Care Research & Quality, 2014 National Healthcare Quality and Disparities Report, Person- and Family-Centered Care Chartbook, AHRQ Pub. No. 15–0007–14, at 3 (May 2015), *http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2014chartbooks/personcentered/personcenteredcare-chartbook.pdf.*

[161] *Id.* at 54183 n.53 (stating that the Department's LEP Guidance takes a similar approach by identifying the factors that OCR will consider, in determining the extent of a recipient's obligations to individuals with limited English proficiency). *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47314–16.

communication as potentially relevant factors in a particular case. We noted that where a communication is particularly long or complex, a covered entity might be required to provide a means for an individual with limited English proficiency to be able to refer back to the information communicated by providing, for instance, a document written in the individual's primary language or an audio file of the information conveyed orally.

In paragraph (b)(2)(iii), we provided that the prevalence of the primary language in which the individual with limited English proficiency communicates, among those eligible to be served or likely to be encountered by the health program or activity, might also be relevant.

In paragraphs (iv) and (v) of proposed § 92.201(b)(2)—the final illustrative factors listed—we noted that the resources available to the covered entity and the costs of language assistance services might also be relevant in a particular case.

In proposed paragraph (c), we clarified that language assistance services required under paragraph (a) must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency.[162]

Specific Requirements for Interpreter Services and Restricted Use of Certain Persons to Interpret or Facilitate Communication § 92.201(d) and (e)

In paragraphs (d) and (e), OCR proposed to codify standards described in the Department's LEP Guidance regarding qualified interpreters for individuals with limited English proficiency and the use of family members or friends as interpreters or to facilitate communication.[163] These proposed standards account for issues of competency, confidentiality, privacy, and conflict of interest that arise as a result of relying on informal (or ad hoc) interpreters. We noted that paragraphs (d) and (e) are consistent with oral interpretation standards that OCR has advanced through its resolution of Title VI cases and compliance reviews.[164]

Specifically, in paragraph (d), OCR proposed to address standards applicable to oral interpretation. We provided that when a covered entity is required by paragraph (a) to provide oral interpretation as a reasonable step to provide meaningful access to an individual with limited English proficiency, the covered entity must offer that individual a qualified interpreter.

In paragraph (e), we proposed restrictions on the use of certain persons to interpret or facilitate communication for an individual with limited English proficiency. We proposed that paragraph (e) apply in addition to, and regardless of, the appropriate level, type or manner of language assistance services a covered entity is required to provide. In paragraph (e)(1), we proposed to prohibit a covered entity from requiring an individual with limited English proficiency to provide his or her own interpreter. However, in paragraphs (e)(2)(i) and (ii), we proposed to identify narrow and finite situations in which a covered entity may rely on an adult accompanying an individual with limited English proficiency to interpret. In paragraph (e)(3), we proposed to prohibit a covered entity from relying on a minor child to interpret or facilitate communication and identified an exception to this prohibition that is narrower in scope than the exception identified in (e)(2)(i) and (ii).

We explained that in lieu of the approach we proposed in paragraphs (d) and (e), we considered proposing that all covered entities have the capacity to provide, in their health programs or activities, qualified interpreters for individuals with limited English proficiency through telephonic oral interpretation services available in at least 150 non-English languages. OCR invited comment on what oral interpretation services, if any, we should require and how such approaches appropriately balance the provision of meaningful access to individuals with limited English proficiency and covered entities' flexibility to identify the means of providing such access.

Acceptance of Language Assistance Services Not Required § 92.201(f)

In paragraph (f), we proposed that no individual with limited English proficiency should be required to accept language assistance services, consistent with an individual's right to self-determination. We provided that a covered entity cannot coerce an individual to decline language assistance services. We also provided that if an individual with limited English proficiency voluntarily declines an offer of language assistance services from the covered entity, a covered entity could denote, in the individual's file or records, the language assistance services offered and the declination.[165]

Alternative Approaches

In the proposed rule, we described alternate approaches we considered and requested comment on these approaches and any others to effectuate Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency. For instance, we noted that independent of the proposed requirements of § 92.201, covered entities, including Health Insurance Marketplaces, State agencies administering Medicaid and Children's Health Insurance Program (CHIP) programs, and qualified health plan issuers, must comply with any applicable language access requirements in other laws and regulations.[166] We invited comment on whether the requirements under different authorities should be harmonized and if so, to what extent and how.

We also stated that we considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with limited English proficiency by providing effective language assistance services, at no cost, unless such action would result in an undue burden or a fundamental alteration of the health program or activity.[167]

We further noted that we considered a regulatory scheme requiring covered entities to provide a range of language assistance services in the non-English languages spoken by State-wide populations with limited English proficiency that meet defined thresholds. Such thresholds would provide a minimum number of non-English languages in which covered entities would be required to deliver oral interpretation services; to translate written vital documents and Web site content; and to include taglines on vital documents and on Web sites.[168] We requested comment on whether OCR

[162] 80 FR at 54183 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47318, 47323 (with respect to privacy), 47316–17, 47322 (with respect to timeliness), and 47318–19, 47320, 47322 (with respect to services free of charge)).

[163] *Id.* at 54183–84 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47317–18, 47323).

[164] *See, e.g.,* HHS OCR VRA with Mee Memorial Hosp., *supra* note 82, at pt. II.J (defining qualified interpreter); HHS OCR VRA with Montgomery County DSS, *supra* note 82, at pts. II.E (defining qualifications of an ''interpreter''), IV.H (requiring timely, competent language assistance), & IV.L (identifying interpreter standards).

[165] 80 FR at 54184 (citing HHS LEP Guidance, *supra* note 49, 68 FR at 47318, 47320 (suggesting that recipients consider whether to record the primary language of an individual with LEP or an individual's choice to provide his or her own interpreter)).

[166] The proposed rule discusses these entities' requirements at 80 FR at 54184–85.

[167] *Id.* at 54185.

[168] *See id.*

should require thresholds, and if so, what thresholds should be required, and to what geographic areas or service areas the thresholds should apply. We also sought comment on whether OCR should permit covered entities to implement their obligations with a phased-in approach.

We also noted that we considered a regulatory scheme that would impose enhanced obligations on a subset of covered entities. We sought comment on what characteristics should define covered entities that could have enhanced obligations, such as whether the covered entity is of a certain type or size, has frequent contact with individuals with limited English proficiency, or operates particularly important health programs or activities, among other potential factors. We listed potential categories of covered entities that could have enhanced obligations, such as State agencies administering Medicaid or CHIP; Health Insurance Marketplaces; the Department in its operation of its health programs or activities; or covered entities that have a minimum number of beds, employees, or locations, such as hospitals, nursing homes or skilled nursing facilities, home health agencies, and retail pharmacies (including mail-order pharmacies).[169] We described that under this alternate approach, instead of evaluating each case on its particular facts, the Director would evaluate a covered entity's compliance based on whether the entity provided the range of language assistance services in the non-English languages specified.[170] We invited comment on this proposal.

We further requested comment on whether covered entities should be required to systematically prepare to provide language assistance services in their health programs or activities, such as through the establishment of policies and procedures or through other advance planning mechanisms. We stated that in OCR's experience, covered entities are in a better position to meet their obligations to provide language assistance services in a timely manner to individuals with limited English proficiency when those entities identify, in advance, the types and levels of services that will be provided in each of the contexts in which the covered entity encounters individuals with limited English proficiency.

OCR noted that an advance planning requirement could require each covered entity to identify all resources for providing language assistance services; annually assess the frequently-encountered or highly prevalent languages in the service area of the health program or activity; establish written procedures to which frontline staff could refer when encountering individuals with limited English proficiency; and monitor and oversee the quality of language assistance services provided. We also noted that an advance planning requirement could require each covered entity to build its capacity to provide language assistance services to meet the needs of the national origin populations that the entity serves. We requested comment on the types of advance planning mechanisms, if any, that should be required and why.

In the proposed rule, OCR advised that covered entities that are already developing or implementing language access plans, or otherwise assessing their language assistance needs, should continue such efforts. However, OCR stated that engaging in such planning is not a defense for failing to provide language assistance services to any particular individual at all, or in an untimely manner, if such services are reasonable steps to provide meaningful access. We advised that covered entities that are conducting advance planning should consider how they can ensure that language assistance services are available in their health programs and activities as they simultaneously improve their operational capacities to provide effective language assistance services into the future.

The comments and our responses regarding § 92.201 are set forth below:

Overall, commenters supported the proposed rule's inclusion of specific provisions addressing meaningful access for individuals with limited English proficiency. We received numerous comments written in non-English languages submitted by individuals with limited English proficiency who expressed how essential it is to have language assistance services, at no cost, to understand forms, invoices, and medication instructions. Many comments from the health care provider and insurance industry, as well as from organizations representing individuals with limited English proficiency, agreed that it is essential that individuals, regardless of national origin, be able to access covered entities' health programs and activities. We received many comments, however, regarding the scope and parameters of covered entities' obligations under the final rule.

Comment: Many commenters recommended revising the categories of individuals to whom a covered entity has an obligation to take reasonable steps to provide meaningful access. Specifically, commenters recommended that a covered entity's obligation should apply to those ''eligible to be served'' or ''likely to be affected by'' the covered entity's health programs and activities. Commenters suggested that proposed § 92.201(a), which stated that the obligation of a covered entity runs to those who the entity ''serves or encounters in its health programs and activities,'' unduly narrowed the scope of the covered entity's obligation.

Response: In response to commenters' recommendations, we have replaced the phrase ''that it serves or encounters'' with ''eligible to be served or likely to be encountered.'' We agree with commenters that a covered entity must be prepared to take reasonable steps to provide meaningful access to individuals beyond those who actually walk into, or contact, that entity. Where a covered entity is likely to encounter, but is unprepared to assist, individuals of particular national origin groups in the languages in which they communicate, those individuals are unlikely to seek services from, or participate in, the entity's health programs or activities, thereby perpetuating barriers to individuals' access to care.

We chose the phrase ''eligible to be served or likely to be encountered'' because it is one of the formulations in the HHS LEP Guidance of the population to which a covered entity has an obligation.[171] In addition, commenters' proposal that a covered entity's obligation applies to individuals ''likely to be affected by'' the covered entity's health programs and activities gave covered entities less concrete guidance about their obligations relative to the phrase ''likely to be encountered.''

Comment: Numerous commenters recommended that OCR revise the general obligation in § 92.201(a) to require that covered entities ''provide meaningful access'' to each individual with limited English proficiency rather than ''take reasonable steps to provide meaningful access.'' Commenters explained that because ''meaningful access'' is already a subjective standard, requiring ''reasonable steps to provide meaningful access'' substantially dilutes covered entities' obligations to provide language assistance services.

These commenters suggested that language assistance should be provided in every situation and that oral interpretation, in particular, should be provided ''on demand.'' Commenters

[169] *See id.*

[170] *See id.*

[171] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47314, 47320, 47322.

suggested that the final rule make this basic obligation clear because some covered entities turn away individuals with limited English proficiency, stating that the entity does not provide language assistance services. For instance, one commenter shared that it is common for individuals with limited English proficiency to use a hospital emergency department as a source of primary care because the individuals' physicians do not offer qualified interpreters for individuals with limited English proficiency. Commenters also suggested that the Director's weighing of the illustrative factors set out in § 92.201(b) should focus exclusively on whether the covered entity provided the appropriate type, form, and manner of language assistance.

Response: We decline to modify the general obligation in § 92.201(a) because it reflects familiar and longstanding requirements applicable under Title VI.[172] In addition, the regulatory scheme provides in 92.201(b)(1) that in assessing this standard, the Director will consider, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, which places covered entities on notice about the way in which we will evaluate the Title VI standard within the context of health programs and activities. OCR interprets the requirement that covered entities take ''reasonable steps to provide meaningful access'' to demand that each entity, as an initial step, assess the need to provide language assistance services to each individual with limited English proficiency and respond to that need by providing the appropriate language assistance services on a timely basis.

As we stated in the proposed rule, safe and quality health care requires an exchange of information between the health care provider and patient for the purposes of diagnoses, treatment options, the proper use of medications, obtaining informed consent, and insurance coverage of health-related services, among other purposes.[173] This exchange of information is jeopardized when the provider and the patient speak different languages and may result in adverse health consequences and even death.[174] Indeed, the provision of health care services, by its ''very nature[,] requires the establishment of a close relationship with the client or patient that is based on sympathy, confidence and mutual trust,'' [175] which cannot be established without effective communication.

Comment: Some commenters expressed concern about the potential financial and administrative burden to provide language assistance services. Many of these commenters expressed support for the proposed rule's inclusion of specific provisions addressing access for individuals with limited English proficiency but also urged that public and private health insurance issuers update medical codes and fee schedules to allow providers to receive reimbursement for the provision of language assistance services.

Some commenters offered proposals for minimizing the costs to covered entities for providing language assistance services—oral interpretation services in particular. These recommendations included that OCR facilitate access to telephonic oral interpretation, at no cost to covered entities, and that OCR ensure that covered entities have adequate funding to provide qualified interpreters for individuals with limited English proficiency.

Response: We appreciate hearing commenters' concerns and having the benefit of commenters' recommendations to lessen potential cost and administrative barriers that covered entities may face. It is beyond the scope of this rulemaking to adopt recommendations that OCR fund qualified interpreters or direct issuers to modify medical codes and fee schedules to reimburse health care providers for their provision of language assistance services.[176]

OCR encourages covered entities to work together to leverage their ability to provide language assistance services in the most cost-effective and efficient ways to meet their respective obligations under § 92.201(a) before using costs as a reason to limit language assistance services.[177] OCR also encourages professional associations and organizations to consider what role they can play in helping their members meet the requirements of § 92.201; we provided similar encouragement in the HIPAA Privacy Rule.[178]

We further remind State agencies receiving Federal financial assistance for Medicaid and the Children's Health Insurance Program that States may claim Federal matching funds for the costs of written translation and oral interpretation as administrative expenses or as medical assistance-related expenses.[179] Further, increased

[172] *See Lau* v. *Nichols, supra* note 154 (interpreting Title VI to require the covered entity to take affirmative steps to provide students with limited English proficiency of Chinese origin with a meaningful opportunity to participate in Federally-funded educational programs); HHS LEP Guidance, *supra* note 49, 68 FR at 47313 (''[T]he failure of a recipient of [F]ederal financial assistance from HHS to take reasonable steps to provide LEP persons with [a] meaningful opportunity to participate in HHS funded programs may constitute a violation of Title VI and HHS's implementing regulations'').

[173] 80 FR at 54183 (citing to the 2000 HHS LEP Guidance, *supra* note 49, 65 FR at 52763). *See generally* Cindy Brach et al., *Crossing the Language Chasm,* Health Affairs, vol. 24, no.2 424, at 424–25 (2005) (describing the impacts of language barriers in health care). In addition, the 2014 National Healthcare Quality and Disparities Report Chartbooks include metrics showing disparities between national origin groups, one of which expressly identifies trends of non-English speaking children who need health care for an illness, injury, or condition who sometimes or never got care as soon as wanted. *See* U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, 2014 National Healthcare Quality and Disparities Report, Chartbook on Health Care for Hispanics at 47, 57 (May 2015), *http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/2014chartbooks/hispanichealth/2014nhqdr-hispanichealth.pdf;* U.S. Dep't of Health & Human Servs., Agency for Health Care Research & Quality, Person- and Family-Centered Care Chartbook, *supra* note 160, at 12.

[174] 80 FR at 54183.

[175] *Id.*

[176] We note, however, that the Department's National Stakeholder Strategy for Achieving Health Equity identifies financing and reimbursement for ''health interpreting services'' as a strategy to achieve the goal of improving cultural and linguistic competency. *See* U.S. Dep't of Health & Human Servs., Office of Minority Health, National Partnership for Action to End Health Disparities. National Stakeholder Strategy for Achieving Health Equity, Section 3, 131 (2011), *http://minorityhealth.hhs.gov/npa/files/Plans/NSS/NSS_07_Section3.pdf.*

[177] We note, for example, that the Washington State Medicaid Interpreter Services Program centralizes the provision of language assistance services to achieve economies of scale. *See* Washington State Health Care Auth., Interpreter Services Program, *www.hca.wa.gov/medicaid/interpreterservices* (last visited May 4, 2016). Similarly, through OCR's Effective Communication in Hospitals Initiative, the Kentucky Hospital Association built the capacity to offer its approximately 120 member hospitals access to a telephonic interpretation service contract that offers a volume-based discount rate. *See* Kentucky Hospital Association, Effective Communication in Hospitals, *http://www.kyha.com/CM/Initiatives/Safety_and_Quality_Resources/Effective_Communication_in_Hospitals.aspx* (last visited May 4, 2016). Although OCR cannot certify that these approaches uniformly enable entities to meet the requirements of Section 1557, they do represent examples of the types of collaborative action that covered entities may consider.

[178] Standards for Privacy of Individually Identifiable Health Information, 65 FR 82462, 82749 (Dec. 28, 2000) (final rule) (codified at 45 CFR pts. 160 and 164) (encouraging professional associations to assist their members in developing policies and procedures required under the Privacy Rule); Standards for Privacy of Individually Identifiable Health Information, 64 FR 59918, 59992 (Nov. 3, 1999) (proposed rule) (encouraging professional associations to assist their members in developing policies and procedures required under the Privacy Rule).

[179] U.S. Dep't. of Health & Human Servs., Center for Medicare & Medicaid Servs., Increased Federal Matching Funds for Translation and Interpretation Services under Medicaid and CHIP 1 (Jul. 1, 2010), *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO10007.pdf* [hereinafter CMS

Continued

funding may be available when States claim the cost of written translation and oral interpretation as administrative expenses if such language assistance services are provided for the ''enrollment, retention, and use of services'' for individuals with limited English proficiency eligible for CHIP and for Medicaid-eligible children and their families.[180] In addition, we remind qualified health plan issuers that the ACA requires, as a condition of an issuer's health plan receiving certification as a qualified health plan, that the issuer implement a quality improvement strategy for the qualified health plan that provides increased reimbursement or other incentives for the implementation of activities to reduce health and health care disparities, including through the use of language services.[181] We encourage health insurance issuers to structure their health plan payment structures to consider health care providers' expenses in providing language assistance services.

We decline to accept the recommendation that OCR facilitate access to telephonic oral interpretation services for all covered entities. Such facilitation is beyond the scope of the Federal government's role and is an impractical solution to address the needs of diverse Section 1557 covered entities. However, OCR does share best practices and useful resources, such as through the Federal government's Interagency Working Group on Limited English Proficiency, at *www.LEP.gov.*

Comment: We received numerous comments on whether the final rule should include an advance planning requirement for covered entities to be systematically prepared to provide language assistance services in their health programs and activities. The vast majority of these comments recommended that the final rule include such an advance planning requirement—specifically, the development and implementation of a language access plan that addresses the needs of the limited English proficient population in the service area of a covered entity's health program or activity. Commenters reasoned that a regulatory requirement is the most effective method of holding covered entities accountable for engaging in meaningful advance planning.

One commenter observed that many covered entities already evaluate the type of language assistance services they are obligated to provide, pursuant to the current HHS LEP Guidance, and thus that codifying this requirement would not impose a significant additional burden on covered entities. This commenter also asserted that an advance planning requirement is analogous to the approach of § 92.7, which requires certain covered entities to have a grievance procedure in place. Another commenter shared that in updating her employer's language access plan, the availability of online tools and resources greatly reduced the commenter's anticipated burden of what advance planning would require.

We received many comments recommending that the final rule identify specific required components of a language access plan, including the types of language access services the covered entity will provide and in what languages, based on the languages spoken by eligible individuals with limited English proficiency in the covered entity's service area. One commenter underscored that to increase efficiency and maximize cost savings, a language access plan should identify multiple types of language assistance services that a covered entity can use for different situations or even within one encounter. This commenter asserted that relying on just one kind of language assistance service may not be appropriate for all communications.

Another commenter recommended that the final rule mirror California's regulations on advance planning mechanisms for the provision of language assistance services.[182] This commenter stated that, consistent with California's regulations, OCR should require that language access plans identify all points of contact with individuals with limited English proficiency; provide a procedure for recording individuals' primary language; identify vital documents; provide a procedure for the translation of vital documents; provide a procedure to request translation of specific other documents; require training on language access services for all staff likely to have contact with individuals with limited English proficiency; require the assessment of the qualifications of bilingual/multilingual staff; and adopt written policies and procedures regarding the provision of language assistance services, including a procedure for contracting with language service vendors. Other commenters agreed that prior to using individuals to provide interpretation or translation services, covered entities should be required to evaluate or verify the individuals' knowledge, skills and abilities to confirm that they meet the definition of a qualified interpreter or a qualified translator for an individual with limited English proficiency.

We received a small number of comments opposing a requirement for advance planning. One commenter acknowledged that a language access plan is important in ensuring that covered entities are systematically prepared to provide language assistance services but recommended that OCR should merely encourage, not require, advance planning activities. The commenter observed that developing a language access plan may be too burdensome for small covered entities.

Response: Based on the comments received, we have added a factor—the only illustrative factor in § 92.201(b)(2)—that requires the Director to consider, if relevant, whether the entity has developed and implemented an effective written language access plan, appropriate to its particular circumstances. The language ''appropriate to its particular circumstances'' conveys our recognition that the nature and extent of the voluntary planning in which a covered entity may choose to engage will vary depending on the entity's particular health programs and activities, its size, its geographic location, and other factors. A language access plan need not be long, complex, or burdensome.

We note that a written language access plan has long been recognized as an essential tool to ensure adequate and timely provision of language assistance services, including compliance with the general obligation in § 92.201(a) and the quality standards in § 92.201(d)–(f). For instance, for over 15 years, Executive Order 13166 has required each Federal agency to create and implement a language access plan responsive to the needs of the limited English proficient population it serves.[183] Moreover, the

Increased Federal Matching Funds]; *id.,* Recently Released Policy Guidance—CHIPRA and the ACA, Information Bulletin 1–2 (Jul. 9, 2010), *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/07-09-2010-CHIPRA-and-ACA.pdf* [hereinafter CMS Information Bulletin 7/9/10].

[180] CMS Increased Federal Matching Funds, *supra* note 179, at 1–2; CMS Information Bulletin 7/9/10, *supra* note 179, at 1–2; U.S. Dep't. of Health & Human Servs., Center for Medicare & Medicaid Servs., Information Bulletin 2 (Apr. 26, 2011), *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/Info-Bulletin-4-26-11.pdf.*

[181] *See* 42 U.S.C. 18031(c)(1)(E), (g)(1)(E) (describing qualified health plan certification requirements in a quality improvement strategy).

[182] *See* 28 CCR 1300.67.04(c) (requiring each health care service plan to develop and implement a language assistance program that contains standards for enrollee assessment; providing language assistance services; staff training; and compliance monitoring).

[183] E.O. 13166, 65 FR 50121 (2000). In 2011, the U.S. Department of Justice renewed the Federal Government's commitment to the Executive Order. Office of the Att'y General, U.S. Dep't of Justice, Federal Government's Renewed Commitment to Language Access Obligations Under Executive

development and implementation of a written language access plan is consistent with OCR's longstanding enforcement processes[184] and resolution agreements regarding Title VI.[185] Although we are not requiring language access plans, we encourage entities to consider whether and how they can engage in advance planning to facilitate their ability to meet their obligations under § 92.201 to serve individuals with limited English proficiency on a timely basis.

We decline to outline the minimum expectations for a language access plan, if a covered entity chooses to develop and implement one, because that approach would be too prescriptive. Nonetheless, in our experience, effective language access plans often, among other components, address how the entity will determine an individual's primary language, particularly if the language is an unfamiliar one; identify a telephonic oral interpretation service to be able to access qualified interpreters when the need arises; identify a translation service to be able to access qualified translators when the need arises; identify the types of language assistance services that may be required under particular circumstances; and identify any documents for which written translations should be routinely available. OCR remains available to covered entities as a resource for technical assistance in the development and implementation of language access plans in their health programs and activities. HHS offers helpful guidance on this subject,[186] as does the U.S. Department of Justice.[187] We encourage covered entities to refer to these materials to assist their advance planning activities.

Comment: Many commenters recommended modifications to, and additional clarification regarding, the list of factors that the Director will take into account, if relevant, among other relevant factors in evaluating a covered entity's compliance with its general obligation in § 92.201(a). These comments fall into four main categories. First, many commenters requested that we add additional factors to the list in § 92.201(b)(2)(i)–(v). Commenters were concerned that absent explicit references to these factors, the Director would not, or could not, consider them. Examples of factors that commenters requested that we add include:

- The frequency with which a covered entity encounters, or is likely to encounter, a particular non-English language;
- the impact to the consumer if language assistance services are not provided;
- the extent to which covered entities can lessen their own cost burdens through technology and reasonable business practices, if the Director considers the costs of language assistance services; and
- if and when a covered entity is permitted to choose a less costly language assistance service than the one an individual may request.

Second, many commenters recommended that we combine the ''costs of language assistance services'' in proposed § 92.201(b)(2)(v) with ''[a]ll resources available to the covered entity'' in proposed § 92.201(b)(2)(iv) into a single factor because the two are inherently intertwined.

Third, some commenters requested that OCR clarify in the final rule how the factors in proposed § 92.201(b)(2)(i)–(v) would be weighted relative to each other, if relevant and thus evaluated by the Director in a given case. Most commenters who requested clarification recommended that the costs of language assistance services and the resources available to the covered entity not be weighted more heavily than the other factors or become dispositive.

Fourth, a number of commenters requested clarification on the function that the length and complexity of the communication in proposed § 92.201(b)(2)(i) would have in the Director's evaluation of a particular case.

Response: After considering the comments received, we have revised the final rule to eliminate the illustrative factors and to articulate only one factor: Whether a covered entity has developed and implemented an effective written language access plan appropriate to its circumstances. We agree with some commenters' concerns that including multiple illustrative factors in the regulatory text may create the erroneous impression that the Director will not consider relevant factors absent from § 92.201(b)(2). Were OCR to modify § 92.201(b)(2) to include all factors suggested by commenters, however, the long list of factors might unintentionally create an unworkable regulatory scheme in the attempt to capture any possible factor that might be relevant in some circumstances.

Given these concerns, § 92.201(b)(1)–(2) of the final rule requires the Director to evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue to the individual with limited English proficiency, and requires the Director to take into account all other relevant factors, including whether the entity has developed and implemented an effective language access plan. We have identified this factor in particular to provide a concrete reminder to covered entities that they may wish to take action to prepare to provide language assistance services to the individuals with limited English proficiency that they will serve or encounter. We reiterate, however, that adoption of a language access plan is a voluntary measure that is not required by the rule; we will continue to evaluate, on a case-by-case basis, whether entities have taken reasonable steps to provide meaningful access and will evaluate all relevant factors in making that assessment.

We recognize that the absence of illustrative factors in regulation text may diminish clarity regarding the Director's evaluation of a covered entity's compliance with § 92.201(a). To provide guidance to covered entities on our intended interpretation of § 92.201(b)(2) and to be responsive to

Order 13166 (Feb. 17, 2011) *https://www.justice.gov/crt/about/cor/AG_021711_EO_13166_Memo_to_Agencies_with_Supplement.pdf.*

[184] For example, as part of the certification process to ensure that recipients of Medicare Part A are in compliance with Title VI, OCR requires Medicare Part A providers to document their written procedures on communicating effectively with individuals with limited English proficiency. U.S. Dep't of Health and Human Servs., Office for Civil Rights, Civil Rights Information Request for Medicare Certification, Form OMB No. 0945–0006, pt. II.7, *http://www.hhs.gov/sites/default/files/ocr/civilrights/clearance/ocr_mctap.pdf* (identifying written policies and procedures with respect to serving individuals with limited English proficiency as required in a provider's application for Medicare certification).

[185] *See, e.g.,* HHS OCR VRA with Mee Memorial Hosp., *supra* note 82, at pt. IV.B (requiring the development and implementation of a language access policy), pt. IV.C.1 (determining the language needs of the affected population), pt. IV.C.2 (determining the language needs of each individual with limited English proficiency); HHS OCR VRA with Montgomery County DSS, *supra* note 82, at pt. IV.B (requiring the development and implementation of a language access policy), pt. IV.C.1 (determining the language needs of the affected population), pt. IV.C.2 (determining the language needs of each individual with limited English proficiency).

[186] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47319–21 (encouraging recipients to develop a language access plan [called an ''LEP Plan'' in the Guidance]). HHS's updated language access plan may be a useful model for covered entities. *See* U.S. Dep't of Health & Human Servs., Language Access Plan (2013), *http://www.hhs.gov/sites/default/files/open/pres-actions/2013-hhs-language-access-plan.pdf.*

[187] *See* U.S. Dep't of Justice, Civil Rights Div., Language Access Assessment and Planning Tool for Federally Conducted and Federally Assisted Programs (May 2011), *http://www.lep.gov/resources/2011_Language_Access_Assessment_and_Planning_Tool.pdf. See also* the Federal government's Interagency Working Group on Limited English Proficiency, at *www.LEP.gov.*

comments received on the illustrative factors proposed, the following preamble discussion sets forth a range of factors that may be relevant in any given case.[188]

As an initial matter, we note that one of the factors commenters recommended we add, which is the impact to the individual of failing to provide language assistance services, is necessarily encompassed within § 92.201(b)(1) regarding an evaluation of the nature and importance of the health program or activity and the particular communication at issue.[189]

Factors that may be relevant in a particular case for the Director to consider pursuant to § 92.201(b)(2) include but are not limited to: the length, complexity, and context of the communication; the prevalence of the language in which the individual communicates among those eligible to be served or likely to be encountered by the health program or activity; the frequency with which a covered entity encounters the language in which the individual communicates; whether a covered entity has explored the individual's preference, if any, for a type of language assistance service, as not all types of language assistance services may work as well as others in providing an individual meaningful access to the covered entity's health program or activity; the cost of language assistance services and whether a covered entity has availed itself of cost-saving opportunities; and all resources available to the covered entity, including the entity's capacity to leverage resources among its partners or to use its negotiating power to lower the costs at which language assistance services could be obtained.

We decline to adopt commenters' suggestions to create a regulatory scheme that assigns particular weight to any specific relevant factor because the Director will consider and weigh all relevant factors pursuant to § 92.201(b)(2) on a case-by-case basis.

Because we have eliminated the factors in proposed 92.201(b)(2)(i)–(v), it is moot whether OCR should combine the proposed factor on the costs of language assistance services with the proposed factor on resources available to the covered entity. Nevertheless, costs and resources are intertwined, which is a principle reflected in the HHS LEP Guidance with respect to Title VI[190] and a principle we reiterated with respect to Section 1557 in the proposed rule.[191]

With respect to commenters' requests for clarification on the relevance that the length and complexity of a particular communication has on the type of language assistance a covered entity should provide, we note that this factor is emblematic of the fact-based nature of the inquiry described in § 92.201(b)(1)–(2). Where a document is long and complex, it may in some cases be necessary for a covered entity to provide a written translation so that an individual with limited English proficiency can refer back to or study it at a later time. In other cases, however, a covered entity may meet the requirements of this section by summarizing the document orally for a qualified interpreter to then convey to the individual with limited English proficiency, if such approach is sufficient to provide the individual with limited English proficiency meaningful access to the information.[192]

Comment: Many commenters supported the requirement in proposed § 92.201(c) that a covered entity provide language assistance services to an individual with limited English proficiency in a timely manner. Some commenters further suggested that the final rule set out specific time frames for the provision of oral interpretation, written translation, and taglines. For instance, some commenters recommended that we revise § 92.201(c) to require oral interpretation immediately upon request, written translations within 30 days after the English version is finalized, and taglines simultaneously with English documents. These commenters asserted that oral telephonic interpretation services should be available, at a minimum, no more than 30 minutes after a covered entity encounters an individual with limited English proficiency.

Response: We decline to include prescriptive timeframes for the provision of language assistance services. There is no one definition of ''timely'' that applies to every type of interaction with every covered entity at all times. Consequently, consistent with the overarching framework of § 92.201, a determination of whether language assistance services are timely will depend on the specific circumstances of each case. We reiterate our statement from the proposed rule that language assistance is timely when it is provided at a place and time that ensures meaningful access to persons of all national origins and avoids the delay or denial of the right, service, or benefit at issue.[193]

Comment: Some commenters suggested that the final rule prohibit the use of computer-automated translation. These commenters suggested that reliance on automated translation is not accurate for the highly specialized vocabulary and terminology used in the health care and health insurance settings, especially for less common non-English languages.

Response: We decline to codify a prohibition on the use of automated translation as part of the final rule because such a requirement may unintentionally stifle innovation in this rapidly developing area. Furthermore, depending on the language at issue as well as the content of the translation, some translation technologies are advantageous to facilitate the translation of written content when used along with a qualified translator who independently verifies the accuracy and quality of the translation.[194] For

[188] Some of these factors were proposed in § 92.201(b)(2)(i)–(v), were suggested by commenters', are grounded in the HHS LEP Guidance, or are staples of the effective communication analysis in § 92.202 of this final rule, consistent with Federal disability rights law.

[189] *See* HHS LEP Guidance, *supra* note 49, 68 FR 47311, at 47315 (describing how and why a recipient of Federal financial assistance should consider the nature and importance of the program or activity in determining the extent of its language access obligations under Title VI).

[190] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47315 (''Resource and cost issues, however, can often be reduced by technological advances; the sharing of language assistance materials and services among and between recipients, advocacy groups, and Federal grant agencies; and reasonable business practices.'' ''Large entities and those entities serving a significant number or proportion of LEP persons should ensure that their resource limitations are well-substantiated before using this factor as a reason to limit language assistance.'').

[191] *See* 80 FR at 54183.

[192] A third party to the communication, such as a qualified interpreter for an individual with limited English proficiency, would orally interpret the covered entity's oral summary from English to a non-English-language and would not alter, summarize, omit, or distort the oral summary that the covered entity provides or judge which information is relevant or important. *See e.g.,* The Nat'l Council on Interpreting in Health Care, A National Code of Ethics for Interpreters in Health Care 8, 13 (2004), *http://www.ncihc.org/assets/documents/publications/NCIHC%20National%20Code%20of%20Ethics.pdf* (discussing the ethical principle of fidelity to the original message).

[193] 80 FR 54172, 54183. The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards) emphasize the importance of timely language assistance. U.S. Dep't of Health & Human Servs., Office of Minority Health, The National CLAS Standards, *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53* (last visited May 4, 2016).

[194] Jessica Sperling, Migration Policy Institute, Communicating More for Less: Using Translation and Interpretation Technology to Serve Limited English Proficient Individuals (2011), 12 *http://www.migrationpolicy.org/research/communicating-more-less-using-translation-and-interpretation-technology-LEP* (noting that translation memory programs are used in the public and private sector to increase the efficiency of translating a high-

instance, translation memory software stores segments of previously translated phrases and can improve a qualified translator's efficiency, especially when updating documents.[195]

We do, however, agree with commenters' concerns regarding the use of some automatic translation technologies, which ''is particularly dangerous, and can lead to very serious misunderstandings and adverse consequences for medical documents.'' [196] For example, machine translation programs translate text by performing simple substitution of words using statistical techniques, which may produce highly unreliable translations for certain languages and written content.[197] As a result, using automated translation as the only tool for translating written documents would fulfill a covered entity's obligation under § 92.201(a) only if a qualified translator reviewed the translation for accuracy and edited it as needed.[198] OCR encourages covered entities to understand the strengths and weaknesses of the technology and software programs that qualified translators use.[199]

Comment: Commenters identified that some covered entities lack policies or practices to confirm or evaluate a staff member's skills as a qualified translator or to serve as a qualified interpreter for an individual with limited English proficiency. For instance, commenters stated that they are aware of situations where individuals who are qualified to interpret—but not translate—are nonetheless translating complex documents such as informed consent forms and discharge instructions. Comments recommended that the final rule require covered entities to evaluate staff members' non-English language proficiency and other skills to ensure that they are qualified before permitting them to interpret, translate, or communicate with individuals with limited English proficiency in the individuals' primary languages.

Response: We share commenters' concerns and, in response, have modified the rule in two ways. First, the final rule requires a covered entity to use a qualified translator for translating written content with respect to its health programs and activities. As the Department stated in its LEP Guidance, ''[t]he permanent nature of written translations [ ] . . . imposes additional responsibility on the recipient to take reasonable steps to determine that the quality and accuracy of the translations permit meaningful access by LEP persons.'' [200] We broadened the title of § 92.201(d) to reflect that this paragraph now addresses specific requirements for written translation in addition to oral interpreter services. The text in proposed paragraph (d) addressing specific requirements for oral interpretation is now reflected as paragraph (d)(1); new paragraph (d)(2) addresses the use of qualified translators.

Second, we added a new paragraph (4) to § 92.201(e) to restrict covered entities from relying on staff who do not meet the definition of ''qualified bilingual/multilingual staff'' in § 92.4. In OCR's enforcement experience, covered entities too frequently rely on staff members who possess only a rudimentary familiarity speaking and understanding a non-English language (for example relying on their ''high school'' level of language proficiency) to communicate with individuals with limited English proficiency. This can result in miscommunication and the omission of relevant information, which can in turn result in a lower standard of care and raise questions about whether consent provided by an individual with limited English proficiency was truly informed. Similarly, we have found that qualified bilingual staff members sometimes serve as interpreters even though they do not possess the non-verbal skills of interpreting nor adhere to generally accepted principles of interpreter ethics.

Comment: Some commenters recommended that the final rule not restrict covered entities from relying on friends or family of individuals with limited English proficiency to provide oral interpretation, even when the companion is a minor. These commenters noted that some individuals with limited English proficiency prefer to use their companions to interpret; they also observed that minor children are frequently involved in many aspects of their parents' health care; accordingly, commenters stated that awareness of their parents' health care needs may equip children of individuals with limited English proficiency to act as patient advocates for their parents.

In contrast, numerous commenters supported the proposed rule's standards for oral interpretation and the proposed restrictions on certain persons to interpret or facilitate communication. For instance, one health care provider shared that a high risk hospital was unprepared to provide oral interpretation to a woman in labor. The patient's child had to interpret what her mother was saying but the child did not know the proper terminology to understand the provider's medical questions about a fatal high risk condition.

In addition, many commenters who are limited English proficient shared that some covered entities have required individuals to bring their own interpreters, at a cost to the individual. Others shared that family members and children have served as interpreters for them, which has been insufficient because such family members and children do not have the requisite skills to interpret accurately.

Response: We decline to eliminate the specific requirements in § 92.201(d)-(e) of the proposed rule regarding oral interpretation or the restrictions on certain persons to facilitate communication or interpret. Commenters' recommendations run contrary to HHS's longstanding guidance under Title VI [201] and to OCR's experience and enforcement practices.[202] In many circumstances,

volume of documents and to assist a qualified translator in improving consistency among translated documents).

[195] *Id.*

[196] Int'l Medical Interpreters Assoc., IMA Guide on Medical Translation, *supra* note 85, at 3.

[197] *Id.* at 3; EM Balk et al., Assessing the Accuracy of Google Translate To Allow Data Extraction From Trials Published in Non-English Languages, (Prepared by the Tufts Evidence-based Practice Center for the Agency for Healthcare Research & Quality, U.S. Dep't of Health & Human Servs.), 12–15, 21- 24, Pub. No. 12(13)–EHC145–EF (2013), *https://www.effectivehealthcare.ahrq.gov/ehc/products/329/1386/Methods_Paper-Google-Translate_1-17-13.pdf.*

[198] This position is consistent with the position on this issue taken by the U.S. Department of Justice and the U.S. Department of Education. *See* U.S. Dep't of Justice & U.S. Dep't of Educ., Dear Colleague Letter: English Learner Students and Limited English Proficient Parents, 38 n.103 (Jan. 7, 2015), *http://www2.ed.gov/about/offices/list/ocr/letters/colleague-el-201501.pdf.*

[199] For considerations on ensuring the quality of translations, see Kleber Palma, Migration Policy Institute, Strategies to Help Covered Entities Ensure Quality of Translations, *http://www.migrationpolicy.org/programs/language-access-translation-and-interpretation-policies-and-practices/practitioners-corner* (last visited Mar. 23, 2016); Jessica Sperling, Migration Policy Institute, Practitioner's Corner: Drafting Request for Proposals and Contracts for Language Assistance Services, *http://www.migrationpolicy.org/programs/language-access-translation-and-interpretation-policies-and-practices/practitioners-corner-drafting* (last visited May 4, 2016).

[200] HHS LEP Guidance, *supra* note 49, 68 FR at 47317.

[201] HHS LEP Guidance, *supra* note 49, 68 FR at 47317–18, 47323.

[202] *See, e.g.,* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and the Rhode Island Department of Human Services, OCR Transaction No. 0876828, pt. IV.K. (Jan. 19, 2011) *http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/ridhhsagreement.pdf* (containing restrictions on the use of family members and friends as interpreters).

family members, friends, and especially children, are not competent to provide quality, accurate oral interpretation. For communications of particularly sensitive information, oral interpretation by an individual's family or friend often also implicates issues of appropriateness, confidentiality, privacy, and conflict of interest. Thus, covered entities may not rely on family members, friends, or other informal interpreters to provide language access services unless the situation meets an applicable exception in § 92.201(e)(2)-(3) of the final rule. This exception sufficiently balances an individual's preferences with an interest in ensuring competent language assistance services by allowing individuals to use accompanying adults to interpret in some circumstances.

Comment: One commenter suggested that entities should be exempt from complying with the HIPAA Privacy Rule when providing a qualified interpreter for an individual with limited English proficiency when required under § 92.201(a) of this final rule. Specifically, the commenter was concerned that Section 1557 covered entities would be forced to use or disclose protected health information in violation of the Privacy Rule when engaging interpreter services.

Response: OCR is responsible for enforcing the HIPAA Privacy Rule in addition to the rule implementing Section 1557. We note that, in most instances, a qualified interpreter will be a business associate or a workforce member of the covered entity. If a qualified interpreter is a business associate, a covered entity may disclose protected health information to the qualified interpreter if it obtains satisfactory assurances that the interpreter will use the information only for the purposes for which the interpreter was engaged and will safeguard the information from misuse. Such satisfactory assurances must be in writing and in the form of a contract between the covered entity and the qualified interpreter. If a qualified interpreter is a workforce member of the covered entity, a covered entity may share information with that interpreter as an employee or another type of agent of the entity (*e.g.,* hired through a contract or on the covered entity's staff as a volunteer).

Determining the relationship between the interpreter and the covered entity is a covered entity's HIPAA obligation and is unchanged by Section 1557 or this part. We encourage covered entities to review OCR's HIPAA Frequently Asked Questions (FAQ) regarding business associates at *http://www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/760.html,* and OCR's HIPAA FAQ regarding interpreters at *http://www.hhs.gov/hipaa/for-individuals/faq/528/can-my-health-care-provider-discuss-my-health-information-with-an-interpreter/.*

Comment: A few commenters suggested that the final rule urge covered entities to provide an in-person qualified interpreter for an individual with limited English proficiency as the default type of oral interpretation. These commenters explained that covered entities should rely on remote interpretation via telephone or video only in urgent situations or if an in-person interpreter is unavailable. These commenters reasoned that use of remote interpretation technologies may miss nuances of the communication and result in less accurate or less comprehensible communication. A few commenters recommended that a covered entity's use of remote interpretation services, via phone or video, be limited to administrative matters that can be addressed in 10 minutes or less. Moreover, in response to comments received in 2013 on OCR's Request for Information on Section 1557, some commenters identified concerns with the use of video remote interpretation services because the video connections used often were of a poor quality.

Response: We believe that commenters' recommendations regarding restrictions on remote oral interpretation are unnecessarily prescriptive and inconsistent with the fact-based, contextualized analysis under Title VI and this final rule. However, in situations where visual cues and other messages depend on physical as well as verbal communication, remote interpretation may not be adequate to provide meaningful access to an individual with limited English proficiency.

To address concerns that video remote interpreting technologies may result in less comprehensible communication, we are setting performance standards in § 92.201(f) of this final rule for video remote interpreting services [203] used for oral interpretation for an individual with limited English proficiency. These standards are designed to achieve parity with the regulation in the disability rights context regarding video remote interpreting technologies. Thus, the standards in § 92.201(f)(1)-(4) of the final rule closely parallel the standards on video remote interpreting services in § 92.202 regarding effective communication for individuals with disabilities, which in turn rely on the standards under Title II for the use of sign language interpreters.[204]

Comment: We received a few comments expressing concern about proposed § 92.201(f), re-designated in the final as § 92.201(g), which provides that an individual with limited English proficiency shall not be required to accept language assistance services offered by a covered entity. Some commenters recommended that proposed § 92.201(f) permit a covered entity to require the presence of a qualified interpreter, even if an individual with limited English proficiency has declined language assistance services.

Commenters suggested that when the individual who declines language assistance services is a patient, the health care provider's ability to accurately diagnose medical conditions is undermined. Commenters similarly stated that when the individual who declines language assistance services is a limited English proficient health care decision-maker for a child, that decision-maker would not be able to appropriately consent to, or participate in, a child's treatment plan. These commenters recommended requiring that a covered entity's insistence on a qualified interpreter be made in a non-coercive and culturally-appropriate manner.

Response: OCR interprets proposed § 92.201(f), which this final rule re-designates as § 92.201(g), to allow a covered entity to use a qualified interpreter when it is a reasonable step to provide an individual with limited English proficiency access to the covered entity's health program or activity. Although an individual with limited English proficiency can decline a qualified interpreter for herself, nothing in the rule is intended to bar a

[203] We intend that ''video remote interpreting services'' used for oral interpretation for individuals with limited English proficiency means the same that it does when used to provide interpretation for individuals with disabilities as defined by reference in § 92.4 of this final rule: ''an interpreting service that uses video conference technology over dedicated lines or wireless technology offering high-speed, wide-bandwidth video connection that delivers high-quality video images as provided in [28 CFR] 35.160(d).'' *See infra* § 92.4 (defining ''auxiliary aids and services'' to include ''video remote interpreting services,'' as defined in Title II of the ADA, 28 CFR 35.104).

[204] 28 CFR 35.160(d)(1)–(4). In contrast to 28 CFR 35.160(d)(2), which regulates the size of the video image to ensure that the screen shows one's face, arms, hands, and fingers, paragraph (f)(2) of § 92.201 in this final rule does not regulate the size of the video image because this component is less relevant for oral interpretation between English and non-English languages.

provider from using a qualified interpreter to assist the provider in communicating with, and assuring appropriate treatment to, the individual.[205] As a result, OCR does not intend for § 92.201(g) of the final rule to restrict a covered entity from using a qualified interpreter in either of the situations commenters raised. We also remind covered entities that, as we stated in the proposed rule, they may not discourage individuals with limited English proficiency from accepting language assistance services.

Comment: Some commenters proposed that OCR regulate the data sources to which covered entities may refer to assess the prevalence of languages spoken by individuals with limited English proficiency in their respective service areas. Commenters also recommended that OCR provide covered entities with resources, such as data-driven maps of languages spoken by limited English proficient populations in their respective service areas, to facilitate covered entities' assessments.

Response: We decline to accept commenters' suggestions, but we support covered entities' efforts to assess the language needs of their respective service areas. An assessment is a foundational best practice for a language assistance services program.[206] Data sources that may be useful include data from the United States Census Bureau, particularly the American Community Survey; utilization data from the covered entity's files for individuals with limited English proficiency; data from State and local governments; school system data; data from community agencies and organizations; and data from refugee or immigrant serving agencies.[207] Covered entities, however, are in the best position to determine what local or regional data sources are best suited to their needs. When using any data source, covered entities should look at the reliability, stability, and currency of the data to understand its strengths and weaknesses.

Comment: Many commenters provided feedback on OCR's request for comments on whether the final rule should set thresholds for the non-English languages in which covered entities must provide a range of language assistance services. The majority of comments on this issue focused on thresholds for the translation of vital documents.

Commenters supporting thresholds for written translation suggested that this policy improves access for individuals with limited English proficiency; streamlines OCR's compliance determinations; eliminates ambiguity by providing clear, quantifiable standards for covered entities; is consistent with other Departmental regulations specifying thresholds for written translation; and mitigates the risk that covered entities forgo written translation entirely.

Commenters recommended a variety of thresholds, such as those requiring translation based on the number of languages, percentage of language speakers, or the number of language speakers in a covered entity's service area, or composite thresholds mixing and matching these approaches. Some commenters simply stated that vital documents should be translated into the most commonly encountered languages in a covered entity's service area. Others suggested that OCR codify the threshold for translation of vital documents that is articulated as a safe harbor in the HHS LEP Guidance: translation into languages spoken by at least 1,000 persons or at least 5% of those present in the service area.[208] Other commenters asserted that numeric thresholds for translation are too rigid to be applied universally, and recommended that the final rule focus on translating materials for certain health programs, such as clinical research or health insurance programs.

Response: Although we have extensively considered whether to include thresholds for written translation and/or oral interpretation as either a safe harbor or as an across-the-board minimum requirement, we decline to set such thresholds in the final rule. First, although thresholds may improve access for some national origin populations, the approach does not comprehensively effectuate Section 1557's prohibition of national origin discrimination. Setting thresholds would be both under-inclusive and over-inclusive, given the diverse range, type, and sizes of entities covered by Section 1557 and the diverse national origin populations within the service areas of entities' respective health programs and activities.

For instance, a threshold requiring all covered entities, regardless of type or size, to provide language assistance services in languages spoken by 5% of a county's limited English proficient population could result in the provision of language assistance services in more languages than the entity would otherwise be required to provide under its obligation in § 92.201(a). This threshold would apply regardless of the number of individuals with limited English proficiency who are eligible to be served or likely to be encountered by the covered entity's health program or activity and regardless of the covered entity's operational capacity. Similarly, this threshold could leave behind significant numbers of individuals with limited English proficiency, served by a covered entity's health program or activity, who communicate in a language that constitutes less than 5% of the county's limited English proficient population.

Although some Departmental regulations set thresholds, those regulations address entities or health programs of similar sizes and types, such as qualified health plan issuers, Marketplaces, Medicare Advantage, and Medicare Part D. In comparison, Section 1557 and this part regulate more diverse types of covered entities with potentially more diverse limited English proficient populations. We are concerned that significant limited English proficient populations might receive no or inadequate language assistance services under a threshold-based regulation. We are also concerned about the burden an across-the-board translation threshold might place on small covered entities.

Moreover, we value the flexibility inherent in the contextualized approach we have chosen to assess compliance with the requirement to take reasonable steps to provide meaningful access. We thus decline to impose the prescriptive standards recommended by the commenters as inconsistent with this customized regulatory approach.

Comment: We received many comments in response to whether the rule should require enhanced language access obligations for some types of

[205] This understanding is consistent with the HHS LEP Guidance, *supra* note 49, 65 FR at 47318 (stating that even if an individual with limited English proficiency declines a qualified interpreter, where precise, complete, and accurate information is critical, or where the competency of the preferred interpreter that the individual desires to use is not established, ''a recipient may want to consider providing its own, independent interpreter, even if the LEP person wants to use his or her own interpreter as well.'').

[206] *See* HHS LEP Guidance, *supra* note 49, 68 FR at 47314, 47320.

[207] *See* Voluntary Resolution Agreement between U.S. Dep't of Health & Human Servs., Office for Civil Rights and Memorial Health System, OCR Transaction No. 08–79513, pt. V.B.1.b, *http://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/mhs_vra.pdf* (last visited Mar. 11, 2016) (listing data sources for an assessment of language needs).

[208] The safe harbor further provides that if a language group with fewer than 50 individuals constitutes 5% of the recipient's service area, the recipient is not obligated to translate written materials but must provide written notice in the primary language of that language group of the right to receive oral interpretation, at no cost to the individual. HHS LEP Guidance, *supra* note 49, 68 FR at 47319.

covered entities and if so, what types of entities should be subject to enhanced obligations. Some commenters suggested that enhanced obligations would be appropriate for certain covered entities that offer particularly significant or large health programs or activities, such as the Department, State agencies administering Medicaid or CHIP, Marketplaces, and qualified health plan issuers. These commenters asserted that these covered entities possess both the resources and the means to meet enhanced obligations and that they can leverage economies of scale. The commenters also asserted that imposing enhanced obligations on these entities would benefit smaller entities by making translated documents more widely available.

Commenters also addressed the scope of enhanced language access obligations, suggesting that such obligations should include requiring oral interpretation in at least 150 languages and the translation of documents into languages spoken by individuals with limited English proficiency when such individuals constitute 5% of, or 500 people in, the State population or the covered entity's service area.

A few commenters opposed enhanced language access obligations for certain types of covered entities. Specifically, one commenter asserted that there was no principled reason for retail pharmacies, which the proposed rule listed as an example of a covered entity that could have enhanced obligations under § 92.201,[209] to be subject to enhanced language access obligations.

Response: We reiterate our view that the contextualized approach in § 92.201 best considers both the needs of individuals with limited English proficiency and the potential burden on covered entities. Creating uniform, across-the-board requirements for particular categories of covered entities is, like thresholds, both under-inclusive and over-inclusive. For example, some smaller entities may operate in areas with significant concentrations of individuals with limited English proficiency; these entities may need to provide a broader scope of language assistance services to meet the requirements of § 92.201 than do other entities of similar size in less diverse areas. Similarly, State agencies that administer Medicaid and CHIP programs will differ with respect to the size and diversity of the limited English proficient populations they serve and the resources available to them.

Comment: Some commenters asserted that HHS, other Federal Departments, and States already heavily regulate health insurance issuers covered by Section 1557, thus subjecting them to multiple language access regulations at the State and Federal level. These commenters recommended two policy approaches to streamline Federal and State language access requirements: (1) Harmonize nondiscrimination rules across all Federal and HHS programs to create a national standard; and/or (2) permit a deeming approach that allows compliance with Federal or State language access laws to suffice for compliance with Section 1557, and similarly allow compliance with Section 1557 to suffice for compliance with other Departmental regulations addressing language access. In contrast, numerous commenters supported our fact-specific, contextualized approach and urged consideration of additional factors (*see* discussion *supra*) that would require the more robust provision of language assistance services.

Response: The Department understands the potential for confusion and burden that can be imposed where entities are subject to multiple sets of overlapping requirements. For this reason, we have harmonized, to the extent possible, the tagline requirement in § 92.8(d)(1) with the tagline requirement applying to Marketplaces and qualified health plan issuers under 45 CFR 155.205(c)(2)(iii)(A).[210] We will continue to coordinate as appropriate within HHS and with other Federal departments to ensure that the application and enforcement of requirements under Section 1557 is consistent with other provisions of Federal law or regulations.

However, we decline to adopt an approach that otherwise automatically harmonizes nondiscrimination rules or deems compliance with other laws sufficient for compliance with Section 1557. As we noted above in the discussion of deeming in the General Comments, it is common for entities to be subject to multiple State and Federal regulations, even when some of those regulations have been adopted by a single Federal agency. Indeed, even under CMS regulations for instance, Health Insurance Marketplaces,[211] State agencies administering Medicaid and CHIP programs,[212] and qualified health plan issuers,[213] are subject to multiple differing requirements with regard to language assistance services.

With specific regard to language assistance services, there are likely numerous situations in which a qualified health plan issuer's compliance with the meaningful access provisions of 45 CFR 155.205(c) would suffice to meet the requirements of Section 1557; indeed, there are instances in which 45 CFR 155.205(c) (*e.g.,* requiring that Marketplaces and qualified health plan issuers provide

[209] *See* 80 FR at 54185.

[210] Qualified health plan issuers are also bound by the tagline requirement in market-wide regulations at 45 CFR 147.136(e) (effective Jan. 19, 2016) described in the preamble to § 92.8, *supra* note 107.

[211] Health Insurance Marketplaces have language access obligations under laws independent of Federal civil rights laws requiring the following to be accessible to individuals with limited English proficiency: a Marketplace's toll-free call center, *see* 45 CFR 155.205(a); a Marketplace's Web site, *see id.* 155.205(b); applications, forms, and notices required to be sent by a Marketplace[SM]; *see id.* 155.230(b); and a Marketplace's consumer assistance functions, including a Marketplace's outreach and education activities and a Marketplace's Navigator program authorized by 42 U.S.C. 18031(i) and regulated at 45 CFR 155.210, *see id.* 155.205(d) and (e). In making information accessible to individuals with limited English proficiency, Marketplaces must do so through a combination of written translation, oral interpretation, posting of taglines, and translation of certain Web site content. *See* 45 CFR 155.205(c)(2)(i)(A) (oral interpretation), (ii) (written translation), (iii)(A) (taglines), (iv)(A) (translation of certain Web site content). With respect to a Marketplace's Navigator program, Navigators are required to provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Marketplace[SM], including individuals with LEP. *See* 42 U.S.C. 18031(i)(3)(E) (statutory requirement); 45 CFR 155.210(e)(5) (regulatory requirement).

[212] State agencies administering Medicaid programs and CHIP have language access obligations under laws independent of Federal civil rights laws. *See, e.g.,* 42 CFR 435.905(a)–(b)(1) (requiring State agencies administering Medicaid programs to provide language assistance services for applicants and beneficiaries who are limited English proficient); 457.340(a) (requiring State agencies administering CHIP to comply with certain regulatory requirements applicable to Medicaid, including 435.905(a)–(b)(1), which requires that program information be accessible to individuals with LEP); 435.1200(f)(2) (requiring States to make their Medicaid Web sites accessible to individuals with limited English proficiency); 438.10(c)(1)–(5) (specifying obligations for States delivering benefits and services through Medicaid managed care plans, including managed care organizations and certain plans themselves, to make written information available in certain non-English languages, to provide oral interpretation, and to notify individuals with limited English proficiency of the availability of language assistance).

[213] *See, e.g.,* 42 U.S.C. 18031(e)(3)(B) (requiring health plans seeking certification as qualified health plans to provide certain information, including claims payment and rating practices, cost-sharing, and enrollee and participant rights in plain language, which means language that the intended audience, including individuals with limited English proficiency, can readily use and understand); 45 CFR 155.205(c)(2)(i)(A), (ii), (iii)(A), (iv)(B) (requiring telephonic interpreter services, written translation, taglines, and translations of certain Web site content, respectively, for information provided to individuals with limited English proficiency); 156.250 (requiring meaningful access to certain qualified health plan information in accordance with the standards described in 155.205(c)).

telephonic oral interpretation in 150 languages [214]) might require more than would be required in a particular case under the fact-based analysis we adopt for Section 1557. However, we are concerned that there may be cases in which using CMS regulations alone to define a covered health insurance issuer's obligations could leave significant numbers of individuals with limited English proficiency without any, or adequate, access to language services.

In addition, automatically harmonizing requirements imposed on particular entities regulated by both Section 1557 and other laws that the Department enforces would undermine an equally important form of consistency: consistency in enforcement of the standards of Section 1557 and this part across all of the diverse categories of entities covered under the law.

For these reasons and the reasons discussed in the General Comments *supra,* we decline to adopt an approach that automatically deems compliance with CMS or other Federal regulations to be sufficient to demonstrate compliance with Section 1557. However, in circumstances where qualified health plan issuers' compliance with § 92.201 requires steps in addition to those required for compliance with 45 CFR 147.136 or 155.205, OCR will work with qualified health plan issuers to bring them into compliance with § 92.201. In addition, OCR will consider a qualified health plan issuer's compliance with other applicable regulations in determining the appropriate enforcement action.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions in § 92.201 with several modifications.

In § 92.201(a), we replaced the phrase ''that it serves or encounters'' with ''eligible to be served or likely to be encountered.''

In § 92.201(b), we implemented a technical revision in paragraph (b)(1) and we modified paragraph (b)(2). With respect to the technical revision in paragraph (b)(1), we modified this proposed phrase: ''the nature and importance of the health program or activity, including the particular communication at issue, to the individual with limited English proficiency'' by replacing ''including'' with the conjunction ''and.'' This technical revision clarifies OCR's intent that the particular communication at issue will routinely be a component of the Director's evaluation when the Director gives substantial weight to the nature and importance of the health program or activity. In addition, we modified § 92.201(b)(2) to state that the Director, in evaluating compliance, will take into account all relevant factors, which includes whether a covered entity has developed and implemented an effective written language access plan, appropriate to its circumstances. We eliminated paragraphs (i) through (v) of § 92.201(b)(2).

In § 92.201(d), we broadened the title to reflect that this paragraph now addresses specific requirements for written translation in addition to oral interpretation services. The text in proposed paragraph (d) addressing specific requirements for oral interpretation is now reflected under a new paragraph (d)(1). We added paragraph (d)(2) to require covered entities to use a qualified translator when translating written content in paper or electronic form for its health programs or activities.

In § 92.201(e)(2)(i) and (e)(3), we added ''for the individual with limited English proficiency'' after ''qualified interpreter'' to conform to the revision of this term as defined in § 92.4 of the final rule. In addition, we added a new paragraph (e)(4) to address restrictions on a covered entity's use of staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency, in their primary languages.

We re-designated paragraph (f) of § 92.201 in the proposed rule as paragraph (g) of § 92.201 in this final rule, and we added a new paragraph (f). New paragraph (f) provides that when a covered entity uses video remote interpreting services as the means to provide an individual with limited English proficiency oral language assistance, the video remote interpreting technology must meet the standards listed in § 92.201(f)(1)–(4) of this final rule.

Effective Communication for Individuals With Disabilities (§ 92.202)

In § 92.202 of the proposed rule, we proposed to incorporate the provisions governing effective communication with individuals with disabilities found in the regulation implementing Title II of the ADA, which applies to State and local government entities and requires covered entities to ensure that communications with individuals with disabilities are as effective as they are with individuals without disabilities. We noted that OCR typically looks to the ADA for guidance in interpreting Section 504 as the two laws contain very similar standards.

In the proposed rule, OCR considered whether to incorporate the standards in the regulation implementing Title II of the ADA or in the regulation implementing Title III of the ADA, or the standards in both regulations. Standards regarding effective communication under both regulations are very similar. We noted that there are, however, limited differences between the Title II and Title III regulations, regarding limitations on the duty to provide a particular aid or service where doing so may impose undue financial and administrative burdens, and the obligation under the Title II regulation to give primary consideration to the choice of an aid or service requested by the individual with a disability.

OCR proposed to apply the Title II standards to all entities covered under the proposed rule. We noted that although OCR could apply Title II standards to States and local government entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. We also noted that it is appropriate to hold HHS itself to the same standards to which the Department subjects the recipients of its financial assistance.

We also proposed that where the regulatory provisions referenced in § 92.202 use the term ''public entity,'' that term shall be replaced with ''covered entity.''

The comments and our responses regarding § 92.202 are set forth below.

Comment: A few commenters suggested that HHS urge covered entities to consider the gender preferences of patients for interpreters. These commenters suggested that patients may not be comfortable with interpreters of the opposite gender, particularly in settings that involve nudity such as in an obstetrics and gynecology appointment.

Response: We recognize the commenters' privacy concern, but we decline to accept the commenters' suggestion. We believe that identification with a certain gender specified by the patient is not a characteristic necessary to interpret for an individual with a disability or an individual with limited English proficiency. The definitions of qualified interpreter for an individual with a disability and qualified interpreter for an individual with limited English proficiency set forth in § 92.4 require an

[214] *See* 45 CFR 155.205(c)(2)(i)(A).

interpreter who adheres to generally accepted interpreter ethics, which would include respecting a patient's privacy and comporting oneself with discretion and professionalism in sensitive situations such as the settings described by the commenters. We believe that an interpreter of any gender can display these qualities and thus adequately perform the interpretation duties required of him or her. In those cases where an interpreter is unable to provide interpretation consistent with these standards, the interpreter would be unqualified for those reasons. In addition, acceding to the commenter's request could result in gender discrimination, which contravenes the purpose of other provisions of this rule.

Comment: A few commenters suggested that OCR apply cultural competency standards, such as the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS), to entities serving people with disabilities.

Response: Although OCR does not codify the CLAS standards as part of this regulation, OCR agrees that the CLAS standards provide valuable guidance to covered entities regarding the provision of services that are responsive to diverse cultural beliefs and practices, preferred languages, health literacy and other communication needs, and that promote compliance with the final rule. OCR encourages adoption of the CLAS standards by covered entities for interactions with all their patients and not simply for those with disabilities.

Comment: Some commenters suggested that OCR strengthen effective communication regulations by including the proposed provision regarding the restricted use of certain persons to interpret or facilitate communication contained in § 92.201(e) for individuals with limited English proficiency in § 92.202 for individuals with disabilities.

Response: We appreciate the commenters' suggestion, and note that § 92.202 incorporates provisions of the ADA regarding the restricted use of certain persons to interpret or facilitate communication; it is comparable to the provision in the final rule regarding restrictions on the use of certain persons to interpret or facilitate communication with individuals with limited English proficiency.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, including comments regarding the auxiliary aids and services requirement in § 92.101(b)(2)(i) (discussed above), we are finalizing the provisions proposed in § 92.202 by re-designating the existing regulation text at § 92.202 as § 92.202(a), and adding a new subsection, § 92.202(b) requiring covered entities—regardless of the number of people they employ—to provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

Accessibility Standards for Buildings and Facilities (§ 92.203)

The Section 504 regulatory provisions incorporated into Subpart B in this regulation contain program accessibility requirements that apply to existing facilities as well as new construction and alterations. In § 92.203 of the proposed rule, we proposed to establish specific accessibility standards for new construction and alterations. We noted that these standards are consistent with existing standards under the ADA.

Under paragraph (a), we proposed that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace℠ shall comply with the 2010 ADA Standards for Accessible Design (2010 Standards), as defined in the ADA Title II regulations,[215] if construction or alteration was commenced on or after January 18, 2018. We proposed that all newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a ''public building or facility'' as defined in Section 106.5 of the 2010 Standards.

We also proposed that new construction and alterations of such facilities would also be subject to the new construction standards found in the Section 504 implementing regulation at 45 CFR 84.23(a) and (b).

Under paragraph (b), we proposed that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace℠ before January 18, 2018 in conformance with UFAS, the 1991 ADA Standards for Accessible Design (1991 Standards), or the 2010 Standards be deemed to comply with the requirements of this section and with 45 CFR 84.23 (a) and (b), cross referenced in § 92.101(b)(2)(i) with respect to those facilities. Thus, we proposed that if the construction or alteration of facilities began prior to the effective date of paragraph (a) of this section, the facilities be deemed in compliance if they were constructed or altered in conformance with applicable standards at the time of their construction or alteration.

In paragraph (c), we proposed that each building or part of a building that is constructed or altered by or on behalf of, or for the use of, the Department must be designed, constructed, or altered so as to be readily accessible to and usable by individuals with disabilities. We proposed that the definitions, requirements, and standards of the Architectural Barriers Act, as established in Appendices C and D to 36 CFR pt 1191, apply to buildings and facilities covered by this section.

OCR considered adding specific language regarding accessibility standards for medical diagnostic equipment. However, we noted that the United States Access Board is currently developing standards for accessible medical diagnostic equipment and, therefore, we are deferring proposing specific accessibility standards for medical equipment. We further noted that a health program or activity's use of medical diagnostic equipment would be covered by Section 1557 under the general prohibition of discrimination on the basis of disability in § 92.101.

The comments and our responses regarding § 92.203 are set forth below.

Comment: Numerous comments supported requiring immediate compliance with the 2010 ADA Standards for new construction and alterations. Commenters urged that OCR not give covered entities an 18-month grace period for compliance because the 2010 Standards already apply to the vast majority of facilities covered by this proposed rule. They maintained that an approach which emphasizes the uniform application of the 2010 Standards upon publication of the 1557 rule will enable greater consistency among implementing agencies, given the overlapping jurisdiction that OCR has with the Department of Justice.

Response: OCR agrees with the comments in part. Because the great majority of entities covered by the final rule are already subject to the 2010 Standards, the regulation has been revised to require covered entities that were covered by the 2010 Standards prior to the effective date of this final rule to comply with the 2010 Standards for new construction or alterations that commence on or after the effective date of the final rule. However, there may be some entities covered by the final rule that were not covered by the 2010 Standards prior to the effective date of the final rule. For those entities,

[215] 28 CFR 35.104.

application of the 2010 Standards would be new; thus, these entities are given 18 months to comply with the final rule with respect to new construction and alterations. We anticipate that these changes will have only a de minimis impact on cost as nearly all of the entities affected are already subject to the 2010 Standards.

Comment: Numerous commenters recommended that OCR not deem compliance with the UFAS as compliance with Section 1557 for facilities that were constructed or altered prior to 18 months after publication of the final rule. They stated that the UFAS is functionally deficient for people with disabilities; barriers are permitted under the old standard that negatively affect people with mobility and strength disabilities; and, as recognized in the preamble to the proposed rule, nearly all of the facilities covered under the proposed rule are already subject to the 2010 Standards.

Response: OCR appreciates the concern raised by the commenters and agrees with the reasoning underlying the recommendation. OCR has thus modified the language in § 92.203(b) to state that each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace℠ in conformance with the 1991 Standards or the 2010 Standards is deemed to comply with the requirements of the final rule with respect to those facilities, if the construction or alteration was commenced before the effective date of the final rule. Conformance with the UFAS will constitute compliance with the requirements of the final rule only with respect to facilities where construction or alteration was commenced before the effective date of the final rule and only where the facility or part of the facility was not covered by the 1991 Standards or 2010 Standards.

Comment: One commenter recommended that OCR limit the facility accessibility requirements to areas of facilities that actually host consumers (patients of providers, in-person enrollees, etc.) and not apply them to covered entities' facilities more generally. The commenter observed that the ADA standards apply to places of public accommodation, and that if a facility is not public–facing, existing ADA requirements for employees already apply and do not need to be incorporated into this rule. The commenter believed that limiting these requirements to public-facing areas of entities would address consumer needs without creating undue financial and administrative burdens. As an example, the commenter stated that many issuers operate call centers that do not provide face-to-face services to their consumers; therefore, the commenter asserted, it is unclear why the call center would need to comply with physical facility accessibility standards.

Response: OCR notes that applying the building accessibility requirement to facilities or parts of facilities not used in any manner by customers or other program beneficiaries in most cases would be inconsistent with the limited application of the final rule to employment and employees. Thus, this provision is interpreted in light of the limitations on coverage of employment in § 92.101(a) (2); as such, the building accessibility requirement does not apply to facilities or parts of facilities that are visited only by employees of the covered entity except as provided in § 92.208. We believe that this approach is consistent with the ACA's goal of increasing consumer access to health care services and with Section 1557's focus on discrimination against patients, enrollees and other beneficiaries in health programs and activities.

However, we also note that the ADA applies to employment and, in addition, that nearly all of the entities subject to the facility access requirements in the final rule are also subject to facility access requirements under Section 504. Complaints of discrimination related to program accessibility can be brought by employees under the ADA and Section 504, and entities should ensure that they are in compliance with accessibility requirements, including the 2010 Standards, under the ADA.

Comment: Several commenters recommended that OCR require covered entities to make each of their existing facilities accessible to and usable by persons with disabilities. These commenters were concerned that if the accessibility requirement is not applied to each individual facility, then a large for-profit insurance carrier could decide that, among the great majority of its providers who operate in existing facilities, only a small percentage need to be physically accessible or have accessible equipment. Moreover, commenters expressed concern that those accessible providers could be clustered together in some central location, and whenever a member called member services and mentioned the need for accessibility, that member would be actively directed toward the more limited subset of accessible provider offices.

Response: The change urged by the commenter would constitute a new requirement that is inconsistent with existing standards under Title II of the ADA and Section 504, neither of which has been interpreted to require each existing facility to be accessible; rather, they require that the recipient operate each program or activity so that, when viewed in its entirety, it is readily accessible to individuals with disabilities.[216] Thus, we decline to accept the recommendation. We do note that issuers covered by this rule are responsible for ensuring that their health programs provide equal access to individuals without discrimination on the basis of disability. OCR also notes that most providers are recipients of Federal financial assistance from HHS and are themselves independently subject to the nondiscrimination requirements, including program accessibility requirements, in the final rule as well as under Title III of the ADA.

Comment: Some commenters urged that the requirement to comply with accessibility standards be primarily placed on the owners of buildings and facilities, rather than on the providers who rent space. One commenter said that OCR should provide resources and training to small business renters so that they understand what terms in their leases are necessary to ensure that landlords take reasonable responsibility for ensuring their facilities comply with Section 1557.

Response: OCR declines to accept the recommendation to place primary responsibility for compliance with accessibility standards on building owners. Under longstanding legal interpretations of the ADA and Section 504, building owners and lessees each have obligations to refrain from discriminating with respect to program access. OCR also is declining to develop resources and training specifically for small business renters, but notes that the Department of Justice has materials on compliance with accessibility standards under the ADA that may be of use to these entities.[217] In addition, the ADA National Network in HHS supports ten regional centers that provide information, guidance and training on the ADA through services tailored to meet the needs of business, government and individuals at local, regional and

[216] *See* 28 CFR 35.150(a); 45 CFR 84.22(a); *Bird.* v. *Lewis and Clark Coll,* 303 F.3d 1015, 1021 (9th Cir. 2002), *cert. denied,* 538 U.S. 923 (2003) (''the central inquiry [under the ADA and Section 504] is whether the program, when viewed in its entirety, is readily accessible to and usable by individuals with disabilities'').

[217] *See* U.S. Dep't of Justice, ADA Title III Technical Assistance Manual Covering Public Accommodations and Commercial Facilities (1993), § III–1.2000, *http://www.ada.gov/taman3.html.*

national levels.[218] OCR also will develop and make available, before the effective date of the final rule, training materials that cover requirements related to accessibility for individuals with disabilities.

Comment: Some commenters urged OCR to exempt entities that are places of public accommodation under Title III of the ADA from the requirements for physical accessibility under Section 1557, stating that additional requirements are confusing and burdensome for small providers. Another commenter recommended that if a health program or activity would not, under Title III of the ADA, be required to be in compliance with a given standard under the 2010 Standards, then the health program or activity should also be exempt from that standard for the purposes of Section 1557 enforcement.

Response: While entities subject to Title III of the ADA include both entities that receive Federal financial assistance and those that do not, the final rule applies only to entities that receive Federal financial assistance, as well as the Department and entities established under Title I of the ACA. We believe it is reasonable to hold entities that receive Federal financial assistance to the accessibility requirements under the final rule, regardless of the standards to which they might be subject under Title III.

Comment: Some commenters said that OCR should require covered entities to make publicly available information on whether medical diagnostic equipment is accessible, so that individuals with disabilities can make informed decisions when choosing a health care provider. A number of commenters recommended that new accessibility standards should be applicable only when physicians upgrade or replace their existing equipment.

Response: As the preamble to the proposed rule noted, standards for accessible medical equipment are in development by the Access Board; thus, OCR is not requiring compliance with specific accessibility standards at this time. In the absence of such standards, covered entities are not in a position to advise or publicize whether their equipment complies with particular standards. Nonetheless, we noted and reiterate here that general accessibility standards that apply to health programs and activities apply to medical equipment, and health service providers must ensure that their health programs and activities offered through the use of medical equipment are accessible to individuals with disabilities.

Summary of Regulatory Changes

For the reasons set forth above and considering the comments received, we have revised § 92.203(a) to state that each covered facility must comply with the 2010 Standards, if the construction or alteration was commenced on or after the effective date of the final rule, except that if a covered facility was not covered by the 2010 Standards prior to the effective date of the final rule, it must comply with the 2010 Standards if the construction was commenced after 18 months after the effective date of the final rule.

For the reasons set forth above and considering the comments received, we have also modified the language in § 92.203(b) to state that each covered facility constructed or altered in conformance with the 1991 Standards or the 2010 Standards will be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced before the effective date of the final rule. Further, each covered facility that was constructed or altered in conformance with UFAS will be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction was commenced before the effective date of the final rule and the facility was not covered by the 1991 Standards or 2010 Standards.

Accessibility of Electronic and Information Technology (§ 92.204)

In § 92.204(a), we proposed to require covered entities to ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of an entity's health program or activity.[219] For example, we stated that a Health Insurance Marketplace℠ creating a Web site for application for health insurance coverage must ensure that individuals with disabilities have an equal opportunity to benefit from the Web site's tool that allows comparison of health insurance coverage options, quick determination of eligibility, and facilitation of timely access to health insurance coverage by making its new Web site accessible to individuals who are blind or who have low vision.

We noted that this provision is consistent with existing standards applicable to covered entities. Specifically, Section 508 of the Rehabilitation Act requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities. Section 508 applies to HHS administered health programs or activities, including the Federally-facilitated Marketplaces. Section 504, which applies to recipients of Federal financial assistance, including issuers that receive Federal financial assistance, and Titles II and III of the ADA, which apply to State and local government entities and places of public accommodation, respectively, similarly have been interpreted to require that covered entities' programs, services, and benefits provided through electronic and information technology be accessible to individuals with disabilities.[220] In addition, some States have adopted Section 508 or Web Content Accessibility Guidelines (WCAG) standards for State agency Web sites or electronic and information technology more broadly.

In paragraph (b), we proposed to require State-based Marketplaces and recipients of Federal financial assistance to ensure that their health programs and activities provided through Web sites comply with the accessibility requirements of Title II of the ADA. We noted that our proposed regulatory text cross-references the Title II regulations as a whole, therefore incorporating any future changes to the Title II regulations. We also noted that these requirements are informed by the Department's extensive experience with web-based technology through Federal grant-making programs, including programs that provide funds for State infrastructure changes to allow electronic applications for coverage through the Medicaid program and the Health Insurance Marketplaces, provider adoption of electronic health records, and the development of web-based curricula for health care professionals.

In the proposed rule, we explained that based on the Department's prior experience in this field, we believe that

[218] For more information or to contact your regional center, please see *https://adata.org/* and *https://adata.org/national-network.*

[219] The terms ''undue financial and administrative burdens'' and ''fundamental alteration'' as used in this part have the same meaning that they have under the ADA.

[220] *See, e.g.,* discussion of case law in U.S. Dep't of Justice, Accessibility of Web Information and Services of State and Local Government Entities and Public Accommodations (Advanced Notice of Proposed Rulemaking), 75 FR 43460, 43463-(Jul. 26, 2010).

including an explicit, rather than implicit, requirement for electronic and information technology is necessary to clarify the obligations of covered entities to make this technology accessible. In addition, we noted that absent an explicit requirement for accessible electronic and information technology, people with disabilities might not have opportunities to participate in services, programs, and activities that are equal to and as effective as those provided to others, further exacerbating existing health disparities for persons with disabilities.

Given the existing requirements under Section 504, Section 508, and the ADA applicable to information provided through electronic and information technology as a whole, and given the importance of technologies, such as kiosks and applications, to access to health care, health-related insurance and other health-related coverage, we proposed to include an explicit accessibility requirement that applies to all of a covered entity's electronic and information technology, rather than to web access only. We sought comment on this proposal.

We also proposed a general accessibility performance standard for electronic and information technology, rather than a requirement for conformance to a specific set of accessibility standards. We provided that the application of this general accessibility performance standard would be informed by future rulemaking by the Access Board and the Department of Justice. We sought comment on whether the regulation should impose a general accessibility performance standard for electronic and information technology or require that electronic and information technology comply with standards developed pursuant to Section 508 by the Access Board,[221] or the Worldwide Web Consortium's Web Accessibility Initiative's WCAG 2.0 AA.

As noted above, we proposed that covered entities would have a defense to making their health programs and activities provided through electronic and information technology accessible if doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of the health program or activity. In determining whether an action would impose such undue burdens, we proposed that a covered entity must consider all resources available for use in the funding or operation of the health program or activity.

[221] 36 CFR pt. 1194.

We noted that when undue financial and administrative burdens or a fundamental alteration are determined to exist, the covered entity is still required to provide information in a format other than an accessible electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration, but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

The comments and our responses regarding § 92.204 are set forth below.

Comment: A few commenters objected to § 92.204's focus on individuals with disabilities. These commenters noted that Section 1557's nondiscrimination mandate guards against discrimination on the basis of race, color, national origin, sex, and age, as well as disability. Therefore, these commenters recommended that OCR state in § 92.204 that covered entities must ensure that their health programs or activities provided through electronic information and technology are accessible to individuals in all protected classes, not just individuals with disabilities.

Response: Section 92.204 addresses the unique accessibility issues for individuals with disabilities. However, § 92.204's focus on disability does not limit the application of general nondiscrimination principles to the accessibility of health programs and activities offered through electronic and information technology to other groups. Thus, the general prohibition of discrimination set forth in § 92.101(a) requires the accessibility of health programs and activities offered through electronic and information technology, without discrimination on the basis of race, color, national origin, sex, age, or disability.

Comment: One commenter expressed concern that many patients and clients lack internet connectivity in their homes and communities. This commenter stated that while providers should design web-based tools and resources that are user-friendly, appropriate, and effective for patients and clients with disabilities, the providers will need to use alternative creative means to meet the needs of those they serve who lack such connectivity in their homes or communities.

Response: OCR recognizes that many persons lack internet connectivity in their homes and communities and may therefore be unable to access web-based tools and resources provided by covered entities, and encourages entities to develop creative means to meet the needs of these individuals.

Comment: Several commenters asked that OCR clarify the scope of the electronic and information technology requirements. Specifically, these commenters asked OCR whether § 92.204's requirements are limited to the provision of health services.

Response: Section 92.204's requirements are coextensive with, and bounded by, the coverage of Section 1557. Thus, the rule requires covered entities to make all health programs and activities provided through electronic and information technology accessible. Accordingly, this requirement reaches activities such as an online appointment system, electronic billing, and comparison of health plans offered by a Health Insurance Marketplace℠. OCR believes that the regulatory text encompasses this approach.

Comment: A few commenters asked OCR to clarify whether the general requirement under subsection (a) to make health programs and activities that are provided through electronic and information technology accessible applies only to health programs or activities provided through electronic and information technology that are accessed by consumers or also to a covered entity's internal facing electronic information technology. Other commenters urged OCR to limit the application of the general requirement under subsection (a) only to health programs or activities provided through electronic and information technology that are directly related to the activity that made the organization a covered entity and that are accessed by consumers. Conversely, several other commenters recommended that OCR extend the application of subsection (a) to employees of covered entities.

Response: OCR addressed a similar issue in considering facility access requirements above. There, OCR noted that extending the facility accessibility requirement to facilities not used in any manner by customers or other program beneficiaries in most cases would be inconsistent with the limited application of the final rule to employment and employees. Thus, we noted that the facility accessibility requirement is interpreted in light of the limitations on coverage of employment in § 92.101(a)(2).

Similarly, in considering the application of the requirement in the final rule to accessibility of health programs and activities offered through electronic and information technology,

we are mindful that the final rule has limited application to employment and employees. In consideration of this limitation, we clarify that the accessibility requirements in the final rule are limited to health programs and activities offered through electronic and information technology that is used by consumers or other program beneficiaries and do not apply to electronic and information technology that is used only by employees of a covered entity and that does not affect or impact customers or program beneficiaries, except as provided in § 92.208.

We also note that the ADA and Section 504 apply to employment, and virtually all of the entities subject to the requirement for accessibility of health programs and activities offered through electronic and information technology in the final rule are also subject to similar general accessibility requirements in the ADA and Section 504. Entities covered by the final rule should be mindful of their obligations under these other laws.

Comment: Some commenters recommended that OCR require different standards for accessibility of electronic and information technology for entities covered under Title II of the ADA, which applies to State and local government entities, and entities covered under Title III of the ADA, which applies to places of public accommodation and commercial facilities.

Response: OCR declines to apply different standards under the final rule. As noted above, State or local government entities that are covered under Section 1557 are already subject to the Title II standards. In addition, the other entities covered under Section 1557 are health programs and activities that either receive Federal financial assistance from HHS or are conducted directly by HHS. Although OCR could apply Title II standards to States and local entities and Title III standards to private entities, we believe it is appropriate to hold all recipients of Federal financial assistance from HHS to the higher Title II standards as a condition of their receipt of that assistance. As a result, OCR declines to impose different standards as recommended by the commenters. This approach is consistent with our approach to § 92.202, in which we are applying Title II standards to all entities covered under Section 1557 with respect to effective communication.

Comment: One commenter asked that OCR exempt places of public accommodation under the ADA from the requirements to make electronic and information technology accessible. Other commenters suggested that the electronic and information technology requirements in the proposed rule are too confusing and burdensome for small providers.

Response: Places of public accommodation covered under the ADA already are required to make health programs and activities offered through electronic and information technology accessible to individuals with disabilities. The ADA does not exempt small providers from this requirement. Thus, the requirements under this final rule should be familiar to entities covered under the ADA.

Comment: Many commenters recommended that OCR require compliance with the accessibility standards set forth in WCAG 2.0, with Level AA as the minimum benchmark. These commenters suggested that compliance with a specific standard would offer clarity to covered entities and consistency to consumers. These commenters also favored WCAG over Section 508 because WCAG is technology agnostic, meaning it is broken down by function rather than product-type, and can apply to future innovations as well as current uses of technology. These commenters also noted that the Access Board is modeling the refreshed Section 508 standards on WCAG 2.0 Level AA, ensuring that HHS's adoption of such a technical standard guarantees that there will be one, universal set of accessibility benchmarks.

Conversely, one commenter stated that OCR should not impose a specific accessibility standard for electronic and information technology, arguing that a specific standard may slow innovation and the establishment of potentially effective electronic information technology alternatives.

Response: OCR has decided not to adopt specific accessibility standards at this time. Nonetheless, we are still requiring covered entities to ensure that health programs and activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would impose undue financial and administrative burdens or would result in a fundamental alteration in the nature of an entity's health program or activity. Thus, when a covered entity chooses to provide a health program or activity through electronic and information technology, the entity must ensure that the technology is accessible as necessary for individuals with disabilities to have equal access to the health program or activity. In our experience, where a covered entity chooses to provide health programs and activities through electronic and information technology, it is difficult to ensure compliance with accessibility requirements without adherence to standards such as the WCAG 2.0 AA standards or the Section 508 standards. Accordingly, OCR strongly encourages covered entities that offer health programs and activities through electronic and information technology to consider such standards as they take steps to ensure that those programs and activities comply with requirements of this regulation and other Federal civil rights laws. Due to the increasing importance of electronic and information technology in health care and health insurance coverage, OCR will continue to closely monitor this area, including developments in the standards developed by the Department of Justice and the Access Board.

Comment: A few commenters asked that OCR give covered entities at least 24 months to come into compliance with the requirements of § 92.204 because they believe there is a significant shortage of available expertise on electronic and information technology. Other commenters recommended that physicians should not be required to comply with new standards until they are ready to upgrade or purchase a new technology product. Still others asked that OCR delay enforcement pertaining to electronic and information technology until health programs and activities can easily select appropriate accessible technology that has been certified by OCR to comply with established standards for accessible technology.

However, many other commenters urged OCR to reject any requests to delay or phase-in the requirements of § 92.204. These commenters pointed out that § 92.204 builds on and reinforces other longstanding accessibility requirements in Federal law; accordingly, it should not be overly burdensome for covered entities to adjust to the requirements of this rule.

Response: OCR is requiring compliance with the requirements of § 92.204 as of the effective date of this regulation. Section 92.204 largely reflects existing standards under the ADA and Section 504, and accordingly, most covered entities are already required to meet § 92.204's standards. Moreover, and with respect to those few covered entities that were not previously subject to the ADA and Section 504 standards, existing undue burden analysis provides adequate safeguards for covered entities that are unable to comply with the requirements of § 92.204 by the effective date.

Comment: One commenter suggested that the responsibility for redesigning health information and technology to improve accessibility should be placed on software vendors and developers rather than on issuers and providers.

Response: The final rule applies to, among other entities, entities that conduct health programs or activities and that receive Federal financial assistance from HHS. Those entities, consistent with longstanding requirements under the ADA and Section 504, must make health programs and activities offered through electronic and information technology accessible to individuals with disabilities. This obligation is not new. Covered entities are not obligated to redesign health information and technology; accessible technology exists and is available to entities covered by the final rule. Thus, HHS is declining to make the change proposed.

Comment: Several commenters suggested that OCR include a reference to specific ADA regulations requiring effective communication in § 92.204.[222] These commenters noted that some of these regulations are the legal origin of the final rule's statement that covered entities must make health programs and activities provided through electronic and information technology accessible. Although these commenters acknowledged that not all of the regulations concerning auxiliary aids and services will apply in the electronic and information technology context, they believe that the explicit incorporation of relevant aspects of these ADA regulations would inform covered entities of other obligations that they might otherwise overlook, such as the obligation to consult and work with individuals with disabilities as part of the entity's effective communication obligation.

Response: OCR believes that intent is clear in the regulation as written. Although OCR is declining to include a reference to 28 CFR 35.160 and succeeding sections in § 92.204, as proposed by the commenters, these sections are incorporated in § 92.202 of the final rule, addressing effective communication with individuals with disabilities. Covered entities are required to comply with both sections of the final rule.

Comment: A few commenters asked OCR to state that electronic information and technology must be functional so that a person with a disability can enjoy all of the same functionality in an equally effective manner and with substantially equivalent ease of use as a user without a disability.

Response: OCR is clarifying here that a covered entity's electronic and information technology must be functional as necessary to ensure that an individual with a disability has equal access to a covered entity's health program and activity. We believe that the regulatory text encompasses this approach.

Comment: Several commenters called attention to problems that persons with disabilities frequently encounter when attempting to access health care. For example, one commenter pointed out that health care service providers' Web sites often include content like videos with audio components. The commenter noted that these videos often lack closed captioning or American Sign Language (ASL) translations that would make the information provided in the video accessible to people with hearing-related disabilities. Accordingly, this commenter suggested that OCR modify § 92.204 to require covered entities to caption or provide ASL translations of audio-based content on their Web sites so that all audio based content is accessible for deaf and hard of hearing individuals.

Another commenter pointed out that, when blind patients seek treatment at a doctor's office, they are often expected to make appointments or fill out required documentation expected of new patients using an inaccessible online portal. In these situations, the blind patient is forced to rely on a third party for assistance and, regardless of their personal relationship, disclose confidential information to that person such as the patient's medical history, illnesses, medications, and history of disease or genetic patterns running in the patient's family. Accordingly, this commenter asked that OCR clarify that covered entities need to make online portals accessible so that blind individuals have the same level of privacy and confidentiality as other individuals.

Response: Under the final rule, covered entities must ensure that the health programs and activities they offer through electronic and information technology are accessible to individuals with disabilities. OCR is not prescribing specific standards for ensuring accessibility and so declines to adopt the commenters' recommendation. However, OCR notes that under § 92.202(a), which incorporates 28 CFR 35.160(b)(2), ''[i]n order to be effective, auxiliary aids and services must be provided [to individuals with disabilities] . . . in such a way as to protect the privacy and independence of the individual with a disability.'' We further remind covered entities to consider the range of accessibility issues that arise for individuals with disabilities and the technology-based solutions that are available to address these issues. The confidentiality of health information is a critical issue, and covered entities must ensure that the private health information of individuals with disabilities is appropriately protected.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.204 without modification.

Requirement To Make Reasonable Modifications (§ 92.205)

In § 92.205, we proposed to require covered entities to make reasonable modifications in policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless they can demonstrate that the modification would fundamentally alter the nature of the health program or activity.

We did not receive any significant comments regarding § 92.205. For the reasons set forth in the proposed rule, we are finalizing the provisions proposed in § 92.205 without modification.

Equal Program Access on the Basis of Sex (§ 92.206)

In § 92.206, we proposed that covered entities be required to provide individuals equal access to their health programs or activities without discrimination on the basis of sex and to treat individuals consistent with their gender identity. We proposed that this provision applies to all covered health programs and activities, and prohibits, among other forms of adverse treatment, the discriminatory denial of access to facilities administered by a covered entity. We noted that this proposed approach is consistent with the principle that discrimination on the basis of sex includes discrimination on the basis of gender identity and that failure to treat individuals in accordance with their gender identity may constitute prohibited discrimination.

We proposed one limited exception to the requirement that covered entities treat individuals consistent with their gender identity: That a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one gender based on the fact that the individual's

[222] Commenters wanted OCR to cite to 28 CFR 35.160(a)(1), (2); 35.160(d); 35.163; and 35.164.

sex assigned at birth, gender identity, or gender otherwise recorded in a medical record or by a health insurance plan is different from the one to which such health services are ordinarily or exclusively available. For example, a covered entity may not deny, based on an individual's identification as a transgender male, treatment for ovarian cancer where the treatment is medically indicated.

For clarity and consistency within the final rule, we have made some technical revisions to § 92.206. First, regarding a covered entity being prohibited from denying or limiting health services, we are adding the words ''to a transgender individual'' after ''a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services, that are ordinarily or exclusively available to individuals of one gender,'' to clarify that the exception is limited to transgender individuals. We note that similar to the discussion in § 92.207(b)(3), we recognize that not every health service that is typically or exclusively provided to individuals of one sex will be a health service that is appropriately provided to a transgender individual. Nothing in the rule would, for example, require a covered entity to provide a traditional prostate exam to an individual who does not have a prostate, regardless of that individual's gender identity. But for health services that are appropriately provided to an individual, the covered entity must provide coverage for those health services on the same terms regardless of an individual's sex assigned at birth, gender identity, or recorded gender. Second, we are deleting the phrase ''in a medical record'' to address concerns that ''medical records'' could be understood as referring only to clinical notes of a health care provider.

The comments and our responses regarding § 92.206 are set forth below:

Comment: A majority of commenters strongly supported the requirement that covered entities provide equal access to health programs and activities without discrimination on the basis of sex and treat individuals consistent with their gender identity. Several commenters noted that discrimination in access to gender-specific facilities remains one of the most common and harmful forms of sex-based discrimination against transgender people, singling them out for humiliation and causing them to avoid the use of such facilities and the associated medical care. Numerous commenters strongly encouraged OCR to strengthen § 92.206 with explicit protections for individuals with non-binary gender identities who need access to gender-specific programs and facilities, and to affirm that individuals with non-binary gender identities should be permitted to determine which facilities are appropriate for them.

Response: OCR recognizes the difficulty that individuals with non-binary gender identities may face in accessing gender-specific programs and facilities. The rule makes clear that in order to meet their obligations under § 92.206, covered entities must treat all individuals consistent with their gender identity, including with regard to access to facilities. OCR has revised the definition of ''gender identity'' to clarify individuals with non-binary gender identities are protected under the rule from all forms of discrimination based on their gender identity. Thus, OCR does not believe that it is necessary to reiterate protections for non-binary individuals in this context.

Comment: Commenters noted that because pregnant women have experienced considerable discrimination in accessing certain health care services such as mental health care and drug treatment services, the final rule should state that equal access without discrimination on the basis of sex includes equal access without discrimination on the basis of pregnancy.

Response: OCR recognizes the difficulty many pregnant people experience in accessing certain health care services. In response to this concern, OCR is clarifying here that the equal program access provision under § 92.206 is simply a specific application of the more general prohibition of discrimination under § 92.101(a). Under both provisions, denial of program access on any of the prohibited bases, including pregnancy or related medical conditions, is prohibited.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provision as proposed in § 92.206 with technical revisions to clarify our intent and ensure consistency with other parts of the final rule.

Nondiscrimination in Health-Related Insurance and Other Health-Related Coverage (§ 92.207)

In § 92.207 of the proposed rule, we provided specific details regarding the prohibition of discrimination on the basis of race, color, national origin, sex, age, or disability in the provision and administration of health-related insurance or other health-related coverage. We proposed that this prohibition applies to all covered entities that provide or administer health-related insurance or other health-related coverage, including health insurance issuers and group health plans that are recipients of Federal financial assistance and the Department in the administration of its health-related coverage programs. We noted that this section is independent of, but complements, the nondiscrimination provisions that apply to the Health Insurance Marketplaces [223] and to issuers of qualified health plans [224] under other Departmental regulations, and that entities covered under those provisions and Section 1557 are obligated to comply with both sets of requirements.

Based on the longstanding civil rights principles discussed in connection with the definition of ''health program or activity'' in § 92.4, we proposed to apply this part to all of the coverage and services of issuers that receive Federal financial assistance, whether those issuers' coverage is offered through the Marketplace SM, outside the Marketplace SM, in the individual or group health insurance markets, or as an employee health benefit program through an employer-sponsored group health plan.[225] We provided an example illustrating that an issuer participating in the Marketplace SM, and thereby receiving Federal financial assistance, that also offers plans outside the Marketplace SM would be covered by the regulation for all of its health plans, as well as when it acts as a third party administrator for an employer-sponsored group health plan.[226]

Paragraph (a) proposed a general nondiscrimination requirement, and paragraph (b) provided specific examples of prohibited actions. Paragraphs (b)(1) and (2) proposed to address the prohibition on denying, cancelling, limiting, or refusing to issue or renew a health-related insurance plan or policy or other health-related coverage, denying or limiting coverage of a claim, or imposing additional cost sharing or other limitations or

[223] 45 CFR 155.120(c).

[224] 45 CFR 156.200(e); 45 CFR 147.104(e); Public Health Service Act section 2705 (codified at 42 U.S.C. 300gg–4).

[225] Like the proposed rule, the final rule separately addresses employer liability for discrimination in employee health benefit programs at § 92.208.

[226] Where an entity that acts as a third party administrator for an employer's employee health benefit plan is legally separate from an issuer that receives Federal financial assistance for its insurance plans, we proposed to engage in a case-by-case inquiry to evaluate whether that entity is appropriately subject to Section 1557. The final rule addresses this further in the discussions under § 92.2 and § 92.208.

restrictions, on the basis of an enrollee's or prospective enrollee's race, color, national origin, sex, age, or disability, and the use of marketing practices or benefit designs that discriminate on these bases.

In the proposed rule, we did not propose to require plans to cover any particular benefit or service, but we provided that a covered entity cannot have coverage that operates in a discriminatory manner. For example, the preamble stated that a plan that covers inpatient treatment for eating disorders in men but not women would not be in compliance with the prohibition of discrimination based on sex. Similarly, a plan that covers bariatric surgery in adults but excludes such coverage for adults with particular developmental disabilities would not be in compliance with the prohibition on discrimination based on disability.

In paragraphs (b)(3) through (5) of the proposed rule, we proposed to address discrimination faced by transgender individuals in accessing coverage of health services. We proposed in paragraph (b)(3) that to deny or limit coverage, deny a claim, or impose additional cost sharing or other limitations or restrictions on coverage of any health service is impermissible discrimination when the denial or limitation is due to the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded by the plan or issuer is different from the one to which such services are ordinarily or exclusively available.[227] Under the proposed rule, coverage for medically appropriate health services must be made available on the same terms and conditions under the plan or coverage for all individuals, regardless of sex assigned at birth, gender identity, or recorded gender.

In addition, we noted that many health-related insurance plans or other health-related coverage, including Medicaid programs, currently have explicit exclusions of coverage for all care related to gender dysphoria or associated with gender transition. Historically, covered entities have justified these blanket exclusions by categorizing all transition-related treatment as cosmetic or experimental.[228] However, such across-the-board categorization is now recognized as outdated and not based on current standards of care.[229]

OCR proposed to apply basic nondiscrimination principles in evaluating whether a covered entity's denial of a claim for coverage for transition-related care is the product of discrimination. We noted that based on these principles, an explicit, categorical (or automatic) exclusion or limitation of coverage for all health services related to gender transition is unlawful on its face under paragraph (b)(4); in singling out the entire category of gender transition services, such an exclusion or limitation systematically denies services and treatments for transgender individuals and is prohibited discrimination on the basis of sex.

Moreover, we proposed in § 92.207(b)(5) to bar a covered entity from denying or limiting coverage, or denying a claim for coverage, for specific health services related to gender transition where such a denial or limitation results in discrimination against a transgender individual. In evaluating whether it is discriminatory to deny or limit a request for coverage for a particular service for an individual seeking the service as part of transition-related care, we provided that OCR will start by inquiring whether and to what extent coverage is available when the same service is not related to gender transition. If, for example, an issuer or State Medicaid agency denies a claim for coverage for a hysterectomy that a patient's provider says is medically necessary to treat gender dysphoria, OCR will evaluate the extent of the covered entity's coverage policy for hysterectomies under other circumstances. We noted that OCR will also carefully scrutinize whether the covered entity's explanation for the denial or limitation of coverage for transition-related care is legitimate and not a pretext for discrimination.

We noted that these provisions do not, however, affirmatively require covered entities to cover any particular procedure or treatment for transition-related care; nor do they preclude a covered entity from applying neutral standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner.

We invited comment as to whether the approach of § 92.207(b)(1)–(5) is over- or underinclusive of the types of potentially discriminatory claims denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.

Paragraph (c) of § 92.207 of the proposed rule provided that the enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section. Paragraph (d) of the proposed rule provided that nothing in § 92.207 is intended to determine, or restrict a covered entity from determining, whether a particular health care service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

The comments and our responses regarding § 92.207 are set forth below.

Comment: Numerous commenters requested clarification regarding the rule's applicability to various health programs or activities that are regulated under other Federal requirements and recommended that OCR deem health programs and activities that comply with existing Federal regulations as in compliance with, or exempt from, Section 1557. For example, commenters requested that compliance with CMS regulations pertaining to qualified health plans or insurance benefit design, such as prescription drug formularies designed by a pharmacy and therapeutics committee,[230] be deemed compliance with the final rule. Numerous commenters also requested that OCR harmonize its language access requirements with existing CMS regulations. This is addressed in the discussion of § 92.201.

In addition, other commenters sought clarification as to the applicability of the rule to wellness programs[231] and value-based insurance designs[232] that are regulated by other Federal departments and agencies, and similarly requested that compliance with other Federal laws regarding these programs be deemed compliance with this final rule. Conversely, regarding employer

[227] We note that under § 92.207(a), a covered entity would be barred from denying coverage of any claim (not just sex-specific surgeries) on the basis that the enrollee is a transgender individual.

[228] Liza Khan, *Transgender Health at the Crossroads,* 11 Yale J. Health Pol'y L. & Ethics 375, 393 (2011).

[229] *See infra* note 263. *See also* discussion in the proposed rule at 80 FR at 54189–90.

[230] 45 CFR 156.122(a)(3) (for plan years beginning on or after Jan. 1, 2017).

[231] U.S. Dep't of the Treasury, U.S. Dep't of Labor, and U.S. Dep't of Health & Human Servs., Incentives for Nondiscriminatory Wellness Programs in Group Health Plans (Final Rule), 78 FR 33158 (June 3, 2013).

[232] For a discussion of Value-Based Insurance Design, see Affordable Care Act Implementation FAQs Set 5, Q1, *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html* (last visited May 4, 2016); U.S. Dep't of the Treasury, Dep't of Labor, and U.S. Dep't of Health & Human Servs., Coverage of Certain Preventive Services Under the Affordable Care Act, Final Rule, 80 FR 41318, 41321 (July 1, 2015); and U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., Medicare Advantage Value-Based Insurance Design Model (Sept. 1, 2015), *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-09-01.html.*

wellness programs, one commenter wanted OCR to expressly prohibit covered entities from implementing outcomes-based employee wellness programs that base financial rewards or penalties on outcome standards that are coextensive with or directly related to a disability, such as an outcome standard related to high glucose levels, which are directly related to diabetes.

Response: For the same reasons discussed in connection with the General Comments above,[233] we reject the recommendation to deem health programs or activities that comply with other Federal regulations as automatically in compliance with, or exempt from, the final rule. As a general matter, OCR does not view a covered entity's compliance with other Federal regulations, adopted with different requirements and for different purposes, as determinative of a covered entity's compliance with Section 1557 or other Federal civil rights laws that we enforce. Moreover, deeming compliance in this context must be considered in light of the potential harmful consequences to consumers' health that may occur if covered entities do not adhere to civil rights obligations.

While we reject deeming, OCR will consider a covered entity's compliance with other applicable Federal laws in evaluating a covered entity's compliance with this final rule, and will continue to coordinate with other Federal agencies to promote consistency and avoid duplication in enforcement efforts.

Further, we clarify that evidence-based insurance designs and wellness programs offered through covered entities, such as a health insurance issuer or a group health plan that receives Federal financial assistance, are health programs or activities that are subject to the final rule. We decline to expressly prohibit a particular type of practice by wellness programs in the final rule, as complaints will be reviewed on a case-by-case basis. We note that CMS has made clear that covered entities are responsible for ensuring compliance with other applicable Federal and State laws, including nondiscrimination obligations under Federal laws.[234] We remind covered entities that employer-sponsored wellness programs are considered an employee health benefit program and that employers will be subject to liability for discrimination in such programs under the circumstances identified in § 92.208.

Comment: Several commenters expressed concern that covered entities would not be able to revise their health insurance coverage or other health coverage to comply with the regulation within 60 days after publication, and requested that the effective date of the final rule, in particular § 92.207, be delayed until January 1, 2017 or 2018.[235] These commenters explained that health insurance plans are filed for review with CMS and State insurance regulators during the year before the calendar year in which the plan is offered for sale. Thus, depending on the publication date of the final rule, the commenters suggested that delaying the effective date to plan years (in the individual market, policy years) beginning in 2017 or 2018 would be necessary for issuers to avoid the administrative challenges associated with applying the final rule's requirements in the middle of a plan year or policy year, including amending benefit designs, revising premium rates if applicable, and refiling the products for review with CMS and State insurance regulators. In addition, the commenters noted that issuers are not permitted to adjust rates mid-year for some insurance products.

By contrast, one commenter supported maintaining the proposed effective date, arguing that the benefits of more immediate implementation of the final rule outweigh any expenses or confusion associated with mid-year policy revisions.

Response: We appreciate the concerns expressed by the commenters but we are maintaining the effective date as 60 days after the date of publication of the final rule, except in the limited circumstances described below. Section 1557 has been in effect since its passage as part of the ACA in March 2010, and covered entities have been subject to its requirements since that time. To delay implementation of the final rule would delay the existing and ongoing protections that Section 1557 currently provides and has provided since enactment.[236]

That said, we recognize that some covered entities will have to make changes to their health insurance coverage or other health coverage to bring that coverage into compliance with this final rule. We are sensitive to the difficulties that making changes in the middle of a plan year could pose for some covered entities and are committed to working with covered entities to ensure that they can comply with the final rule without causing excessive disruption for the current plan year.

Consequently, to the extent that provisions of this rule require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

Comment: Several commenters representing issuers and large employers recommended that the rule exempt from Section 1557 benefits that constitute excepted benefits under section 2791(c) of the Public Health Service Act (codified at 42 U.S.C. 300gg–91(c)), which generally are exempt from market reforms under the ACA and HIPAA portability requirements. Excepted benefits include, but are not limited to: limited scope dental and vision plans; coverage only for a specified disease or illness; and Medicare supplemental health insurance (also known as Medigap).[237] Commenters suggested that being excepted from the ACA market reforms and HIPAA portability requirements should result in exemption from Section 1557. Others stated that covering excepted benefits under the rule would serve as a disincentive to employers to provide these benefits due to increased litigation risk.

Response: We are not exempting benefits excepted from ACA market reforms and HIPAA portability requirements from the final rule. If an issuer providing these benefits receives Federal financial assistance and is principally engaged in providing health benefits, all of its operations will be covered by the rule; if it is not principally engaged, we will apply the rule to its federally funded health

[233] *See supra* discussion on deeming compliance with other laws in the General Comments section.

[234] 78 FR at 33168; U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., Affordable Care Act Implementation FAQs Set 2, Q5, *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html* (last visited May 4, 2016).

[235] The comments addressed in this section pertain to comments related to the implementation date of § 92.207. OCR also received comments requesting a delayed effective date for the rule in general, which are discussed *supra* under § 92.1 of this preamble.

[236] We note that issuers have been provided notice that they are subject to Section 1557 in other Departmental regulations (HHS's Notice of Benefit and Payment Parameters for 2017, Final Rule, 80 FR 12204, 12312 (Mar. 8, 2016); HHS's Notice of Benefit and Payment Parameters for 2017, Proposed Rule, 80 FR 75488, 75553 (Dec. 2, 2015); HHS's Notice of Benefit and Payment Parameters for 2016, Final Rule, 80 FR 10750, 10823 (Feb. 27, 2015)).

[237] 42 U.S.C. 300gg–91(c).

programs and activities. Many of the benefits excepted from the ACA market reforms and HIPAA portability rules will meet the definition of ''health program and activity.'' [238]

Nothing in the text of Section 1557 limits its coverage only to health programs and activities created or regulated by other provisions of the ACA. Indeed, Section 1557's incorporation of the four civil rights laws to which it refers, as those laws were amended by the CRRA, conclusively suggests otherwise. Moreover, Title VI, Section 504, and the Age Act independently apply to these benefits,[239] and other civil rights laws, such as Title VII, apply to these benefits when they are provided as a fringe benefit of employment by employers covered by that law.

There are several statutorily-defined categories of excepted benefits that are exempt from the ACA market reforms and HIPAA portability requirements if certain conditions are satisfied, such as when medical benefits are incidental or secondary to other insurance benefits, when the benefits are limited in scope or supplemental, or when the benefits are provided as independent, non-coordinated benefits.[240] Excepted benefits do not provide comprehensive medical coverage and do not satisfy the individual or employer responsibility provisions under the ACA. But these characteristics do not justify an exemption from the requirements of Section 1557, which reflects the fundamental policy that entities that operate health programs and activities, any part of which receives Federal funds, cannot use those funds to discriminate—however broad or narrow the scope of those health programs and activities may be.

Comment: Some commenters requested that OCR address a number of issues that are not within the purview of OCR or Section 1557, including the scope of essential health benefit coverage and establishing minimum network adequacy requirements.

Response: OCR appreciates the commenters' suggestions, but the commenters' requests are beyond the scope of this regulation. CMS is statutorily responsible for establishing and regulating the scope of essential health benefits and network adequacy requirements for health insurance issuers. Absent any allegation that a covered entity has discriminated on a basis prohibited by Section 1557, OCR lacks authority to address the terms of these CMS regulations.

Comment: Several commenters asked that OCR exercise more stringent and consistent oversight over consumer access to a wide range of specialists and subspecialists. Commenters pointed out that many qualified health plans in the Marketplace[SM] offer network-based plans, and enrollee cost-sharing can be substantially lower when care is delivered by an in-network provider. The commenters expressed concern that some issuers appear to systematically exclude from their provider networks high-cost providers or those in certain high-cost specialties. The commenters suggested that narrow networks could potentially be discriminatory if they deprive patients of reasonable access to a specialty provider or if they discourage enrollment by individuals with specific health needs.

Response: OCR agrees that provider networks with a wide range of specialists and subspecialists are beneficial for consumers and appreciates the concerns expressed about the effect of the exclusion of certain specialists from an issuer's network. We clarify, however, that it is beyond the scope of this regulation to establish uniform or minimum network adequacy standards. Qualified health plan issuers are subject to network adequacy requirements under CMS regulations.[241]

Comment: Some commenters asked OCR to clarify that issuers cannot discriminate against providers based on a provider's protected status. That is, these commenters recommended that OCR make clear that Section 1557's prohibition of discrimination is not limited in scope to the health care consumer and extends to other entities that may be engaged in health programs and activities.

Response: OCR clarifies that covered entities providing or administering health-related insurance or other health-related coverage may not discriminate against or exclude health care providers they contract with on the basis of the provider's race, color, national origin, sex, age, or disability. OCR reminds covered entities that they may have obligations under other Federal laws prohibiting discrimination against providers [242] or against employees.[243]

Comment: A few commenters asked OCR to amend § 92.207(a) so that it more clearly describes the various activities that a covered entity may perform that are considered ''administering'' health-related insurance or other health-related coverage. Specifically, these commenters asked that OCR add language to § 92.207(a) explaining that administering health-related insurance or other health-related coverage may include claims processing, rental of a provider network, designing plan benefits or policies, drafting plan documents, processing or adjudicating appeals, administering disease management services, and pharmacy benefit management.

Response: We appreciate the commenters' suggestion, but we believe the regulatory text is clear as written and does not require further clarification. The term ''administering'' is broad enough to encapsulate a variety of activities related to the administration of health-related insurance or other health-related coverage.

Comment: We received a number of comments related to the proper handling of claims alleging discrimination in employee health benefit plans that are covered by both this rule and other Federal laws and regulations. For example, several commenters recommended that the rule not apply to the services of third party administrators providing administrative services to self-insured group health plans. These commenters asserted that Congress did not intend for third party administrators to be covered by Section 1557 and asserted that third party administrators do not design plans, are not responsible for determining the benefits covered under the plan, and are required by ERISA [244] to administer plans as they are written. Commenters also asserted that coverage of third party administrators would indirectly subject self-insured group health plans to Section 1557 and create an unlevel playing field between third party administrators operated by issuers that receive Federal financial assistance and those that do not, thereby creating a disincentive for self-insured group health plans to contract with third party administrators that participate as issuers in the Marketplace[SM] and a resulting

[238] We note that non-health-related excepted benefits would be covered under the rule if offered by a covered entity that is principally engaged in providing health care or health coverage.

[239] Title IX applies to these benefits to the extent they are provided in connection with federally funded educational programs or activities.

[240] 42 U.S.C. 300gg–91(c).

[241] 45 CFR 156.230.

[242] *See, e.g.,* 42 U.S.C. 300gg–5(a); 42 CFR 422.205(a).

[243] *See, e.g.,* Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e–2000e–17), the ADA (42 U.S.C. 12101 *et seq.*), the Age Discrimination in Employment Act (29 U.S.C. 621–634); Executive Order 11246 (30 FR 12319, 12935, 3 CFR, 1964–1965, as amended), Section 503 of the Rehabilitation Act of 1973 (29 U.S.C. Sec. 793), and the Vietnam Veterans' Readjustment Assistance Act of 1974 (38 U.S.C. Sec. 4212).

[244] 29 U.S.C. 1001 *et seq.*

disincentive for issuers to offer qualified health plans on the Marketplace[SM]. These commenters also emphasized that self-insured group health plans are already subject to extensive Federal regulation under ERISA.

Some commenters representing issuers and larger employers also objected to language in footnote 73 [245] in the preamble of the proposed rule stating that when an entity that acts as a third party administrator is legally separate from the issuer that receives Federal financial assistance, we will engage in a case-by-case analysis to determine whether the third party administrator is subject to the rule. These commenters stated that the rule should never extend beyond the legal entity that receives the Federal financial assistance.

Response: We are not excluding third party administrator services from the final rule; however, we are adopting specific procedures to govern the processing of complaints against third party administrators.

Third party administrator services are undeniably a health program or activity, as they involve the administration of health services. Under the final rule, if an entity that receives Federal financial assistance is principally engaged in providing or administering health services, health insurance coverage, or other health coverage, then, consistent with the approach taken under the civil rights laws referenced in Section 1557 and under the CRRA, as discussed *supra,*[246] all of its operations are covered. Thus, if an issuer that receives Federal financial assistance is principally engaged in providing health insurance and also provides third party administrator services, there is no principled basis on which to exclude the law's application to the third party administrator services or to treat them differently from other entities and services covered by the rule.

Commenters' assertion that employers or group health plans may have an incentive to contract with third party administrators that are operated by entities that do not receive Federal financial assistance does not justify exempting third party administrator services from the rule. Commenters' rationale would undermine the application of all of the civil rights laws that attach obligations to the receipt of Federal financial assistance; if any competitive disparity exists here, it is no different than in other types of businesses in which some entities receive Federal financial assistance and others do not.

Moreover, the fact that third party administrators are governed by other Federal laws such as ERISA is not a reason to exempt them from Section 1557. ERISA itself explicitly preserves the independent operation of civil rights laws, by providing that nothing in ERISA ''shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States . . . or any rule or regulation issued under any such law.'' [247] And in any event, the fact that entities are subject to regulation under other Federal statutory schemes adopted for other purposes does not justify insulating them from the obligation to comply with civil rights requirements.[248]

Commenters expressed a number of concerns related to the relationship between third party administrators and the employers whose self-insured group health plans they administer. OCR clarifies here that, contrary to the understanding of some commenters, Section 1557's coverage of a third party administrator under the rule does *not* extend to the coverage of an employer providing a group health plan that is being administered by the third party administrator. The rule addresses employer liability separately from that of issuers that receive Federal financial assistance; [249] under Section 1557, an employer is liable for discrimination in its employee health benefit programs only if the employer is principally engaged in health services, health insurance coverage, or other health coverage, or otherwise satisfies one of the criteria set forth in § 92.208. Whether an employer's group health plan is administered by a third party administrator that is a covered entity is not relevant in this analysis.

In response to commenters' arguments on this point, however, OCR recognizes that third party administrators are generally not responsible for the benefit design of the self-insured plans they administer and that ERISA (and likely the contracts into which third party administrators enter with the plan sponsors) requires plans to be administered consistent with their terms.[250] Thus, if a plan has a discriminatory benefit design under Section 1557, a third party administrator could be held responsible for plan features over which it has no control.

Based on these comments, OCR is adjusting the way in which it will process claims that involve alleged discrimination in self-insured group health plans administered by third party administrators that are covered entities. Fundamentally, OCR will determine whether responsibility for the decision or other action alleged to be discriminatory rests with the employer or with the third party administrator. Thus, where the alleged discrimination is related to the administration of the plan by a third party administrator that is a covered entity, OCR will process the complaint against the third party administrator because it is that entity that is responsible for the decision or other action being challenged in the complaint. Where, for example, a third party administrator denies a claim because the individual's last name suggests that she is of a certain national origin or threatens to expose an employee's transgender or disability status to the employee's employer, OCR will proceed against the third party administrator as the decision-making entity. Where, by contrast, the alleged discrimination relates to the benefit design of a self-insured plan—for example, where a plan excludes coverage for all health services related to gender transition—and where OCR has jurisdiction over a claim against an employer under Section 1557 because the employer falls under one of the categories in § 92.208, OCR will typically address the complaint against that employer.

As part of its enforcement authority, OCR may refer matters to other Federal agencies with jurisdiction over the entity. Where, for example, OCR lacks jurisdiction over an employer responsible for benefit design, OCR typically will refer or transfer the matter to the EEOC and allow that agency to address the matter. The EEOC has informed OCR that, provided the filing meets the requirements for an EEOC charge, the date a complaint was filed with OCR will be deemed the date it was filed with the EEOC (although any subsequent denial of a renewed coverage request could be separately challenged by a timely complaint).

This approach is consistent with our efforts to ensure coordination with other Federal agencies that can also exercise jurisdiction over the subject of a particular complaint. Thus, we will also coordinate with the Office of Personnel Management (OPM) in the handling of claims alleging discrimination in the Federal Employees Health Benefits (FEHB) Program. OPM is charged by

[245] 80 FR at 54189 n.73.

[246] *See supra* discussion of the CRRA under the discussion of ''health program or activity'' under § 92.4.

[247] 29 U.S.C. 1144(d).

[248] *See supra* discussion on deeming compliance with other laws in the General Comments section.

[249] *See* § 92.208 and discussion of § 92.208 *infra.*

[250] *See* 29 U.S.C. 1104(a)(1)(D).

Federal statute [251] with offering FEHB plans as a fringe benefit of Federal employment and, in that role, approves benefit designs and premium rates, sets rules generally applicable to FEHB carriers, adjudicates and orders payment of disputed health claims, and adjusts policies as necessary to ensure compliance with nondiscrimination standards. As a result, OCR will refer to OPM complaints that allege discrimination in the FEHB Program where OPM is the entity with decision-making authority over the challenged action; OPM will treat these claims as complaints filed against OPM and will seek relief comparable to that available were these claims to be processed by OCR under Section 1557.

In response to the comments requesting additional clarification on footnote 73 in the proposed rule, we reiterate that we will engage in a case-by-case inquiry to evaluate whether a third party administrator is appropriately subject to Section 1557 as a recipient in situations in which the third party administrator is legally separate from an issuer that receives Federal financial assistance for its insurance plans. This analysis will rely on principles developed in longstanding civil rights case law, such as the degree of common ownership and control between the two entities,[252] and will also examine whether the purpose of the legal separation is a subterfuge for discrimination—that is, intended to allow the entity to continue to administer discriminatory health-related insurance or other health-related coverage.[253] But we note that a third party administrator is unlikely to be covered by this final rule where it is a legal entity that is truly independent of an issuer's other, federally funded, activities.

Comment: Commenters requested clarification on OCR's approach when evaluating whether a prohibited discriminatory action occurred under § 92.207(b).

Response: We clarify that OCR's approach in applying basic nondiscrimination principles, as discussed in the proposed rule under § 92.207(b)(5) [254] relating to coverage for specific health services related to gender transition, is the same general approach that OCR will take when evaluating denials or limitations of coverage for other types of health services. In other words, OCR will evaluate whether a covered entity utilized, in a nondiscriminatory manner, a neutral rule or principle when deciding to adopt the design feature or take the challenged action or whether the reason for its coverage decision is a pretext for discrimination. For example, if a plan limits or denies coverage for certain services or treatment for a specific condition, OCR will evaluate whether coverage for the same or a similar service or treatment is available to individuals outside of that protected class or those with different health conditions and will evaluate the reasons for any differences in coverage. Covered entities will be expected to provide a neutral, nondiscriminatory reason for the denial or limitation that is not a pretext for discrimination.

Comment: One commenter asked OCR to clarify that targeted marketing practices designed to reach certain populations to increase enrollment, such as specific segments of those who are uninsured or underserved, are not considered discriminatory. This commenter pointed out that some issuers sometimes launch targeted campaigns to reach a high number of uninsured in their service areas. In so doing, issuers may study the profile of uninsured populations, and based on the results of that study, may concentrate their marketing efforts on certain demographic groups that are disproportionately uninsured or underserved. The commenter cited a Gallup Poll that indicated that roughly one-third of Hispanics remain uninsured, which the commenter stated creates a particular need for issuers to help educate and expand coverage for this community. The commenter sought reassurance that OCR will not consider it discriminatory to target enrollment efforts where they will make the most difference.

Response: Congress intended the ACA to help uninsured and underserved populations gain access to care. Nothing in this regulation is intended to limit targeted outreach efforts to reach underserved racial or ethnic populations or other underserved populations. Indeed, it is OCR's intention that this regulation will increase access for uninsured and underserved populations, much as other Departmental regulations implementing the ACA have strived to do.[255]

Comment: Several commenters recommended that we define ''marketing practices'' in the regulatory text of § 92.207(b)(2). These commenters suggested that the inclusion of a precise definition for ''marketing practices'' would serve to clarify the scope of § 92.207(b)(2).

Response: We decline to define ''marketing practices'' in the final rule because to do so would be overly prescriptive. We emphasize, however, that we intend to interpret the term ''marketing practices'' broadly; such practices would include, for example, any activity of a covered entity that is designed to encourage individuals to participate or enroll in the covered entity's programs or services or to discourage them from doing so, and activities that steer or attempt to steer individuals towards or away from a particular plan or certain types of plans. We remind covered entities that other Departmental regulations address marketing practices,[256] and covered entities are obligated to comply with all applicable Federal and State laws regarding such practices.

Comment: Many commenters recommended that we define ''benefit design'' in the regulatory text of the final rule. These commenters suggested that the inclusion of a precise definition of ''benefit design'' would serve to clarify the scope of § 92.207(b)(2). In addition, numerous commenters requested that we codify or provide examples of benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability. A number of commenters urged OCR to consider specific types of benefit designs as constituting per se discrimination under § 92.207(b)(2) of the final rule.

Response: We appreciate commenters' requests for guidance and clarification regarding potentially discriminatory benefit designs and suggestions for scenarios that constitute per se discrimination. However, we decline to

[251] 5 U.S.C. 8901 *et seq.*

[252] *See, e.g., Papa* v. *Katy Indus., Inc.,* 166 F.3d 937, 939 (7th Cir. 1999), *cert. denied,* 528 U.S. 1019 (1999) (ADA, ADEA); *Arrowsmith* v. *Shelbourne, Inc.,* 69 F.3d 1235, 1240–42 (2d Cir. 1995) (Title VII).

[253] *Papa* v. *Katy Indus., Inc.,* 166 F.3d at 941.

[254] 80 FR at 54190.

[255] *See, e.g.,* 45 CFR 155.210(b)(2)(i) (requiring Exchanges to develop and publically disseminate Navigator training standards that ensures expertise in the needs of underserved and vulnerable populations); 81 FR 12204, 12338 (Mar. 8, 2016) (establishing new requirement at 45 CFR 155.210(e)(8) to require Navigators to provide targeted assistance to serve underserved or vulnerable populations).

[256] 45 CFR 156.225(b) (prohibiting qualified health plans from employing marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs); 45 CFR 147.104(e) (prohibiting a health insurance issuer from employing marketing practices or benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, gender identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions); 42 CFR 422.2260–422.2615 (establishing Part D marketing requirements).

define ''benefit design'' in the final rule because to do so would be overly prescriptive.[257] We also decline to codify examples of discriminatory benefit designs because determining whether a particular benefit design results in discrimination will be a fact-specific inquiry that OCR will conduct through its enforcement of Section 1557. For the same reason, we avoid characterizing specific benefit design practices as per se discriminatory in the final rule.[258]

OCR will analyze whether a design feature is discriminatory on a case-by-case basis using the framework discussed above. We reiterate that our determination of whether a practice constitutes discrimination will depend on our careful analysis of the facts and circumstances of a given scenario. OCR recognizes that covered entities have discretion in developing benefit designs and determining what specific health services will be covered in their health insurance coverage or other health coverage. The final rule does not prevent covered entities from utilizing reasonable medical management techniques; nor does it require covered entities to cover any particular procedure or treatment. It also does not preclude a covered entity from applying neutral, nondiscriminatory standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner. The rule prohibits a covered entity from employing benefit design or program administration practices that operate in a discriminatory manner.

Comment: We received a number of comments requesting that OCR add language to § 92.207(b) clarifying that categorical exclusions of certain conditions, such as coverage related to developmental disabilities or maternity care, are prohibited.

Response: While categorical exclusions of all coverage related to certain conditions could raise significant compliance concerns under Section 1557, OCR believes that existing regulatory language is sufficient to address this scenario. For example, the law has long recognized that discrimination based on pregnancy is a form of sex discrimination,[259] and OCR has interpreted Section 1557 in the same manner by defining the term ''on the basis of sex'' in this regulation to include ''discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions.'' As a result, it is unnecessary to add language in response to commenters' concerns.

We note that some products known as excepted benefits, which are subject to this final rule as discussed *supra,* provide limited scope benefits or coverage only for a specified disease or illness.[260] It would not be discriminatory for such products to include exclusions of coverage for conditions that are outside the scope of the benefits provided in those products. Accordingly, the purpose and scope of the coverage provided under health-related insurance or health-related coverage are factors that OCR will consider in determining whether an exclusion of all coverage for a certain condition is discriminatory under this final rule.

Comment: In light of OCR's statement in the preamble to the proposed rule that ''[t]he proposed rule does not require plans to cover any particular benefit or service, but a covered entity cannot have a coverage policy that operates in a discriminatory manner,'' [261] a few commenters asked OCR to clarify that the solution to a potentially discriminatory benefit design could be addition of coverage for a benefit or service.

Response: OCR agrees that the solution to a potentially discriminatory benefit design could be coverage, or added coverage, of a benefit or service.

Comment: The proposed rule invited comment as to whether the approach of § 92.207(b)(1)–(5) is over- or under-inclusive of the types of potentially discriminatory claim denials experienced by transgender individuals in their attempts to access coverage and care, as well as on how nondiscrimination principles apply in this context.[262] Many commenters supported OCR's approach in prohibiting a range of practices that discriminate against transgender individuals by denying or limiting coverage for medically necessary and medically appropriate health services. Numerous commenters asserted that the protections at § 92.207(b)(3)–(5) are vital to ensuring that transgender individuals are able to access the health coverage and care they need and urged OCR to preserve these provisions in the final rule.

For instance, many commenters strongly supported the proposed rule's prohibition against categorical or automatic exclusions of coverage for all health services related to gender transition. These commenters further supported the proposed rule's prohibition against otherwise denying or limiting coverage, or denying a claim, for health services related to gender transition if such a denial or limitation results in discrimination against a transgender individual. These commenters expressed hope that these prohibitions will serve to eliminate the significant barriers that transgender individuals have faced in accessing coverage for transition-related care, such as counseling, hormone therapy, and surgical procedures that they said had previously been denied to them because they have been viewed as cosmetic or experimental. Many commenters also favored the prohibition against denying, limiting, or otherwise restricting coverage for health services that are ordinarily or exclusively available to individuals of one sex based on an individual's gender identity. Commenters indicated that the proposed rule's protections will help to resolve various health care disparities suffered by transgender individuals.

Several commenters, however, opposed the protections that the proposed rule affords to transgender individuals. Some commenters suggested that covered entities should

[257] We note that ''benefit design'' is a term of art used in other Departmental and Federal regulations governing the private health insurance industry. *See e.g.,* 42 CFR 422.100(f)(3); 45 CFR 156.225(b); 45 CFR 147.104(e); 29 CFR 2510.3–40(c)(1)(iv)(A).

[258] CMS has identified benefit design features that might be discriminatory. For example, placing most or all prescription medications that are used to treat a specific condition on the highest cost formulary tiers (U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicare Servs., Patient Protection and Affordable Care Act: HHS Notice of Benefit and Payment Parameters Rule, (Final Rule), 80 FR 10750, 10822 (Feb. 27, 2015); U.S. Dep't of Health & Human Servs., Centers for Medicare and Medicaid Servs., Final 2016 Letter to Issuers in the Federally-facilitated Marketplace, 37 (Feb. 20, 2015)); applying age limits to services that have been found clinically effective at all ages (80 FR at 10822 (Feb. 27, 2015); Final 2016 Letter to Issuers in the Federally-facilitated Marketplace, 36–37 (Feb. 20, 2015)); and requiring prior authorization and/or step therapy for most or all medications in drug classes such as anti-HIV protease inhibitors, and/or immune suppressants regardless of medical evidence (Centers for Medicare and Medicaid Servs., Qualified Health Plan Master Review Tool, Non-Discrimination in Benefit Design (2017), *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/Master-Review-Tool_v1-1_03302016.zip* (open ''Master Review Tool_2017v1.0.xlsm'' document; then open ''Non-Discrimination Guidance'' tab)).

[259] Title VII prohibits discrimination in employment practices ''because of sex,'' 42 U.S.C. 2000e–2(a), which is defined to include ''because of or on the basis of pregnancy, childbirth, or related medical conditions. . . .'' 42 U.S.C. 2000e(k); *Newport News Shipbuilding & Dry Dock Co.* v. *EEOC,* 462 U.S. 669, 684 (1983) (''discrimination based on a woman's pregnancy is, on its face, discrimination because of her sex.'').

[260] 42 U.S.C. 300gg–91(c).

[261] 80 FR at 54189.

[262] 80 FR at 54191.

be permitted to categorically exclude coverage for transition-related health services based on moral or religious convictions that an individual's biological sex, or sex assigned at birth, should not be altered. Other commenters suggested that OCR is exceeding its legal authority by addressing covered entities' provision of coverage to transgender individuals because discrimination based on gender identity should not be recognized as a form of sex discrimination.

Response: We agree with the commenters who expressed their general support of the protections for transgender individuals afforded by the provisions at § 92.207(b)(3)–(5), and therefore we are keeping the provisions as proposed. We believe that it is important to ensure that civil rights protections are extended to transgender individuals to afford them equal access to health coverage, including for health services related to gender transition. As we stated in the preamble to the proposed rule, the across-the-board categorization of all transition-related treatment, for example as experimental, is outdated and not based on current standards of care.[263]

Further, we disagree with commenters who asserted that sex-based discrimination does not include discrimination based on gender identity. As discussed previously,[264] OCR's definition of discrimination ''on the basis of sex'' is consistent with the well-accepted interpretations of other Federal agencies and courts. Further, as previously noted in this preamble,[265] we decline to adopt a blanket religious exemption in the final rule as any religious concerns are appropriately addressed pursuant to pre-existing laws such as RFRA and provider conscience laws.

Comment: A significant number of commenters recommended that OCR revise the language in § 92.207(b)(4) that prohibits categorical exclusions or limitations of ''all health services related to gender transition'' to remove the word ''all,'' and proposed modifications to § 92.207(b)(3)–(5) relating to the medical necessity or medical appropriateness of coverage for health services related to gender transition and sex-specific services. Other commenters, concerned that the rule may be too broadly interpreted, requested clarification as to when gender transition services or sex-specific services must be provided and recommended that the rule specify that such health services are to be provided only when medically necessary or medically appropriate. These commenters also requested that OCR clarify that the rule's intent is not to require covered entities to cover elective services or mandate that it cover certain services. Conversely, other commenters specifically requested that the rule clarify that covered entities cannot deny medically necessary services for gender transition-related care because such treatment is medically necessary for transgender individuals. Further, some commenters suggested that covered entities must provide coverage for procedures or services to treat gender dysphoria or associated with gender transition when substantially similar procedures or services are covered for other conditions. For example, commenters observed that a hysterectomy to treat gender dysphoria is substantially similar to a hysterectomy performed for cancer treatment or prevention in a cisgender woman (*i.e.,* a woman whose gender identity is consistent with her sex assigned at birth).

Response: OCR appreciates the array of comments provided but does not believe it is necessary to revise the regulatory text. As noted in the preamble to the proposed rule, we will evaluate whether a particular exclusion is discriminatory based on the application of longstanding nondiscrimination principles to the facts of the particular plan or coverage. Under these principles, issuers are not required to cover all medically necessary services. Moreover, we do not affirmatively require covered entities to cover any particular treatment, as long as the basis for exclusion is evidence-based and nondiscriminatory.

Thus, we reject commenters' suggestion that the rule require covered entities to provide coverage for all medically necessary health services related to gender transition regardless of the scope of their coverage for other conditions.

At the same time, the rule does require that a covered entity apply the same neutral, nondiscriminatory criteria that it uses for other conditions when the coverage determination is related to gender transition. Thus, if a covered entity covers certain types of elective procedures that are beyond those strictly identified as medically necessary or appropriate, it must apply the same standards to its coverage of comparable procedures related to gender transition. As a result, we decline to limit application of the rule by specifying that coverage for the health services addressed in § 92.207(b)(3)–(5) must be provided *only* when the services are medically necessary or medically appropriate.

With regard to § 92.207(b)(3), we recognize that not every health service that is typically or exclusively provided to individuals of one sex will be a health service that is appropriately provided to a transgender individual. Nothing in the rule would, for example, require an issuer to cover a traditional prostate exam for an individual who does not have a prostate, regardless of that individual's gender identity. However, the issuer must cover the health services that are appropriately provided to an individual by applying the same terms and conditions, regardless of an individual's sex assigned at birth, gender identity, or recorded gender.

We also clarify that the prohibition in § 92.207(b)(4) on categorically limiting coverage for all health services related to gender transition is intended to prevent issuers from placing categorical, arbitrary limitations or restrictions on coverage for all gender transition-related services, such as by singling out services related to gender transition for higher co-pays; it is not intended to prevent issuers from placing nondiscriminatory limitations or restrictions on coverage under the plan. We have revised the language of the provision to clarify that intent.

Comment: Some commenters requested that the final rule define ''health services related to gender transition.''

Response: We decline to include a definition of ''health services related to gender transition.'' OCR intends to interpret these services broadly and recognizes that health services related to gender transition may change as standards of medical care continue to evolve.

The range of transition-related services, which includes treatment for gender dysphoria, is not limited to surgical treatments and may include, but is not limited to, services such as

[263] 80 FR at 54189 *See e.g.,* World Professional Association for Transgender Health (WPATH), *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People* (7th ed. 2011), *http://www.wpath.org/uploaded_files/140/files/* Standards Of Care, V7 Full Book.pdf; Institute of Medicine of the National Academies, *The Health of Lesbian, Gay, Bisexual and Transgender People: Building a Foundation for Better Understanding (2011); www.nationalacademies.org/hmd/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx. See also* U.S. Dep't of Health & Human Servs., Departmental Appeals Bd., Appellate Division NCD 140.3, Docket No. A–13–87, Decision No. 2576, 22–24 (May 30, 2014), *http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf.*

[264] *See supra* discussion of the definition ''on the basis of sex'' under § 92.4.

[265] *See supra* discussion on including a religious exemption under § 92.2.

hormone therapy and psychotherapy, which may occur over the lifetime of the individual. We believe the flexibility of the general language in the final rule best serves transgender individuals and covered entities.

Comment: Several commenters expressed concern that some issuers do not yet have the technological capability to avoid initial denials of coverage for sex-specific services for transgender individuals due to their computer systems flagging a mismatch between the gender of the individual identified at enrollment and the billing code associated with the biological sex that typically receives the health service. The commenters explained that issuers' computer systems accommodate only binary gender billing codes (*e.g.,* ''male'' or ''female'') and cannot accommodate descriptions of an enrollee's gender identity. Further, commenters observed that the Health Insurance Marketplace℠ enrollment application available through *HealthCare.gov* permits applicants to identify themselves only as male or female and does not currently allow applicants to denote their gender identity. These commenters noted that, as a result, qualified health plan issuers receive incomplete information about an enrollee's gender identity and biological sex. Moreover, these commenters requested that OCR clarify that an initial denial of a transgender enrollee's claim due to the discrepancy between the enrollee's recorded gender and the sex with which the health service is generally associated does not constitute discrimination if the enrollee is able to reverse the denial through an internal appeals process.

Response: As we indicated in the proposed rule,[266] we recognize that some issuers use computer systems that accommodate only binary gender billing codes that flag a gender mismatch for coverage of certain sex-specific services. We noted that such flagging, by itself, would not be impermissible if it does not result in a delay or denial of services or a claim for services. We reject, however, the commenters' suggestion that an initial denial of a transgender enrollee's claim should never be considered discriminatory as long as the enrollee is able to correct the denial through the internal appeals process. Requiring transgender enrollees to repeatedly go through the internal appeals process to obtain coverage for certain services would subject these enrollees to a burdensome process that is likely to delay their receipt of coverage.

Moreover, there are available interim methods for correcting initial coverage denials due to computer systems flagging a gender mismatch that issuers can use as their computer systems are updated. For instance, we understand that current billing code practices include general billing code modifiers that are used to identify situations in which issuers need to evaluate further claims that might otherwise be automatically rejected. As a result, issuers could advise health care providers to submit an existing billing code modifier along with a claim for sex-specific services for a transgender patient to flag the billing for the issuer's further review.[267] Issuers are free to develop another method of processing claims for sex-specific services by transgender individuals as long as the process is not overly burdensome and provides timely access to care. We note that commenters have raised concerns about the Health Insurance Marketplace℠ enrollment application and will address these concerns as appropriate.

Comment: One commenter recommended that we extend a safe harbor protection to issuers who demonstrate their good faith compliance with § 92.207(b)(3) for the time period during which they update their computer systems and operations to prevent inappropriate denials of coverage for sex-specific services for transgender enrollees.

Response: While we reject the commenter's recommendation of a safe harbor protection, OCR is willing to work with issuers to help identify potential interim solutions and to come into compliance.

Comment: One commenter requested clarification regarding whether an issuer may require transgender enrollees to provide additional information related to their biological sex to enable the issuer to override inappropriate denials of coverage for sex-specific health services. Another commenter inquired as to whether an issuer is permitted to request information about an applicant's biological sex on an insurance application form.

Response: We understand that, in some instances, a covered entity may need to ask transgender enrollees for additional information, including information related to their biological sex or sex assigned at birth, to facilitate overriding denials of coverage for sex-specific health services due to gender billing code mismatches in their computer systems. We clarify in this preamble that a covered entity is permitted to ask transgender enrollees to provide such additional information, as long as the covered entity does not unduly burden enrollees or make unreasonable inquiries that serve to delay their receipt of coverage. In addition, we clarify that it is permissible for a covered entity to request information about the biological sex of the applicant on an insurance application form to assist the covered entity in identifying the medical appropriateness of sex-specific health services, as long as the information requested is not used in a discriminatory manner, and the collection and use of the information is otherwise lawful and complies with applicable HIPAA privacy requirements.

Comment: Many commenters recommended revisions to § 92.207(d), which provides that nothing in this section is intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case. Some commenters requested that we revise this provision to ensure that a covered entity does not use criteria that lead to a discriminatory result in its medical necessity or coverage determinations. For example, some commenters suggested that we require covered entities to use certain treatment guidelines when determining medical necessity or coverage for transgender-related health services, such as those published by the WPATH. Conversely, other commenters expressed concern that Section 1557 may unduly restrict a covered entity's ability to evaluate medical necessity in its coverage determinations and requested clarification that covered entities are permitted to require certain treatment, such as mental health services for gender dysphoria, as part of their medical necessity or coverage determinations.

Response: We appreciate the concerns raised by commenters, but we are maintaining the language in § 92.207(d) without revision. OCR will not second-guess a covered entity's neutral

[266] 80 FR at 54189 n.75.

[267] The Medicare program already directs providers to use this approach. *See* Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Medicare Claims Processing Manual, Chapter 32, Transmittal 240: Special Instructions for Certain Claims with a Gender/Procedure Conflict *(last revised Jan. 20, 2015),* (directing providers to use an approved national billing code for sex-specific services for transgender patients to alert the contractor that it is not an error and to allow the claim to continue with normal processing), *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf.*

nondiscriminatory application of evidence-based criteria used to make medical necessity or coverage determinations. Therefore, we refrain from adding any regulatory text that establishes or limits the criteria that covered entities may utilize when determining whether a health service is medically necessary or otherwise meets applicable coverage requirements. Nevertheless, we caution covered entities that, although § 92.207(d) does not dictate the criteria that a covered entity must use, a covered entity must use a nondiscriminatory process to determine whether a particular health service is medically necessary or otherwise meets applicable coverage requirements.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.207 with minor technical revisions for clarity, to make our intent clear, and to ensure consistency with other parts of the final rule. We are making technical corrections to paragraphs (b)(1), (b)(3) and (b)(5) to add the word ''coverage'' where appropriate to reconcile with other parts of the rule. In (b)(1), we are making two modifications to the language. We are reconciling the usage of ''health-related insurance'' and ''other health-related coverage'' by adding ''related'' to those terms in (b)(1). We are also removing reference to ''enrollees'' as it unintentionally limited application of the paragraph. In (b)(2), we are replacing text that prohibited employing discriminatory marketing practices or benefit designs with text that prohibits having or implementing discriminatory marketing practices or benefit designs to clarify our intent that both having and applying discriminatory marketing practices and benefit design are prohibited. This clarification does not substantively modify the prohibition set forth in the proposed rule. In (b)(3), we are adding the words ''to a transgender individual'' for clarity, and are deleting the words ''by the plan or issuer'' for consistency with other parts of the rule. In (b)(4), we are revising the language to be clear that our intent was to prohibit categorical exclusions or limitations in both benefit design and administration; thus, we are replacing language prohibiting categorical or automatic exclusions or limitations of coverage with language that prohibits having or implementing a categorical exclusion or limitation of coverage. This clarification does not substantively modify the prohibition set forth in the proposed rule. In (b)(5), we also are revising the description of the prohibited actions to reconcile the language with other paragraphs in § 92.207(b).

Employer Liability for Discrimination in Employee Health Benefit Programs (§ 92.208)

In § 92.208, we proposed to address the application of Section 1557 to employers that offer health benefit programs to their employees. Under our proposed approach, where an entity that receives Federal financial assistance provides an employee health benefit program to its employees, it will be liable for discrimination in that employee health benefit program under this part only in three defined circumstances.[268] In paragraph (a), we proposed that where an employer is principally engaged in providing or administering health services or health coverage and receives Federal financial assistance, the employer would be subject to Section 1557 in its provision or administration of employee health benefit programs to its employees. Thus, if a hospital provides health benefits to its employees, it will be covered by Section 1557 not only for the services it offers to its patients or other beneficiaries but also for the health benefits it provides to its employees.[269]

In paragraph (b), we proposed that where an entity receives Federal financial assistance the primary objective of which is to fund an employee health benefit program, that entity's provision or administration of the health benefit program will be covered by Section 1557 regardless of the business in which the entity is engaged.

In paragraph (c), we proposed that an employer that is not principally engaged in providing or administering health services or health insurance coverage, but that operates a health program or activity (that is not an employee health benefit program) that receives Federal financial assistance, will be covered for its provision or administration of an employee health benefit program, but only with regard to employees in the health program or activity. Thus, we noted that when a State receives Federal financial assistance for its Medicaid program, the State will be governed by Section 1557 in the provision of employee health benefits for its Medicaid employees, but not for its transportation department employees, assuming no part of the State transportation department operates a health program or activity.

In summary, unless the primary purpose of the Federal financial assistance is to fund employee health benefits, we proposed that Section 1557 would not apply to an employer's provision of employee health benefits where the provision of those benefits is the only health program or activity operated by the employer.

We explained that absent the limitations in § 92.208, employers that receive Federal financial assistance for any purpose could be held liable for discrimination in the employee health benefit programs they provide or administer, even where those employers are not otherwise engaged in a health program or activity and where the use of Federal funds for employee health benefits is merely incidental to the purpose of the assistance. We noted that claims of discrimination in such benefits, brought against employers that do not operate other health programs or activities, could be better addressed under other applicable laws. For example, Title VII of the Civil Rights Act of 1964,[270] the ADA,[271] and the Age Discrimination in Employment Act[272] address claims that an employer has discriminated in the provision of benefits, including health benefits, to its employees.

We proposed to apply the same analysis of employer liability under Section 1557 whether the employee health benefit program is self-insured or fully-insured by the employer. We provided that where an employer that would otherwise be covered under this section creates a separate legal entity to administer its employee health benefit plan, the employer would continue to be liable for the nondiscriminatory provision of employee health benefits to its employees; the employer, as a recipient, may not, through contractual or other arrangements, discriminate on

[268] As reflected in § 92.101(a)(2) and as discussed in the preamble of the proposed rule, 80 FR at 54180, except as provided here, the proposed rule does not generally apply to discrimination by a covered entity against its own employees. Thus, the rule does not generally extend to hiring, firing, promotions, or terms and conditions of employment outside of those identified in § 92.208; such claims would continue to be brought under other laws, including Title VII, Title IX, Section 504, the ADA and the Age Discrimination in Employment Act, as appropriate.

[269] This approach is consistent with the basic principle underlying the rule and derived from longstanding civil rights interpretations: Where an entity that receives Federal financial assistance is principally engaged in providing or administering health services, health insurance coverage, or other health coverage, all of its operations are covered by Section 1557. *See* discussion *supra* of § 92.2.

[270] 42 U.S.C. 2000e–2000e–17.

[271] 42 U.S.C. 12101 *et seq.*

[272] 29 U.S.C. 621–634.

a prohibited basis against its employees.[273]

The comments and our responses regarding § 92.208 are set forth below.

Comment: One commenter expressed the view that while most churches or church boards providing employee health benefits through a church plan would not be covered under § 92.208, some might be covered under § 92.208(c). The commenter expressed the concern that churches that sponsor plans on behalf of numerous employers would not know whether any of those employers operated a health program or activity and received Federal financial assistance and thus would be required to either comply with Section 1557 requirements, even though most or all of the participating employers do not receive Federal financial assistance, or exclude the employer that receives Federal financial assistance from the plan.

Response: The comment reflects a misunderstanding about the application of § 92.208. This section of the regulation applies to employers, not to plan sponsors. In a church plan with multiple participating employers, the plan sponsor will be an entity other than the employer.[274] In this scenario, when an employer is covered under § 92.208(c) and the plan sponsor is a different entity that does not receive Federal financial assistance, it is the employer's obligation, not the plan sponsor's, to ensure that the benefits it provides to employees of its health program or activity do not violate Section 1557. We note that a plan sponsor will be separately covered under Section 1557 if it receives Federal financial assistance and is considered a covered entity under this rule.

Comment: One commenter expressed the view that treating a group health plan as an entity principally engaged in health coverage—and thereby subjecting all of its operations to Section 1557—undermines the limitations on employer liability under § 92.208. The commenter expressed concern that any employer that offers a self-insured group health plan to its employees would be accountable under Section 1557 for any discrimination by that group health plan.

Response: The commenter has misunderstood the relationship between the obligations of an employer and the application of the rule to a separate group health plan providing the employer's employee health benefit program. The fact that a group health plan is principally engaged in providing health services, health insurance coverage, or other health coverage, and therefore must comply with Section 1557 in all of its operations does not necessarily mean that an employer offering an employee health benefit program will be liable for a Section 1557 violation by the group health plan.[275] Employers will be liable under Section 1557 only under the circumstances set forth in 92.208.

Comment: Two commenters requested clarification of whether tax credits claimed by an employer that purchases health insurance coverage through the Small Business Health Options Program (SHOP) Marketplace[SM] and the health insurance plan purchased through a SHOP are covered by the rule.

Response: The tax credit to a small employer participating in the SHOP Marketplace[SM] is not considered Federal financial assistance from the Department under this rule because the tax credit is not administered by the Department.

Comment: Some comments suggested eliminating or drastically revising § 92.208 to make clear that all covered entities are covered in their provision of employee health benefits. One commenter suggested adding ''employee health benefits plan'' to the definition of ''health program or activity.'' Another asserted that § 92.208 is unnecessary because all group health plans are health programs or activities. One commenter recommended that OCR include in the regulatory text the substance of footnote 93 from the preamble of the proposed rule,[276] which clarifies that, regardless of whether an employer is liable for a discriminatory employee health benefit plan, an issuer that is a covered entity will be liable for discrimination in the health insurance coverage it offers to employers.

Response: We decline to eliminate or revise § 92.208 in the manner proposed by these commenters. As we explained in the preamble to the proposed rule,[277] absent the limitations in § 92.208, employers that receive Federal financial assistance for any purpose could be held liable for discrimination in the employee health benefits they provide or administer, even where those employers are not otherwise engaged in a health program or activity and where the use of Federal funds for employee health benefits is merely incidental to the purpose of the Federal assistance. We do not believe that Congress intended for Section 1557 to apply in such circumstances. We reiterate that issuers that receive Federal financial assistance and are principally engaged in providing or administering health services, health insurance coverage, or other health coverage are liable for the health insurance coverage offered to employers in connection with a group health plan.

Comment: Some commenters asked us to make clear that employer-provided benefits are covered by the rule even if the employer does not contribute to the cost of these benefits and the entire cost is borne by the employee or other beneficiary.

Response: The rule does not limit employer liability for discrimination in employee health benefit programs to those benefits for which the employer pays for part or all of the cost. Thus, if an employer would otherwise be liable for discrimination in an employee health benefit program, the fact that the employer did not pay for part of the cost of these benefits does not remove it from the reach of 92.208.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.208 with minor technical revisions to ensure consistency with other parts of the final rule by adding the words ''or other health coverage.''

Nondiscrimination on the Basis of Association (§ 92.209)

In § 92.209 of the proposed rule, we specifically addressed discrimination

[273] By contrast, with regard to the liability of the legal entity that an employer creates to administer its employee health benefit plan, *i.e.,* a group health plan, we proposed to analyze questions related to the application of Section 1557 on a case-by-case basis consistent with longstanding principles of nondiscrimination law. We will ask, for example, whether the group health plan itself receives Federal financial assistance, such as through receipt of Medicare Part D payments. If it does not, we will evaluate the group health plan's relationship with the employer in assessing whether Section 1557 applies to the group health plan. 80 FR at 54191 n. 94. We noted that a group health plan may be a covered entity under this rule if the group health plan receives Federal financial assistance, as it operates a health program or activity by virtue of its provision or administration of the employee health benefit program. 80 FR at 54191 n. 93.

[274] Under ERISA, when a group health plan is established or maintained by a single employer, the plan sponsor is the employer, but when a group health plan is established or maintained by two or more employers, the plan sponsor is the association, committee, joint board of trustees, or other similar group of representatives of the parties who establishes or maintains the plan. In the case of a plan established or maintained by an employee organization, the plan sponsor is the employee organization. 29 U.S.C. 1002(16)(B).

[275] However, under employment discrimination laws like TItle VII, the employer may be liable for the health plan's discrimination. *See, e.g., Los Angeles Dept. of Water and Power* v. *Manhart,* 435 U.S. 702 (1978).

[276] 80 FR at 54191 n. 93.

[277] *Id.*

faced by an individual or an entity on the basis of the race, color, national origin, age, disability, or sex of an individual with whom the individual or entity is known or is believed to have a relationship or association. We explained that the language of Section 1557 makes clear that individuals may not be subject to any form of discrimination ''on the grounds prohibited by'' Title VI and other civil rights laws; the statute does not restrict that prohibition to discrimination based on the individual's own race, color, national origin, age, disability or sex. Further, we noted that a prohibition on associational discrimination is consistent with longstanding interpretations of existing anti-discrimination laws, whether the basis of discrimination is a characteristic of the harmed individual or an individual who is associated with the harmed individual.[278] A prohibition on associational discrimination is also consistent with the approach taken in the ADA, which includes a specific prohibition of discrimination based on association with an individual with a disability.[279]

The comments and our responses regarding § 92.209 are set forth below.

Comment: A few commenters recommended that OCR add the words ''or deter'' to the prohibition on associational discrimination, so that § 92.209 would read as follows: ''A covered entity shall not exclude or deter from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, age, disability, or sex of an individual with whom the individual or entity is known or believed to have a relationship or association.''

Response: We believe the regulatory text, as it is currently written, encompasses this approach. It is well established in civil rights law that deterrence is a form of exclusion.[280]

Comment: Several comments recommended that the rule state that unlawful discrimination based on association occurs when a provider is subject to adverse treatment because the provider is known or believed to furnish, refer or support services that are medically appropriate for, ordinarily available to, or otherwise associated with a patient population protected by Section 1557.

Response: To clarify, the rule prohibits covered entities from discriminating against any individual or entity on the basis of a relationship or association with a member of a protected class. The term ''individual or entity'' includes providers. Thus, for example, an issuer covered by the rule may not use the fact that a provider's clientele is primarily composed of individuals with limited English proficiency to disqualify an otherwise eligible and qualified provider from participation in the issuer's network; such a decision would discriminate against the provider on the basis of the provider's association with a national origin group. We believe that the regulatory text encompasses this approach.

Comment: Commenters asked OCR to clarify whether § 92.209's prohibition of discrimination on the basis of association prohibits discrimination against individuals in same sex relationships.

Response: We will interpret the language of § 92.209 consistent with our interpretation of the term ''on the basis of sex,'' as described in § 92.4 above.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.209 as proposed without modification.

Subpart D—Procedures

Enforcement Mechanisms (§ 92.301)

In proposed § 92.301, we restated the language of Section 1557 regarding enforcement, which provides that the enforcement mechanisms under Title VI, Title IX, the Age Act, or Section 504 apply for violations of Section 1557. We noted that these existing enforcement mechanisms include requiring covered entities to keep records and submit compliance reports to OCR, conducting compliance reviews and complaint investigations, and providing technical assistance and guidance. We further noted that where noncompliance or threatened noncompliance cannot be corrected by informal means, the enforcement mechanisms provided for and available under the civil rights laws referenced in Section 1557 include suspension of, termination of, or refusal to grant or continue Federal financial assistance; referral to the Department of Justice with a recommendation to bring proceedings to enforce any rights of the United States; and any other means authorized by law.[281] In addition, we provided that based on the statutory language, a private right of action and damages for violations of Section 1557 are available to the same extent that such enforcement mechanisms are provided for and available under Title VI, Title IX, Section 504, or the Age Act with respect to recipients of Federal financial assistance. We further provided that a private right of action and damages are available for violations of Section 1557 by Title I entities. We invited comment on these positions.

The comments and our responses regarding § 92.301 are set forth below.

Comment: Many commenters requested that OCR clarify that all enforcement mechanisms available under the statutes listed in Section 1557 are available to each Section 1557 plaintiff, regardless of the plaintiff's protected class. Thus, for example, an individual could bring a race claim under the Age Act procedure and an age claim under the Title VI procedure.

Under this approach, given that the Age Act authorizes a private right of action for disparate impact claims, a private right of action would exist for disparate impact claims of discrimination on the basis of race, color, or national origin.

The commenters primarily rely on reasoning in *Rumble* v. *Fairview Health Services,*[282] in which the U.S. District Court for the District of Minnesota discussed the standards to be applied to Section 1557 private right of action claims and stated: ''It appears Congress intended to create a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of plaintiff's protected class status. Reading Section 1557 otherwise would lead to an illogical result, as different enforcement

[278] *See, e.g., McGinest* v. *GTE Service Corp.,* 360 F. 3d 1103, 1118 (9th Cir. 2004), cert. denied, 552 U.S. 1180 2008) (holding that harassment of white employee who associated with African American employees was discrimination under Title VII); *Tetro* v. *Elliot Popham Pontiac,Oldsmobile, Buick & GMC Trucks Inc.,* 173 F.3d 988, 993–96 (6th Cir. 1999) (holding that white plaintiff with biracial child stated a claim under Title VII based on his own race because Title VII protects victims of discriminatory animus towards third persons with whom one associates); *Parr* v. *Woodmen of the World Life Ins.,* 791 F.2d 888, 892 (11th Cir. 1986) (''Where a plaintiff claims discrimination based upon an interracial marriage or association, he alleges by definition that he has been discriminated against because of his race.'')

[279] 42 U.S.C. 12182(b)(1)(E)(Title III); 28 CFR 35.130(g) (Title II). *See generally http://www.eeoc.gov/facts/association_ada.html. Cf. Loeffler* v. *Staten Island Univ. Hosp.,* 582 F.3d 268, 277 (2d Cir. 2009) (permitting associational discrimination claim under Section 504); *Falls* v. *Prince George's Hosp. Ctr.,* No. Civ. A 97–1545, 1999 WL 33485550 at * 11 (D. Md. Mar. 16, 1999) (holding that parent had an associational discrimination claim under Section 504 when hospital required hearing parent to act as interpreter for child who was deaf). *Cf.* Questions and Answers About the Americans with Disabilities Act's Association Provision.

[280] *See* discussion of § 92.101(a) *supra.*

[281] See 45 CFR 80.8(a).

[282] No. 14–CV–2037 2015 WL 1197415 (D. Minn. Mar. 16, 2015).

mechanisms and standards would apply to a Section 1557 plaintiff depending on whether plaintiff's claim is based on her race, sex, age, or disability. For example, it would not make sense for a Section 1557 plaintiff claiming race discrimination to be barred from bringing a claim using a disparate impact theory but then allow a Section 1557 plaintiff alleging disability discrimination to do so.'' [283]

Similarly, many commenters requested that the regulation clarify that a private right of action exists for disparate impact claims, arguing, like commenters discussed above, that all enforcement mechanisms should be available to all Section 1557 complainants. A few commenters requested that the availability of a private right of action be addressed in the final rule itself, rather than in the preamble.

Response: OCR interprets Section 1557 as authorizing a private right of action for claims of disparate impact discrimination on the basis of any of the criteria enumerated in the legislation. At the same time, OCR is incorporating its existing procedures for its administrative processing of complaints; thus, we will use our current processes to address age discrimination on the one hand and race, color, national origin, sex, or disability on the other hand. This approach will enable us to be consistent in our processing of complaints under OCR's other authorities in instances where we have concurrent jurisdiction under Section 1557 and the other civil rights laws it references. This approach is not intended to limit the availability of judicial enforcement mechanisms. We note as well that both the proposed and the final rule specify that a private right of action is available under Section 1557.

Comment: A few commenters suggested that the text of the regulation specifically mention the availability of compensatory damages. Although OCR discussed the availability of compensatory damages in the preamble of the NPRM, commenters recommended that explicit authorization for compensatory damages in the regulation would strengthen the enforcement of Section 1557.

Response: OCR has added a provision to § 92.301 to make clear in the regulation that compensatory damages are available. Our interpretation of Section 1557 as authorizing compensatory damages is consistent with our interpretations of Title VI, Section 504, and Title IX.

[283] *Id.* at *11.

Comment: Many commenters requested that OCR involve the Department of Justice (DOJ) in all Section 1557 investigations and compliance reviews where DOJ has concurrent jurisdiction, and that OCR refer cases to DOJ for litigation, where appropriate.

Response: Although OCR recognizes the importance of working with DOJ and other agencies, it would not be a productive use of resources to include DOJ in every case in which it has concurrent jurisdiction. OCR has been enforcing Section 1557 since it became effective in 2010 and continues to investigate and resolve Section 1557 cases over which it has jurisdiction. OCR involves DOJ in investigations where appropriate and will continue to do so. And, as § 92.209 makes clear, OCR has the authority to refer cases to DOJ for litigation where efforts at compliance have been unsuccessful.

Comment: Some commenters recommended that HHS agreements with State agencies and State contracts with Medicaid managed care organizations include nondiscrimination provisions that obligate the State agencies to ensure compliance with nondiscrimination requirements.

Response: OCR agrees that nondiscrimination provisions in contracts help covered entities to ensure that contractors do not discriminate against program beneficiaries. Although this rule does not require such provisions in contracts, OCR has worked with HHS entities to include such language in their contracts in the past, and OCR will continue to look for opportunities to promote compliance with civil rights laws through nondiscrimination provisions in contracting in the future.

Comment: Several commenters recommended that the regulatory text specifically provide that OCR will conduct compliance reviews and perform outreach. These commenters expressed concern that individual complaint resolution, as an enforcement mechanism, will be inadequate to achieve widespread compliance with the Section 1557 final rule.

Response: We recognize the need for OCR to employ the full range of enforcement tools in order to ensure compliance with the law, and we intend to continue in our robust enforcement of Section 1557. We do not believe that any changes to regulatory text are necessary, since the rule contemplates and authorizes the suite of enforcement mechanisms that OCR has long employed.

Comment: Some commenters recommended that HHS, and not States, should be the primary enforcement agency for benefit design issues. These commenters asserted that State enforcement would lead to inconsistent results.

Response: OCR is responsible for enforcement with respect to benefit design issues under Section 1557. States have an important role in ensuring compliance with nondiscrimination requirements respecting insurance, including benefit design, under CMS regulations and applicable State laws. It is beyond the scope of this rulemaking to change State obligations under those laws.

Comment: Some commenters recommended that OCR be required to publish the outcomes of all resolved Section 1557 complaints and statistics regarding Section 1557 complaints received by OCR.

Response: We decline to accept this recommendation, but OCR will continue to include information and corrective action plans and resolution agreements on the OCR Web site.

Comment: Some commenters recommended that OCR allow at least a one-year period with no administrative sanctions if a covered entity can demonstrate good faith compliance. These commenters suggested that this approach will promote compliance while covered entities, OCR, and consumers become familiar with the requirements of the regulation.

Response: We appreciate the commenters' recommendation, but we decline to accept it because, while good faith is relevant under certain CMS regulations with which covered entities may be familiar, courts have not treated good faith as a consideration in assessing whether a covered entity is in compliance with the civil rights laws referenced in Section 1557. We are retaining this principle in interpreting whether a covered entity is in compliance with Section 1557. That said, OCR has the authority and discretion to consider a range of factors when reviewing cases and determining appropriate remedies, including consideration of steps taken by covered entities to ensure compliance with the law, compliance with other Federal regulations regarding the issue, timeframes for implementation of corrective action and resources to facilitate compliance.

Comment: Some commenters suggested that the final rule mandate training for employees of entities required to comply with the requirements of Section 1557.

Response: Although OCR encourages covered entities to train employees on compliance with Section 1557 periodically, OCR does not believe it is necessary for the final rule to mandate training. However, to facilitate training that covered entities choose to provide, we are preparing and will make available a training curriculum for their use in advance of the effective date of the rule. We also expect to engage in outreach and technical assistance to promote understanding of and compliance with the final rule.

Comment: Several commenters stated that the final rule should require OCR to perform unannounced, onsite reviews of covered entities to ensure compliance with Section 1557.

Response: While OCR may consider performing unannounced, onsite reviews where appropriate, OCR does not believe it is necessary to include a requirement to do so in the final rule.

Comment: Some commenters recommended that the regulation permit class actions and third party complaints in court. Other commenters recommended that the regulation provide for the availability of attorneys' fees in successful private suits. These commenters pointed out that many individuals who are subject to discrimination will be unable to afford a retainer for an attorney. Some commenters recommended that suits be allowed only in the State where the Marketplace℠ is located, not any Federal district court in a district in which a complainant resides.

Response: Although these issues are outside the scope of this regulation, nothing in Section 1557 changes the laws that otherwise would govern eligibility for attorneys' fees, including the Civil Rights Attorney's Fees Award Act of 1976,[284] laws that otherwise would govern venue,[285] or laws that otherwise would govern initiation of class action lawsuits.[286]

Comment: Some commenters suggested that the regulation prohibit issuers from including clauses requiring mandatory binding arbitration of Section 1557 complaints. These commenters asserted that such arbitration is unfair to consumers.

Response: We decline to accept the commenters' suggestion because it is outside the scope of this regulation.

Summary of Regulatory Changes

For the reasons set forth above and in the proposed rule and considering the comments received, we have revised § 92.301 to re-designate existing text as § 92.301(a) and add a new subsection (b) stating that compensatory damages for violations of Section 1557 are available in administrative and judicial actions, as they are under authorities referenced in Section 1557.

Procedures for Health Programs and Activities Conducted by Recipients and State-Based Marketplaces (§ 92.302)

In § 92.302, we proposed the procedures that will apply to enforcement of Section 1557 in health programs and activities conducted by recipients and State-based Marketplaces. We noted that the administrative procedures provided for and available under Title VI are found in the regulation implementing Title VI.[287] We explained that these administrative procedures are incorporated into the regulation implementing Title IX [288] and Section 504 with respect to recipients.[289] In paragraph (a), we proposed to incorporate these procedures into Section 1557 with respect to race, color, national origin, sex, and disability discrimination.

We also explained that the administrative procedures provided for and available under the Age Act are found in the regulation implementing the Age Act.[290] In paragraph (b), we proposed to incorporate these procedures into Section 1557 with respect to age discrimination.

In paragraph (c), we provided that an individual may bring a civil action in a United States District Court in which a recipient or State-based Marketplace℠ is located or does business, as provided for and available under Section 1557.

The comments and our responses regarding § 92.302 are set forth below.

Comment: A few commenters asserted that any enforcement provisions that apply to Health Insurance Marketplaces should apply whether the Marketplace℠ is operated by the State or Federal government.

Response: OCR declines to incorporate the commenter's request that Marketplaces operated by the Federal government be subject to the same enforcement provisions as Marketplaces operated by State governments. Under the regulations implementing Section 504, federally assisted programs, including federally assisted programs operated by States, and federally conducted programs are subject to separate enforcement procedures.[291] OCR believes that this approach has worked successfully in the past and has decided to retain separate procedures for federally conducted health programs and activities, including Health Insurance Marketplaces operated by HHS, and other health programs and activities, including Health Insurance Marketplaces operated by States.

Comment: Some commenters suggested that OCR use the enforcement scheme of Title VI for all discrimination under Section 1557. By contrast, some commenters recommended that the final rule should require mediation for all Section 1557 complaints. A few commenters requested that OCR require exhaustion of administrative remedies before individuals could pursue a private right of action.

Response: OCR declines to adopt these recommendations. OCR has decided to retain administrative procedures and application of the procedures consistent with OCR's existing procedures for complaints. Mediation and exhaustion of administrative remedies will still be required for age discrimination allegations in complaints, but not for allegations of other covered types of discrimination.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 92.302 with two modifications. As addressed previously in the discussion of the comments on § 92.5 (Assurances), the text that was previously found at § 92.302(c) has been moved to § 92.302(d), and § 92.302(c) now clarifies OCR's ability to initiate enforcement procedures where a recipient or State-based Marketplace℠ fails to provide OCR with requested information.

Procedures for Health Programs and Activities Administered by the Department (§ 92.303)

In the proposed rule, we noted that Section 1557 expressly states that the enforcement mechanisms provided for and available under Title VI, Title IX, Section 504, or the Age Act shall apply for purposes of violations of Section 1557. We also noted that the administrative procedures provided for and available under Section 504—the only one of these statutes that applies to federally conducted, as well as federally assisted, programs—for programs and activities administered by the

[284] 42 U.S.C. 1988.

[285] *See, e.g.,* 28 U.S.C. 1391.

[286] *See, e.g.,* 28 U.S.C. 1332.

[287] 45 CFR 80.6–.11; 45 CFR pt. 81.

[288] 45 CFR 86.71.

[289] 45 CFR 84.61.

[290] 45 CFR 91.41–.50.

[291] *Compare* 45 CFR 84.61 *with* 45 CFR 85.61–.62.

Department are found in the regulation implementing Section 504.[292] We provided that these procedures shall apply with respect to complaints and compliance reviews of health programs or activities administered by the Department, including the Federally-facilitated Marketplaces, concerning discrimination on the basis of race, color, national origin, sex, age, or disability.

In the proposed rule, we proposed to add two provisions that are not found in Section 504 enforcement procedures for programs conducted by the Department. We proposed that the first provision, which reflects OCR's practice under Section 504 and mirrors similar requirements under the Title VI regulation with regard to access to information, is designed to ensure that OCR has the ability to obtain all of the relevant information needed to investigate a complaint or determine compliance in a particular health program or activity administered by the Department.

We further proposed language prohibiting the Department, including Federally-facilitated Marketplaces, from retaliating against any individual for the purpose of interfering with any right or privilege under Section 1557 or the proposed rule or because the individual has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under Section 1557 or this proposed rule. We explained that Section 504 of the Rehabilitation Act, to which the Department is already subject, provides that the procedures, rights, and remedies under Title VI are available to any individual aggrieved by an act or failure to act by any recipient of Federal financial assistance or Federal provider of such financial assistance under Section 504. Thus, we noted that the prohibition on retaliation under Title VI[293] would apply to the Department under Section 504. We noted that the retaliation provision in the proposed rule is simply an extension of this existing prohibition. We further noted that this provision is also in accordance with a similar requirement for recipients under the Title VI regulations. The Department should hold itself to the same standards to which it holds recipients of Federal financial assistance.[294]

Summary of Regulatory Changes

We did not receive any significant comments regarding § 92.303. For the reasons set forth in the proposed rule, we are finalizing the provisions proposed in § 92.303 without modification.

Information Collection Requirements

The notice of proposed rulemaking called for new collections of information under the Paperwork Reduction Act of 1995.[295] As defined in implementing regulations,[296] ''collection of information'' comprises reporting, recordkeeping, monitoring, posting, labeling and other similar actions. In this section, we first identify and describe the entities that must collect the information, and then we provide an estimate of the total annual burden. The estimate covers the employees' time for reviewing and posting the collections required.

The final rule calls for the same collections of information as the notice of proposed rulemaking, with one addition: The cost estimates for covered entities to develop and implement a language access plan, should the covered entities choose to do so, given that development and implementation of a language access plan is one of the factors that the Director will consider, if relevant, in assessing whether a covered entity has met its obligation to take reasonable steps to provide meaningful access to each individual with limited English proficiency.

Title: Nondiscrimination in Health Programs and Activities.

OMB Control Number: XXXX–XXXX.

Summary of the Collection of Information: The final rule estimates four categories of information collection: (1) Submission of an assurance of compliance form, per § 92.5; (2) posting of a nondiscrimination notice and posting of taglines, under § 92.8; (3) development and implementation of a language access plan, anticipated per § 92.201; and (4) designation of a compliance coordinator and adoption of grievance procedures for covered entities with 15 or more employees, per § 92.7. Each category is described in the following analysis.

Under the final rule, each entity applying for Federal financial assistance, each health insurance issuer seeking certification to participate in a Marketplace℠, and each entity seeking approval to operate a Title I entity is required to submit an assurance that its health programs and activities will be operated in compliance with Section 1557.

In addition, each covered entity subject to the final rule is required to post a notice of individuals' civil rights and covered entities' obligations, including acknowledging that the covered entity provides auxiliary aids and services, free of charge, in a timely manner, to individuals with disabilities, when such aids and services are necessary to provide an individual with a disability an equal opportunity to benefit from the entity's health programs or activities; and language assistance services, free of charge, in a timely manner, to individuals with limited English proficiency, when those services are necessary to provide an individual with limited English proficiency meaningful access to a covered entity's health programs or activities. Furthermore, each covered entity is required to post taglines in the top 15 languages spoken by individuals with limited English proficiency by relevant State or States, informing individuals with limited English proficiency that language assistance services are available.

Although the final rule does not require covered entities to develop a language access plan, the development and implementation of a language access plan is one factor that the Director will consider when evaluating a covered entity's compliance with this rule. We anticipate that some proportion of covered entities will develop and implement a language access plan following issuance of the rule.

Additionally, each covered entity that employs 15 or more persons is required to adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557. Each covered entity is also required to designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557.

Need for Information: The requirement that every entity applying for Federal financial assistance, seeking certification to participate in a Health Insurance Marketplace℠, or seeking approval to operate a Title I entity, submit an assurance of compliance, is similar to the current regulatory

[292] 45 CFR 85.61–.62.

[293] 45 CFR 80.7(e).

[294] Further, as the U.S. Supreme Court observed in *Jackson* v. *Birmingham Bd. of Educ.,* 544 U.S. 167, 180 (2005), protecting individuals from discrimination under Title IX ''would be difficult, if not impossible, to achieve if persons who complain about sex discrimination did not have effective protection against retaliation.'' (citing to the brief of the United States as Amicus Curiae). The same principle is true for discrimination under Section 1557.

[295] 44 U.S.C. 3501–3520.

[296] 5 CFR 1320.3(c).

requirements under Title VI,[297] Section 504,[298] and the Age Act.[299] These requirements protect individuals by assuring that covered entities will comply with all applicable nondiscrimination statutes and their implementing regulations.

The posting of a notice of individuals' rights and covered entities' obligations and the posting of taglines in the top 15 languages spoken by individuals with limited English proficiency by relevant State or States are necessary to ensure that individuals are aware of their protections under the law, and are grounded in OCR's experience that failures of communication based on the absence of auxiliary aids and services and language assistance services raise particularly significant compliance concerns under Section 1557, as well as Section 504 and Title VI.

The development and implementation of a language access plan helps ensure meaningful access to persons with limited English proficiency to a covered entity's health programs and activities. While Title VI has long required covered entities to take reasonable steps to provide persons with limited English proficiency meaningful access, the addition of a language access plan brings specificity and increased probability of implementation of the requirement. Although the final rule does not require development and implementation of a language access plan, covered entities may choose to develop and implement a language access plan because the Director will consider, if relevant, the language access plan as one factor when assessing a covered entity's compliance with this rule.

The requirements that every covered entity that employs 15 or more persons adopt grievance procedures and designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 are similar to requirements included in the Title IX and Section 504 implementing regulations. Through its case investigation experience, OCR has observed that the presence of a coordinator and grievance procedures helps to bring concerns to prompt resolution within an entity, leading to lower compliance costs and more efficient outcomes.

Use of Information: OCR will use this information to ensure covered entities' adherence to the statutory requirements imposed under Section 1557 and this final rule. OCR will enforce the requirements by verifying during investigations of covered entities that an entity has submitted an assurance of compliance and posted the notice and taglines and, for each covered entity that employs 15 or more persons, that an individual has been designated to coordinate its compliance efforts and that appropriate grievance procedures have been adopted, as required.

Description of the Respondents: The respondents are: the Department, each entity that operates a health program or activity, any part of which receives Federal financial assistance, and each entity established under Title I of the ACA that administers a health program or activity. These include such entities as hospitals, home health agencies, community mental health centers, skilled nursing facilities, and health insurance issuers.

Number of Respondents: The number of respondents is estimated to include the 275,002 covered entities affected by the final rule.

Burden of Response: Because the Department provides the assurance of compliance and the final rule provides a sample Notice, sample taglines in 64 languages, and sample grievance procedures, the burden on respondents is minimal. Additionally, because all recipients of Federal financial assistance with 15 or more employees are already expected under other laws to have in place grievance procedures and a designated individual to coordinate their compliance responsibilities, the burden to comply with this requirement will be minimal for most respondents.

The requirement to sign and submit an assurance of compliance exists under other civil rights regulations (Title VI, Section 504, Title IX, the Age Act), and since the Department provides a copy of the Assurance of Compliance form to covered entities, OCR believes this requirement adds no extra burden. OCR believes that the time, effort, and financial resources necessary to comply with this requirement are considered part of the usual and customary business practice and would be incurred by covered entities during their ordinary course of business.

OCR estimates that the burden for responding to the proposed notice requirement is an average of 17 minutes to download and post the notice and that the burden to download and post taglines in the top 15 languages by relevant State or States is also an average of 17 minutes, for a burden total of 34 minutes on average at each of the 405,534 affected establishments (associated with the affected covered entities) in the first year following publication of the final rule. (See Regulatory Impact Analysis, II. Costs, B.2.for a more detailed explanation of the differences between ''firm'' and ''establishment.'') We estimate that administrative or clerical support personnel would perform these functions. Based on the wage rate for a Clerical Support Worker ($15.52) we estimate the annual burden for these two requirements to be approximately $7.1 million after adjusting for overhead and benefits by adjusting the wage rate upward by 100%.

OCR estimates that the burden for developing a language access plan is approximately three hours of medical and health service manager staff time in the first year, and an average of one hour of medical and health service manager staff time per year to update the plan in subsequent years. The value of an hour of time for people in this occupation category, after adjusting for overhead and benefits, is estimated to be $89.24 based on Bureau of Labor Statistics (BLS) data. As discussed later in this analysis, we estimate that approximately 135,000 entities will develop and implement language access plans, as part of the requirement to take reasonable steps to provide meaningful communication with persons with limited English proficiency. These assumptions imply that the total cost of the development of language access plans will be approximately $36.0 million (269,141 entities × 50% of entities × 3 hours per entity × $89.24 per hour) in the first year and approximately $12.0 million (269,141 entities × 50% of entities × 1 hour per entity × $89.24 per hour) per year in subsequent years.

Regarding the requirement that every covered entity that employs 15 or more persons adopt grievance procedures and designate at least one individual to coordinate its efforts to comply with and carry out its responsibilities under Section 1557, based on OCR's complaint workload increase since the enactment of Section 1557, we anticipate that within the first five years following the rule's enactment, complaints will increase approximately 0.5% in the first year, 0.75% in the second year, and 1% in years three through five, but eventually will drop off as covered entities modify their policies and practices in response to this final rule. We estimate that medical and health service managers will handle the grievances, and that a 1% increase in complaints will require 1% of an FTE at each covered entity. Using the annual wage rate for medical and health service managers ($103,680), adjusting for fringe benefits and overhead, and multiplying by the 41,250 entities

[297] 45 CFR 80.4(a).

[298] 45 CFR 80.5.

[299] 45 CFR 91.33.

affected by this requirement, we estimate the annual burden for this requirement to be approximately $42.8 million in year one, $64.2 million in year two, and $85.5 million for each year in years three, four, and five following publication.

Thus, the total estimated annual burden cost for the proposed information collection requirements will be approximately $86.0 million in the first year, $76.2 million in the second year, and $97.5 million per year in years three through five following publication of the final rule.

We asked for public comment on the proposed information collection to help us determine:

1. Whether the proposed collection of information is necessary for the proper performance of the functions of OCR, including whether the information will have practical utility;
2. The accuracy of the estimated burden associated with the proposed collection of information;
3. How the quality, utility, and clarity of the information to be collected may be enhanced; and
4. How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology.

We received no comments with specific data in response to numbers one, two, or three above. With regard to question four, we received comments asking that the proposed collection of information be minimized and stating that it is burdensome for covered entities to develop notices to put in several locations in all their facilities. OCR responded by proposing that OCR develop a model notice of important information and model taglines, to minimize the burden on covered entities. The new cost analysis is included above, in this Information Collection section, as well as in the Regulatory Impact Analysis.

Regulatory Impact Analysis

I. Introduction

A. Executive Orders 12866 and 13563

Executive Order 12866 [300] directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 [301] is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. OMB has determined that this final rule is a ''significant regulatory action'' under Executive Order 12866. Accordingly, OMB reviewed this final rule.

In general, we received few comments with regard to the Regulatory Impact Analysis (RIA), and thus the analysis in the final rule remains fairly similar to the proposed rule, although there are some changes. The comments will be addressed in each section below, as appropriate.

B. The Need for a Regulation

Section 1557 of the ACA prohibits an individual from being excluded from participation in, denied the benefits of, or otherwise subjected to discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. It applies to any health program or activity, any part of which is receiving Federal financial assistance, and to any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA.[302] The Secretary of the Department is authorized to promulgate regulations to implement Section 1557 under the statute and 5 U.S.C. 301. The purpose of this regulatory action is to implement Section 1557 of the ACA.[303]

One of the central aims of the ACA is to expand access to health care and health coverage for all individuals. Equal access for all individuals without discrimination is essential to achieving this goal. Discrimination in the health care context can often lead to poor and inadequate health care or health insurance or other coverage for individuals and exacerbate existing health disparities in underserved communities. Individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care; individuals who are subject to discrimination are denied opportunities to obtain health care services provided to others, with resulting adverse effects on their health status. Moreover, discrimination in health care can lead to poor and ineffective distribution of health care resources, as needed resources fail to reach many who need them. The result is a marketplace comprised of higher medical costs due to delayed treatment, lost wages, lost productivity, and the misuse of people's talent and energy.[304]

We received comments suggesting that we consider either writing a more informative than prescriptive regulation or delaying the regulation. The Department's current experience, however, points to the importance of a regulation that is prescriptive in the sense that it provides concrete guidance. The Department continues to receive many complaints of discrimination and continues to provide technical assistance and outreach in order to promote compliance. In addition, the majority of the comments from the public in response to the proposed rule favored speedy issuance of a strong regulation.

To help address the issues of nondiscrimination in health programs and activities, this regulation seeks to clarify the application of the nondiscrimination provision in the ACA to any health program or activity receiving Federal financial assistance from or administered by HHS or any entity established under Title I. Such clarity will promote understanding of and compliance with Section 1557 by covered entities and the ability of individuals to assert and protect their rights under the law.

In addition, Executive Order 13563 directs Federal agencies to improve regulations and regulatory review by promoting the simplification and harmonization of regulations and to ensure that regulations are accessible, consistent, and easy to understand. Regulations implementing the civil rights laws referenced in Section 1557 contain certain inconsistencies across common areas and subject matters, reflecting, among other things, differences in time and experience when the regulations were issued. The regulation attempts to harmonize these variations where possible.

We received comments asking that the regulation be written in plain language. The approach we adopt in the final rule is to simplify and make uniform, consistent, and easy to understand the various nondiscrimination requirements

[300] Exec. Order No. 12866, 58 FR 51735 (1993).

[301] Exec. Order No. 13563, 76 FR 3821 (2011).

[302] Patient Protection and Affordable Care Act, Public Law 111–148, 1557, 124 Stat. 119, 260, (2010) (codified at 42 U.S.C. 18116).

[303] 42 U.S.C. 18116(c).

[304] Kristen Suthers, American Public Health Association: Issue Brief: Evaluating the Economic Causes and Consequences of Racial and Health Disparities (2008), *http://hospitals.unm.edu/dei/documents/eval_cause_conse_apha.pdf;* Timothy Waldmann, Urban Institute, Estimating the Cost of Racial and Ethnic Health Disparities (2009), *http://www.urban.org/sites/default/files/alfresco/publication-pdfs/411962-Estimating-the-Cost-of-Racial-and-Ethnic-Health-Disparities.PDF;* LaVera M. Crawley, David K. Ahn, and Marilyn A. Winkleby, Perceived Medical Discrimination and Cancer Screening Behaviors of Racial and Ethnic Minority Adults, 17(8), Cancer Epidemiol Biomarkers Prev., 1937–1944 (2008), *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2526181/.*

and rights available under Section 1557, as appropriate.

The analysis that follows is similar to the analysis set forth in the proposed rule, except as specified in each of the sections that follow.

C. Examples of Covered Entities and Health Programs or Activities Under the Final Regulation

This final rule applies to any entity that has a health program or activity, any part of which receives Federal financial assistance from the Department, any health program or activity administered by the Department, or any health program or activity administered by an entity created under Title I of the ACA. The following are examples of covered entities as well as health programs or activities under the final rule.

1. Examples of Covered Entities With a Health Program or Activity, Any Part of Which Receives Federal Financial Assistance From the Department

This Department, through agencies such as the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS), provides Federal financial assistance through various mechanisms to health programs and activities of local governments, State governments, and the private sector. An entity may receive Federal financial assistance from more than one component in the Department. For instance, federally qualified health centers receive Federal financial assistance from CMS by participating in the Medicare or Medicaid programs and also receive Federal financial assistance from HRSA through grant awards. Because more than one funding stream may provide Federal financial assistance to an entity, the examples we provide may not uniquely receive Federal financial assistance from only one HHS component.

(1) Entities receiving Federal financial assistance through their participation in Medicare (excluding Medicare Part B) or Medicaid (about 133,343 facilities).[305] Examples of these entities include:

Hospitals (includes short-term, rehabilitation, psychiatric, and long-term)
Skilled nursing facilities/nursing facilities—facility-based
Skilled nursing facilities/nursing facilities—freestanding
Home health agencies
Physical therapy/speech pathology programs
End stage renal disease dialysis centers
Intermediate care facilities for individuals with intellectual disabilities
Rural health clinics
Physical therapy—independent practice
Comprehensive outpatient rehabilitation facilities
Ambulatory surgical centers
Hospices
Organ procurement organizations
Community mental health centers
Federally qualified health centers

(2) Laboratories that are hospital-based, office-based, or freestanding that receive Federal financial assistance through Medicaid payments for covered laboratory tests (about 445,657 laboratories with Clinical Laboratory Improvement Act certification).

(3) Community health centers receiving Federal financial assistance through grant awards from HRSA (1,300 community health centers).[306]

(4) Health-related schools in the United States and other health education entities receiving Federal financial assistance through grant awards to support 40 health professional training programs that include oral health, behavioral health, medicine, geriatric, and physician's assistant programs.[307]

(5) State Medicaid agencies receiving Federal financial assistance from CMS to operate CHIP (includes every State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(6) State public health agencies receiving Federal financial assistance from CDC, SAMHSA, and other HHS components (includes each State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(7) Qualified health plan issuers receiving Federal financial assistance through advance payments of premium tax credits and cost-sharing reductions (which include at least the 169 health insurance issuers in the Federally-facilitated Marketplaces receiving Federal financial assistance through advance payments of premium tax credits and cost sharing reductions and at least 11 issuers operating in the State-Based Marketplaces that we were able to identify).[308]

(8) Physicians receiving Federal financial assistance through Medicaid payments, ''meaningful use'' payments, and other sources, but not Medicare Part B payments, as the Department does not consider Medicare Part B payments to physicians to be Federal financial assistance. The Medicare Access and CHIP Reauthorization Act amended Section 1848 of the Act to sunset ''meaningful use'' payment adjustments for Medicare physicians after the 2018 payment adjustment.

In the proposed rule, we estimated that the regulation would likely cover almost all licensed physicians because they accept Federal financial assistance from sources other than Medicare Part B. We noted that most physicians participate in more than one Federal, State, or local health program that receives Federal financial assistance, and many practice in several different settings, *e.g.,* they may practice in a hospital but also practice privately and develop nursing home plans of care at the local nursing home. We noted that although we have data, by program, for the number of physicians receiving payment from each program, there is no single, unduplicated count of physicians across multiple programs.[309]

In the proposed rule, we provided our best estimate of the number of physicians receiving Federal financial assistance by analyzing and comparing different data sources and drawing conclusions from this analysis. We noted that, based on 2010 Medicaid Statistical Information System data, about 614,000 physicians accept Medicaid payments and are covered under Section 1557 as a result.[310] This figure represents about 72% of licensed physicians in the United States when compared to the 850,000 in 2010.[311] In addition, we noted that physicians receiving Federal payments from non-Part B Medicare sources would also come under Section 1557.[312]

Earlier, before issuing the proposed rule, we identified several grant programs from various Department

[305] U.S. Dep't of Health & Human Servs., Center for Medicare & Medicaid Servs., CMS Provider of Service file, June 2014, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/ProviderofServicesFile.html.*

[306] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, *http://www.hrsa.gov/about/budget/budgetjustification2016.pdf.*

[307] *Id.* at 69.

[308] Qualified Health Plans Landscape Individual Market Medical, Data.HealthCare.gov (2015), *https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7* (last visited May 3, 2016).

[309] 80 FR at 54195.

[310] John Holahan and Irene Headen, Kaiser Commission on Medicaid and the Uninsured, Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL (2010), *http://kff.org/health-reform/report/report-and-briefing-on-medicaid-coverage-and/.* Estimates are based on data from FY 2010 Medicaid Statistical Information System.

[311] Aaron Young, Humayun J. Chaudhry, Jon V. Thomas, & Michael Dugan, *A Census of Actively Licensed Physicians in the United States, 2012,* 99 no.2 J. Med. Reg. 11 (2013), *https://www.fsmb.org/Media/Default/PDF/Census/census.pdf.*

[312] 80 FR at 54195.

agencies that fund a variety of health programs in which physicians participate and thus come under Section 1557, such as the National Health Service Corps, HRSA-funded community health centers, programs receiving National Institutes of Health (NIH) research grants, and SAMHSA-funded programs. In the proposed rule, we noted that physicians participating in a CMS gain-sharing demonstration project who receive gain-sharing payments would be covered under Section 1557 even if they did not participate in Medicare and Medicaid or any other health program or activity that receives Federal financial assistance. We also noted that there will be duplication and overlap with physicians who accept Medicaid or Medicare meaningful use payments, or other payments apart from Medicare Part B payments. Nevertheless, we noted that at least some of these physicians add to the total number of physicians reached under Section 1557 because some of them are not duplicates and do not accept Medicaid or Medicare meaningful use payments. We noted that although we do not have an exact number, adding these physicians may bring the total participating in Federal programs other than Medicare Part B to over 900,000.

In the proposed rule, when we compared the upper bound estimated number of physicians participating in Federal programs other than Medicare Part B (over 900,000) to the number of licensed physicians counted in HRSA's Area Health Resource File (approximately 890,000), we concluded that almost all practicing physicians in the United States are reached by Section 1557 because they accept some form of Federal remuneration or reimbursement apart from Medicare Part B.[313]

We invited the public to submit information regarding physician participation in health programs and activities that receive Federal financial assistance. We received no comments that would change the estimates that we provided; thus, the analysis in this final rule includes the same numbers of physicians as in the proposed rule.

2. Examples of Health Programs or Activities Conducted by the Department

This final rule applies to the Department's health programs and activities, such as those administered by CMS, HRSA, CDC, Indian Health Service (IHS), and SAMHSA. Examples include the IHS tribal hospitals and clinics operated by the Department and the National Health Service Corps.

3. Examples of Entities Established Under Title I of the ACA

This final rule applies to entities established under Title I of the ACA. According to the CMS Center for Consumer Information and Insurance Oversight (CCIIO), there are Health Insurance Marketplaces covering 51 jurisdictions: (17 State-based-Marketplaces and 34 Federally-facilitated Marketplaces). The final rule covers these Health Insurance Marketplaces.

II. Costs

It is important to recognize that this final rule, except in the area of sex discrimination, applies pre-existing requirements in Federal civil rights laws to various entities, the great majority of which have been covered by these requirements for years. Because Section 1557 restates existing requirements, we do not anticipate that covered entities will undertake new actions or bear any additional costs in response to the issuance of the regulation with respect to the prohibition of race, color, national origin, age, or disability discrimination, except with respect to the voluntary development of a language access plan. However, we also note that the prohibition of sex discrimination is new for many covered entities, and we anticipate that the enactment of the regulation will result in changes in action and behavior by covered entities to comply with this new prohibition. We note that some of these actions will impose costs and others will not.

Section 1557 applies to the Health Insurance Marketplaces. We note that these entities, along with the qualified health plan issuers participating in the Health Insurance Marketplaces, are already covered by regulations issued by CMS that prohibit discrimination on the basis of race, color, national origin, sex, gender identity, sexual orientation, age, or disability. Thus, we note that the impact of Section 1557 on these entities is limited.

We received a few comments that indicated that the costs of compliance may be more than anticipated in the proposed rule. We have revised the analysis in this final rule based upon the comments and upon an updated statistical review of the health programs and activities.

The following regulatory analysis examines the costs and benefits that are attributable to this regulation only.

We first analyze the costs we expect the final rule to create for covered entities. We anticipate that the final rule will place costs on the covered entities in the areas of: (1) Training and familiarization, (2) enforcement, (3) posting of the nondiscrimination notice and taglines, and (4) revisions in policies and procedures, and may place costs on covered entities in the voluntary area of development of a language access plan. Then we examine the potential benefits the rule is likely to produce. In the subsequent analyses of costs in this RIA and the Regulatory Flexibility Act (RFA), we use data sets from the Census Bureau[314] and BLS[315] for estimating burdens.

A. Assumptions

In the proposed rule, we made the following cost assessment based on certain key assumptions, which include: (1) We assume that promulgation of this regulation will trigger voluntary activity on the part of covered entities that would not have occurred absent the promulgation of the regulation—which generates both costs and corresponding benefits; (2) to the extent that certain actions are required under the final rule where the same actions are already required by prior existing civil rights regulations, we assume that the actions are already taking place and thus that they are not a burden imposed by the rule; (3) although the regulation does not require training at any specific time, we assume that covered entities may voluntarily provide one-time training to some employees on the requirements of the regulation at the time that the regulation is published; and (4) we assume that employers are most likely to train employees who interact with the public and will therefore likely train between 40% and 60% of their employees, as the percentage of employees that interact with patients and the public varies by covered entity. For purposes of the analysis, we assume that 50% of the covered entity's staff will receive one-time training on the requirements of the regulation. We use the 50% estimate as a proxy, given the lack of certain information as described below. For the purposes of the analysis, we do not distinguish between employees whom covered entities will train and those who obtain training independently of a covered entity.

B. Training and Familiarization

In the proposed rule, we counted the cost of training on all aspects of the

[313] The Area Health Resource File itself double counts physicians who are licensed in more than one state. *See infra* discussion below at II.C.1.a.

[314] U.S. Census Bureau, Statistics of U.S. Businesses, *http://www.census.gov/econ/susb/* (last visited May 3, 2016).

[315] U.S. Dep't of Labor, Bureau of Labor Statistics, May 2015 National Occupational Employment and Wage Estimates, *http://www.bls.gov/oes/2014/may/oes_nat.htm (last visited May 3, 2016).*

regulation, not only on the new responsibilities under the regulation, as we believe covered entities will want to offer comprehensive training to employees, recognizing that refresher training can provide value. We invited comment on whether we should count only the cost of training on new responsibilities under the regulation. The comments we received supported our assumption regarding training on all aspects of the regulation, and therefore the final rule keeps this assumption.

In the proposed rule, we also assumed that covered entities will provide some workers (not all workers) a one-time awareness or familiarization training regarding the requirements in the regulation at the time of its issuance. We noted that many employees may work ''behind the scenes'' at large entities, and may not have contact with patients or the general public or otherwise have duties impacted by the final rule's requirements and therefore may have little need for training. However, we noted that we are uncertain which employees those are. Furthermore, we noted that we do not know whether an entity rotates employees into different positions that may have patient contact or relevant duties, or whether, over time, an employee will switch to a position that places him or her in such a position, which may create a need for training. Although we received one comment suggesting that we include all employees in the training, the comment did not provide evidence or data to support including all employees. Otherwise, we received no comments to the contrary; therefore, the final rule makes the same assumption that the proposed rule did, that covered entities will provide some (not all) workers a one-time familiarization training.

In the proposed rule, we also noted that we lack information on State and local regulations that may require employees to receive training on civil rights provisions and whether those provisions are more or less rigorous than the ones we propose. Thus, workers in covered entities in State and local jurisdictions with civil rights provisions more robust than the ones we propose may need only minimal training. In State and local jurisdictions where civil rights provisions are not more robust, workers may need more training. As stated above, because we lack data on covered entities' training practices, we are assuming that covered entities will voluntarily provide training on the final rule for between 40% and 60% of their staffs. Further analysis of state requirements revealed that the states do vary in the robustness of their civil rights requirements, as we assumed in the proposed rule. Therefore, we chose 50% of the employees, the average between 40% and 60%.

Based on comments we received, we added a category of training, for a one-time familiarization by a manager, after the final rule has been published. The manager will need to study and understand the regulation well enough to make assessments of how the entity will promote compliance with the rule, including assessing the training needs of the staff and the costs associated with the training.

In the following section, we identify the pool of workers and staff that we anticipate may need education about the final rule. Next, we identify the covered entities that may choose to train their staffs to provide this knowledge. Last, we estimate the costs of the training materials and the worker time that will be spent in training.

1. Number of Individuals Who Will Receive Training

a. Health Care Staffs and Managers

The first category of health care staff that may receive training is comprised of health diagnosing and treating practitioners. This category includes physicians, dentists, optometrists, physician assistants, occupational, physical, speech and other therapists, audiologists, pharmacists, registered nurses, and nurse practitioners. The BLS occupational code for this grouping is 29–1000 and the 2014 reported count for this occupational group is approximately 4.8 million.

The second category of health care staff that we assume will receive training is comprised of degreed technical staff (Occupation code 29–2000) and accounts for 2.9 million workers. Technicians work in almost every area of health care: From x-ray to physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of health care staff that we assume will receive training is comprised of non-degreed medical assistants (Occupation code 31–0000), and includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Health care support staffs (technical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates. We refer to this workforce as non-degreed compared to medical technicians who generally have degrees or certificates. There are approximately 3.9 million individuals employed in these occupations.

The fourth category of health care staff that we assume will receive training is health care managers (approximately 0.3 million based on BLS data for occupation code 11–9111). Because we assess costs of familiarization with the regulation for one manager at each entity, we assume that those managers will have already become familiar with the regulation and will not need additional training.

The fifth category of health care staff that we assume will receive training is office and administrative assistants—Office and Administrative Support Occupation (Occupation code 43–0000). These workers are often the first staff patients encounter in a health facility and, because of this, covered entities might find it important that staff, such as receptionists and assistants, receive training on the regulatory requirements. Approximately 2.7 million individuals were employed in these occupations in health facilities in 2014.[316]

One comment asked that outreach workers be explicitly included as a category to be trained. We assume that outreach workers are included in the five categories listed above, especially in the manager category.

Below is a summary table of individuals employed in the health care sector.

TABLE 1—HEALTH CARE EMPLOYEES WHO MAY NEED TRAINING

Health diagnosing and treating practitioners	4,833,840
Degreed technicians	2,876,000
Non-degreed technicians	3,940,500
Medical and health services managers	310,320
Office and administrative support staff	2,747,330
Total	14,707,990

b. Employees Working for the Federally-Facilitated Marketplaces and State-Based Marketplaces and Issuers in Those Marketplaces

We have data from CMS/CCIIO on the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces.[317] We assume that many issuers that operate in the Federally-facilitated Marketplaces also operate in the State-based Marketplaces. However, to the extent there are issuers who operate in a State-based Marketplace[SM]

[316] U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates, United States, *http://www.bls.gov/oes/2014/may/oes_nat.htm* (last visited May 3, 2016). This code includes health care sector data for health care and social assistance (including private, State and local government hospitals).

[317] Qualified Health Plans Landscape Individual Market Medical (2015), *supra* note 308.

only, an estimate of their employees will not be included in our count of issuers (derived from the CCIIO tables of issuers participating only in the 34 jurisdictions with Federally-facilitated Marketplaces). We are basing our calculations on the number of employees working for those issuers participating in the Federally-facilitated Marketplaces and we assume, as noted above, that some of the same issuers and employees serve the State-based Marketplaces. Determining the number of employees working for issuers participating in the Health Insurance Marketplaces is challenging because we have no data directly linking the number of employees to our data on participating issuers in the Federally-facilitated Marketplaces. Consequently, we must impute the number of employees working for issuers participating in the Federally-facilitated Marketplaces and, by extension, employees working for issuers in State-based Marketplaces.

We performed this imputation by first identifying the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces. To determine the number of issuers offering qualified health plans in the Federally-facilitated Marketplaces, we looked at the 2015 Qualified Health Plan Landscape Individual and Small Business Health Options Program Market Medical files.[318] The Qualified Health Plan Landscape Individual Market Medical file contains over 100,000 line items, and the Small Business Health Options Program Market Medical file contains over 50,000 line items listing each Federally-facilitated Marketplace[SM] plan for each county by metal level (bronze, silver, gold, and platinum) and catastrophic plans provided by each issuer. To determine the number of issuers in the individual and Small Business Health Options Program Marketplaces, we removed all plan line items to reduce the count to an unduplicated count of the issuers in the Federally-facilitated Marketplaces. We identified 155 individual plan issuers and 14 issuers in the Small Business Health Options Program that only issued group plans to employees of employers participating in the Small Business Health Options Program. Our total count of 169 issuers differs from the CCIIO sources, which counted issuers in each State in which they operated. For example, a national issuer such as Aetna that offers coverage through Federally-facilitated Marketplaces operating in several States was counted separately by CCIIO for each State in which it was qualified, whereas we counted it only once.[319]

In addition to 169 issuers participating in Federally-facilitated Marketplaces, we are aware of 11 issuers participating only in the State-based Marketplaces. Thus, we calculated that the total number of issuers included in the analysis of covered issuers equals 180.

We next analyzed the number of employees working in the health insurance industry in the following way. Using Census Bureau 2011 payroll and employment data (the latest data available) for North American Industry Classification System 524114—Direct Health Insurance,[320] we attempted to match the number of employees to the health insurance entities. The Census data permitted us to divide all health insurance issuers into ''large'' (500 or more employees) and ''small'' (fewer than 500 employees) issuers, and from that we were able to estimate the number of employees for large and small issuers.

The Census data shows 805 small issuers and 180 large issuers. The ratio of small to large issuers is about 4.5 small issuers for every large issuer. We assume the ratio of small to large issuers in the Health Insurance Marketplaces is approximately the same as the ratio in the Census table. We asked for public comment on this assumption, and we received no comments to the contrary.

Applying this ratio to the issuers in the Federally-facilitated Marketplaces, we get 131 small issuers and 38 large issuers. We assume that the 11 issuers (for which we have data and have thus identified) operating in the State-based Marketplaces are likely to be classified as small, based on Census workforce data. Therefore, we are adding them to the 131 small issuers identified above, bringing the total number of small issuers to 142.

Based on the Census data, the average number of employees in a small issuer is 34 and the average number of employees in a large issuer is 2,300. If we multiply the number of issuers by the number of employees, there are 4,828 employees of the 142 small issuers and 87,400 employees of the 38 large issuers. The combined total number of employees for small and large issuers in the Marketplaces is estimated to be 92,228 employees.

With respect to the majority of issuers operating in a State-based Marketplace[SM] that we have not been able to identify but would also be subject to the regulation, we do not have any direct data. However, the workforce data we have from the Census tables covers employees regardless of their work site. If any of the 169 issuers identified above operating in the Federally-facilitated Marketplaces also operate in the State-based Marketplaces, then some portion of the nearly 92,000 employees imputed to be working for the issuers in the Federally-facilitated Marketplaces may also be working for issuers operating in the State-based Marketplaces. Thus, in effect, we are including employees working for issuers that operate in both the State-based Marketplaces and the Federally-facilitated Marketplaces in our count of employees who likely will receive training on the regulation.

At the same time that we include employees who work for issuers operating in both the Federally-facilitated Marketplaces and State-based Marketplaces, we lack direct data on issuers participating only in State-based Marketplaces. We are not able to include employees that work for insurance issuers that operate only in State-based Marketplaces, such as New York or California, which would be subject to the proposed rule. We invited public comment on ways we could identify issuers that participate only in State-based Marketplaces and the number of employees they employ. We did not receive any comments that identified ways we can better identify these issuers.

A third category of workers who may need to be trained are navigators receiving Federal financial assistance to support the functions they perform in Federally-facilitated Marketplaces, such as assisting applicants to enroll in qualified health plans through the Marketplace[SM]. CMS has awarded grant funding to 100 Navigator entities.[321] In the proposed rule, we estimated that 2,797 navigators worked for 92 Navigator entities, which implies 30.4 employees per entity. We lacked data on the number of employees of these Navigator entities, and we thus applied the previous estimate of 30.4 employees per Navigator entity to estimate in the

[318] *Id.*

[319] We count the issuer only once because we assume the same enterprise will minimize training costs by preparing the same training materials for all its employees nationally.

[320] U.S. Census Bureau, Statistics of U.S. Businesses (SUSB) (2011), *http://www.census.gov/econ/susb/.*

[321] CMS awards $67 million in Affordable Care Act funding to help consumers sign-up for affordable Health Insurance Marketplace[SM] coverage in 2016, *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-09-02.html* (last visited May 3, 2016).

final rule that 3,040 employees work for these entities.

We invited public comment on our approach to estimating the number of employees per issuer based on the Census data and sought any public information on issuers who operate only in State-based Marketplaces. We did not receive comments that changed our assumptions regarding types and numbers of employees working for Marketplaces. Thus, the final rule applies the estimate of the number of navigators per Navigator entity to the most recent number of Navigator grantees.

c. Medicaid and State and Local Health Department Employees

The Census Bureau State government payroll and employment data for 2012 shows the number of full-time employees working in State hospitals and departments of health as 531,251.[322] The State Medicaid Operations Survey: Fourth Annual Survey of Medicaid Directors reports that State Medicaid agencies employed between 27 and 3,853 full-time employees with a median workforce level of 455 employees.[323] Multiplying the median level of workers by 56 Medicaid agencies adds 25,480 workers to the number of State health and hospital workers in health departments, bringing the total to 556,731 employees. (Although a more appropriate method of calculating the total would be to use the mean as the multiplier, OCR used the median because the mean was unavailable.) However, this number double counts medical personnel that were previously counted as discussed in part I.C.1.a (regarding health care staffs and managers who will receive training) in this RIA.

To address this problem, we looked at the BLS industry data for North American Industry Classification System code 999201: State government, including schools and hospitals, we identified 442,680 personnel employed by State governments.[324] Subtracting this number from the 556,731 employees we identified employed in State government health services and Medicaid programs, results in 114,051 additional State employees who may obtain training on the provisions of the regulation.

d. Non-Health Care Personnel in Pharmacies

The 2012 Census data for all U.S. industries identifies 43,343 pharmacy establishments. The number of employees presented in the Census data includes both pharmacists and non-pharmacist personnel. At this point, we must refer back to the BLS data on the number of health care workers reported for 2014 because the BLS data divides the pharmacy workforce by occupation. The number of employees that BLS reports were employed in pharmacies for 2014 is 708,660. The number of health care workers discussed in subsection II.C.1.a. above includes 348,190 individuals counted above in occupation codes 11–9111, 29–0000 and 31–0000 reported to be working in pharmacies.[325] Because we already counted the costs of health care workers employed in pharmacies in the analysis of health care staff, to achieve a more accurate estimate of the number of non-health care pharmacy workers, we must subtract the 348,190 health care staff from the total workforce BLS reports. Removing health care staff from the BLS data yields a net of 360,470 non-health care pharmacy workers in pharmacies who may receive training on the final rule.

The following table shows the total number of employees whom we estimate will receive training; that is, the table shows the 50% of total workers whom we estimate may receive training. The table does not include HHS employees conducting HHS health programs or activities because there are roughly 65,000 HHS total employees and many of these employees do not work in health programs or activities administered by HHS. For those employees who do work in health programs or activities administered by HHS, many may not have direct beneficiary contact. Given these limitations, we estimate the number of employees added would be small and have little impact on overall cost.

TABLE 2—WORKERS WHO MAY RECEIVE TRAINING ON THE REGULATION

Medical health staffs and managers	7,216,494
Employees working for 180 issuers in the Health Insurance Marketplaces	46,114
State health employees	55,442
Navigators	1,520
Pharmacy workers (excluding health care personnel)	180,235
Total	7,637,306

2. Number of Covered Entities That May Train Workers

Just as there are a number of data sources for counting workforce, there are various sources for counting the number of health care entities. Many covered entities are controlled or owned by a single corporate entity, and one can count each individual entity separately or count only the single corporate enterprise. For example, a multi-campus facility or vertically integrated entity that owns a hospital, a nursing home, and a home health agency and also operates an accountable care organization could count each of these entities separately—as does Medicare—or count them only once, with each entity treated as part of the corporate entity. At this point, we make two assumptions: (1) Albeit not required to do so by the regulation, each covered entity will provide some training to its staff on the requirements of the regulation; and (2) when entities are controlled or owned by a corporate entity, the corporate entity will supplement or make any desired modification to the OCR training materials and distribute the training materials. We believe this last point to be especially true because rather than have each entity prepare its own training materials, the corporate entity is more likely to prepare one set of training materials and distribute the materials to its individual entities. This is because the corporate entity saves money by preparing a limited set of training materials and assures uniform quality and consistency in its policies across all its entities. It is also possible that some local health centers in a State may be managed from a central location that handles logistics and training materials. Therefore, we propose using the 2012 Census table that presents the number of entities, referred to as firms in the Census tables, to count the number of health care entities. In the Census data, a corporate entity is referred to as a ''firm'' and the corporation's facilities are ''establishments.'' When a firm has one

[322] U.S. Census Bureau, Government Employment & Payroll (2013), *http://www.census.gov/govs/apes/*.

[323] Nat'l Ass'n of State Medicaid Dirs, State Medicaid Operations Survey: Fourth Annual Survey of Medicaid Directors, at 5 (Nov. 2015) *http://medicaiddirectors.org/wp-content/uploads/2015/11/namd_4th_annual_operations_survey_report_-_november_2_2015.pdf*.

[324] U.S. Dep't of Labor, Bureau of Labor Statistics, May 2015 National Occupational Employment and Wage Estimates by ownership, *http://www.bls.gov/oes/2014/may/oes_nat.htm* (last visited May 3, 2016).

[325] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Area Health Resource Files, *http://ahrf.hrsa.gov/* (last visited May 3, 2016). The Area Health Resource File reports 272,022 pharmacists licensed in 2014.

establishment, the establishment is the firm.

Another difficulty we face in using these data sources is that the Census data captures all entity types that fit the definition of a health care service entity, including entities such as private retirement communities that are unlikely to receive Federal financial assistance and thus would not be covered by Section 1557. In our use of the Census data, we attempted to exclude types of entities that are not likely to receive Federal financial assistance by excluding retirement communities and other similar type entities in the file, but we have included entities that may receive Federal financial assistance, such as community health centers and residential centers for individuals with intellectual disabilities.

To test our success in producing a list of covered entities from the Census data, we compared the number of entities we selected from the Census data and the number of entities included in the CMS Provider of Service file. However, to make the lists comparable, we had to remove the count of Clinical Laboratory Improvement Act laboratories from the CMS Provider of Service data files. There are close to 450,000 Clinical Laboratory Improvement Act laboratories located in hospitals, clinics, outpatient centers, and doctors' offices. Only a few thousand of these laboratories serve the public. The majority of laboratories serve the facility in which they are housed—including them in our comparison would grossly distort this comparison.

If we add the entities in the Provider of Service file (excluding Clinical Laboratory Improvement Act laboratories) and the number of community health centers to our list of affected entities that are not included in the Provider of Service file, we get a total of 134,543 entities. Using the Census data, minus the categories for medical laboratories, we obtain a total of 139,164 covered entities. It is evident that these numbers are very similar. However, as discussed earlier, we propose using only the number of firms for the analysis of the number of entities possibly conducting training, that is, 70,384 firms. As noted, we believe firms and not establishments will modify or supplement materials and train employees.

In addition to the firms we include from the Census file, we must add physicians' office firms and pharmacy firms because they may also need to train some workers. Physicians' office firms and pharmacy firms are generally referred to as physician group practices and pharmacy chains.

Below we present the types and number of firms that we estimate will take part in the training for the regulation.

TABLE 3—NUMBER OF HEALTH CARE ENTITY FIRMS EXPECTED TO TAKE PART IN TRAINING

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
621491	HMO medical centers	104
621492	Kidney dialysis centers	492
621493	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential intellectual and developmental disability facilities	6,225
6221	General medical and surgical hospitals	2,904
6222	Psychiatric and substance abuse hospitals	411
6223	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	18,852
6211	Offices of physicians	185,649
524114	Insurance Issuers	180
	Navigator grantees	100
Total Entities		275,002

3. Training and Familiarization Costs

a. Cost of Training Materials and Presentations

There are two components to the cost of training the workers we identified in the previous section: (1) The cost of training materials that is based on the number of covered entities identified in the previous section; and (2) the cost of employee time spent in training.

OCR estimates, based on its experience of training employees on other regulations it enforces, that training employees on this regulation will take about one hour of an employee's time. Based on discussions with firms that develop training materials, we estimate that developing or presenting materials for a one-hour course would cost about $500. However, before the effective date of the rule, OCR will provide covered entities with training materials that will cover the key provisions of the regulation that can be used by entities in conjunction with their own training materials. We estimate that OCR preparing the training materials on the regulation will substantially reduce the material preparation burden to covered entities and reduce the cost by about three quarters, or about $375 per entity. Therefore, the costs to entities will equal $125 multiplied by the number of entities that will prepare and present training materials. Based on its experience in preparing training materials for other civil rights and HIPAA regulations, OCR expects to spend $10,000 to develop training materials that will prepare health care workers and managers to effectively implement the Section 1557 regulation.

Training materials can be presented in a number of ways. A common method for offering training materials is through e-courses that are distributed over an entity's computer network. Another method is to offer lectures to selected employees/staff and then have attendees present the materials to their co-workers as part of train-the-trainer programs. For small entities, one lecture session may be given to all employees. Regardless of presentation mode, we estimate that the cost of training via an e-course will be

the same as the cost of training through a lecturer for a train-the-training approach: $125 per entity.

Applying the $125 per course materials to the number of firms ($125 × 275,002)—including the 169 health insurance issuers—equals $34.4 million for the cost of developing training materials.

b. Cost of Employee Time

The next step is to compute the cost of employee time for training and familiarization. This involves taking the hourly wage rate times the amount of time that a new activity will require, times the number of employees expected to undertake the activity as a result of the rule. We use data from the BLS on median wage rates by occupation to estimate wages throughout this analysis. We are uncertain about how many employees identified in the workforce above will actually seek and obtain training and how many firms in the health sector will offer training. However, for the purposes of this analysis we assume that all firms may offer some training to their staffs, but because the training is voluntary, and because only a portion of employees who have direct patient contact or otherwise have duties impacted by the regulation may require or take training, we assume that 50% of employees will receive training. We assume that training will require an average of one hour of time for each participating employee.

The occupation code 29–1000 (health care practitioners) applies to the 4.8 million professional staff and degreed technical staffs we discussed above. The BLS reports the median hourly wage for this code as $36.26. We estimate one hour of a worker's time would be required for training. To this amount we must add 100% for fringe benefits and overhead, which yields an adjusted hourly wage per employee of $72.52. Assuming that half of the 4.8 million health care practitioners identified earlier receive or obtain training (2.4 million workers), and multiplying this number by the hourly employee wage plus fringe benefits and overhead for one hour equals slightly more than $175.3 million in training costs for practitioners.

We note that one commenter suggested that we use a factor higher than 100% to adjust wages for overhead and benefits. However, the commenter's argument is based on Federal overhead rates for contracts, and not evidence of the resource costs associated with reallocating employee time. As a result, we do not adopt the commenter's recommendation, and we continue to use the Department's standard of 100% for overhead and fringe benefits.

For the degreed health care work force in occupation 29–2000, the median hourly wage is $19.92. Adding 100% for fringe benefits and overhead equals $39.84. The total training cost for one hour of training for half of the 2.9 million degreed technical staff (1.44 million workers) is about $57.3 million. In addition, we must add the cost of training non-degreed staff (reported in occupation 31–0000) who earn a median hourly wage of $12.71. Adding 100% for fringe benefits and overhead to the $12.71 median hourly wage rate yields an adjusted wage of $25.42. Multiplying this amount by half of the 3.9 million workforce yields a cost of $50.1 million.

To these amounts we must add the cost associated with familiarization and training for the medical and health service managerial staff, of which there are 300,320 individuals with a median hourly pay rate of $44.62. Adding 100% for fringe benefits and overhead gives us an adjusted hourly wage of $89.24. We assume that an average of one person in this occupation will spend an average of two hours becoming familiar with the final rule's requirements upon its publication at each of the 275,002 entities covered by the rule. These assumptions imply familiarization costs of $49.1 million. We assume that half of the remaining managers receive training. This implies that 12,659 managerial staff will receive an hour of training, which results in a cost of $1.1 million. This implies that total costs for training and familiarization for this occupation category comes to $50.2 million.

The cost of training occupation code 43–0000, office and administrative support workers employed in covered health care entities, is the product of the median hourly rate of $15.52 adjusted for fringe benefits and overhead multiplied by the 2.7 million workers reported for North American Industry Classification System code 62: Health Care and Social Assistance (including private, State, and local government hospitals). Adding 100% for fringe benefits and overhead to the $15.52 equals $31.04. Multiplying the pay rate by half the number of support and administrative personnel equals $42.6 million.

The 2013 BLS data for North American Industry Classification System pharmacies and drugstores reports a total workforce of 708,660 workers. As with the analysis for State employees, we must remove the 348,190 health care workers who are already counted in our training costs analysis of the health care workforce. To avoid double counting training costs for these occupations, we removed them from the count of the pharmacy workforce. (The entities that employ these workers will still bear the cost for training them.) Their median weighted wage is $17.22, which is derived from BLS data for medical pharmacy personnel, and the cost associated with an hour of their time is $34.44 after adjusting for overhead and benefits. We estimate $6.0 million in costs for training half of these medical pharmacy personnel.[326]

For the 360,470 non-medical pharmacy personnel, their weighted median hourly rate for pharmacy employees is $11.87, which is derived from BLS data for non-medical pharmacy personnel. After adjusting for overhead and benefits, the cost of one hour of time in this category is $23.74. We estimate $4.3 million in costs for training half of these non-medical pharmacy personnel.

For the 3,040 navigators, we lack data to determine their wages. As a proxy, we use the wage rate for medical and health service managerial staff, with a median hourly pay rate of $44.62. Adding 100% for fringe benefits and overhead gives us an adjusted hourly wage of $89.24. We estimate $0.1 million in costs for training half of these navigators.

For the remaining entities for which we cannot use BLS data, we must use the industry payroll and employment Census data. To arrive at an estimate of the cost of time for training employees of health insurance issuers and State health and Medicaid agencies, we must divide the total annual payroll reported for these entities by the total number of employees and divide that number by the annual hours paid (2,080 hours), adjusted for fringe benefits and overhead.

For workers employed by the issuers participating in the Health Insurance Marketplaces, it was necessary to determine the hourly wage rate for workers employed in small and large issuers as we have described them above. The total number of workers in small entities (fewer than 500 workers) is 27,269 and the annual payroll is $1.68 billion. The average wage per employee is $61,895. Using the 2,080 hours for the annual number of work hours, we obtain an hourly rate of $29.76.

[326] Determining the cost to train employees other than pharmacists and medical staff who work in pharmacies requires use of the Bureau of Labor Statistics industry data for North American Industry Classification System. These data show that for 2013, 348,380 medical practitioners, technologists and medical support staff were employed in pharmacies and drug stores. U.S. Dep't of Labor, Bureau of Statistics, Occupational Employment Statistics, *supra* note 316.

Assuming that the payroll amounts reported in the Census data do not include fringe benefits and overhead, we add 100% to the hourly rate to yield $59.51 per hour. Multiplying this amount by half of the 4,454 employees in small issuers equals $132,540 in training costs.

The total number of employees employed by large issuers (500 or more) is 415,017 and the annual payroll is $30.8 billion. The average annual wage is $74,219. Dividing this figure by 2,080 hours yields an hourly wage rate of $35.68. Multiplying by 100% for fringe benefits and overhead yields $71.36. Multiplying this amount by 50% of the 87,400 workers equals slightly more than $3.12 million in training costs.

For State government workers employed in welfare, health, and hospital services, we divided the total number of workers the 2012 Annual Census Bureau reported (873,289 employees) into the monthly payroll reported for the period ($3,774,775,691).[327] On an annual basis, the average salary per employee equals $51,870. The hourly rate equals $24.94 and multiplied by 100% for fringe benefits and overhead yields $49.87 per worker for training costs.

In the State Medicaid Operations Survey: Second Annual Survey of Medicaid Directors, States reported the median number of full-time Medicaid employees is 421. Using this number multiplied by the 53 Medicaid agencies in the 50 States, the District of Columbia, Puerto Rico, Guam, and the other territories, we added 22,313 workers to the total of health and hospital workers reported in the Census data, bringing the total number of workers in covered State government entities to 553,564. We then subtracted the 442,680 medical personnel we accounted for in the training costs for all health care personnel and therefore were considered to be duplicative of the medical personnel previously counted in our analysis of medical staff workforce (occupations 29–1000, 29–2000 and 31–0000). This left a net of 110,884 State employees receiving training. Taking half of this number and multiplying it by $49.87 equals a training cost of slightly more than $2.76 million.

Although we removed the cost of training the 442,680 medical personnel from the State training cost analysis to avoid double counting training costs, the cost of training half the medical staff may still fall to the States where they are employed. We estimate the cost to train State medical personnel to be approximately $11.1 million.[328]

As noted above, total familiarization costs are estimated to be $49.1 million. The following table summarizes the training costs we estimate for this rule.

TABLE 4—TOTAL TRAINING COSTS

	Number of entities/workers	Cost (millions)
Training preparation costs ($125/entity)/entity	* 275,002	$34.4
Health care staff and managers training	* 7,214,862	326.9
Small Issuers in the Health Insurance Marketplace℠ training	2,414	0.1
Large issuers in the Health Insurance Marketplace℠ training	43,700	3.1
Navigators	1,399	0.1
State health, hospital and Medicaid worker training	55,442	2.8
Pharmacy worker training	180,235	4.3
Total	7,498,052	371.7

* Not included in column total.

C. Notification and Other Procedural Requirements

1. Designation of Responsible Employee and Adoption of Grievance Procedures

Pursuant to the regulations implementing Section 504, recipients of Federal financial assistance with 15 or more employees are required to designate a responsible employee to coordinate compliance with respect to nondiscrimination requirements and to have grievance procedures to address complaints of discrimination under this law. Of the 275,002 covered entities, approximately 15% employ more than 15 employees, resulting in approximately only slightly more than 41,250 covered entities being required to have grievance procedures and designate a responsible official. Thus, all recipients of Federal financial assistance with 15 or more employees are already expected to have in place grievance procedures and a designated employee to coordinate their compliance responsibilities. The rule standardizes the requirement to designate a responsible employee and adopt grievance procedures across all bases of discrimination prohibited under Section 1557.

To implement the rule, a recipient of Federal financial assistance could increase the responsibilities of an already-designated employee to handle compliance with the rule's nondiscrimination requirements. In addition, a recipient of Federal financial assistance could increase the scope of existing grievance procedures to accommodate complaints of discrimination under all bases prohibited under Section 1557. The costs associated with these requirements are the costs of training the designated employee on the employee's increased responsibilities and the costs associated with modifying the existing grievance procedures to reflect the additional bases of race, color, national origin, sex, and age. Here we are referring to employee training to perform their specific enforcement responsibilities, not one-time training in the provisions of the final rule described in the training section above. We also note that grievance officials will probably receive specific training on their new responsibilities and that covered entities will probably provide this additional training and absorb the costs, which are expected to be de minimis. Many covered entities already may be using their existing grievance procedures to address the additional cases covered under Section 1557.

State-based Marketplaces are required to designate an employee to handle compliance responsibilities and to adopt grievance procedures under the ADA. The duties of the employee and

[327] U.S. Census Bureau, Government Employment & Payroll, *http://www.census.gov/govs/apes/* (last visited May 3, 2016).

[328] We calculated the cost of training the medical personal using the weighted median hourly rate, $47.22, multiplied by the 446,210 medical staff identified as employed in State governments.

the grievance procedures could be modified to reflect all the bases covered under Section 1557.

We have not estimated the additional costs of training grievance officials on their individual enforcement responsibilities, but we believe such cost would be absorbed in general training costs of all employees on their job responsibilities. Costs associated with modifying existing grievance procedures are covered in the section of the analysis on enforcement.

2. Notice Requirement

The implementing regulations of Title VI, Section 504, Title IX, and the Age Act require recipients of Federal financial assistance and, in the case of Section 504, the Department, to notify individuals that recipients (and, under Section 504, the Department) do not discriminate. The content of the nondiscrimination notices varies based on the applicable civil rights law.

The final rule harmonizes notification requirements under Title VI, Section 504, Title IX and the Age Act, and standardizes the minimum information for a notice. The final rule also requires initial and continuing notification of individuals. OCR drafted a sample notice (located in Appendix A to Part 92) in English that meets the requirements and will translate that notice into 64 additional languages, in advance of the effective date of this rule. Covered entities have discretion to use the OCR sample notice or their own notice, if preferred, and to post the notice in non-English languages.

As all Section 1557 covered entities will need to create or update an existing notice of nondiscrimination, all covered entities can discharge their responsibilities under § 92.8(a) by replacing their current notices with the sample notice developed by OCR (found in Appendix A), available to all covered entities pursuant to § 92.8(c). Using the sample OCR notice means that covered entities will not have to compose their own notices; we expect nearly all covered entities will use the sample OCR notice.

All covered entities will incur costs, however, to implement § 92.8(a) of the final rule, which requires ''initial and continuing'' notification. Such notification is expected to involve:

- Downloading the notice from the OCR Web site;
- Printing copies of the notice for posting;
- Posting hard copies of the notice in public spaces of the office or facility; and
- Posting the notice on the entity's Web site, if it has one.

While many costs to comply with this rule are incurred at the entity level, the costs of downloading, printing, and posting the notice are incurred at the establishment level. There are approximately 275,000 covered entities covered by this final rule. According to 2012 Census data, these covered entities are associated with 405,534 establishments. We estimate that a clerical worker at each establishment would spend an average of one minute downloading the notice from the OCR Web site, an average of one minute printing copies of the notice for posting, an average of five minutes posting hard copies of the notice in public areas, and an average of ten minutes total between preparing the OCR notice for posting on the facility's Web site and posting the notice on the Web site. This implies that the estimated cost associated with posting is $8.79 ($31.04 per hour × 17 minutes × 1 hour per 60 minutes) per establishment, which implies that the total estimated cost associated with this requirement is $3.6 million ($8.79 per establishment × 405,534 establishments).

Covered entities will need to update their significant publications and significant communications to include the new notice. However, as noted above, OCR is allowing entities to exhaust their current publications, rather than do a special printing of the publications to include the new notice. When covered entities restock their printed materials, they will be expected to include in those printed materials the notice that OCR will provide with this final rule.

Because we are permitting covered entities to exhaust their existing stock of publications with the current notices before using the new notice, we conclude that the notice requirement imposes no resource costs related to including updated notices in the publications.

Section 92.8 provides covered entities discretion to post the OCR sample notice of nondiscrimination in non-English languages, which can include languages that differ from OCR's list. In addition, covered entities can draft and translate their own notice in however many languages they choose, if they prefer.

We examined CMS contractual cost for translating a one page notice into 13 languages. It was $1,000 per page. Based on this figure, we expect total costs to the government to be limited to $64,000 to translate the notice into 64 languages and place the translated notices on OCR's Web site. The sample notice is one page long. In addition, we expect total costs to the government for translating the statement of nondiscrimination for small-size publications to be $50 for each of the 64 languages. We count the nondiscrimination statement as .05 pages long.

Although not required, we expect that many covered entities would choose to post the OCR-provided notice in one or more non-English languages on their Web sites, in their physical office space, and in certain publications they may have. We do not know how many covered entities would take this action or how many non-English language versions of the notice they would choose to post, or where they would make the non-English versions of the notice available.

Section 92.8 requires covered entities to publish taglines indicating the availability of language assistance services in the top 15 languages of the relevant State or States. Before the effective date of the rule, OCR will make these taglines available electronically in 64 languages; therefore, there will be no burden to the covered entity other than the cost of printing and posting these taglines, as described above with respect to the notice. We are uncertain of the exact volume of taglines that will be printed or posted, but we estimate that covered entities will print and post the same number of taglines as notices and therefore the costs would be comparable to the costs for printing and disseminating the notice, or $3.6 million. The costs to the Federal government for translating the taglines will be approximately $50, based on counting each tagline as being .05 pages long. We estimate that the combined costs of printing and distributing notices, nondiscrimination statements, and taglines will be $7.1 million for entities and $70,400 for the Federal government.

D. Meaningful Access for Individuals With Limited English Proficiency

In the proposed rule, we said that § 92.201, which effectuates Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency, does not pose any new burden on covered entities. This is because, with regard to recipients of Federal financial assistance, the proposed rule adopted recipients' existing obligations under Title VI to take reasonable steps to provide meaningful access to individuals with limited English proficiency and codified the standards consistent with long-standing principles from the HHS LEP Guidance regarding the provision of oral interpretation and written translation services. However,

we anticipate that, as a result of issuance of the final rule, covered entities may choose to take one extra step: To develop and implement a language access plan, in order to ensure that they provide meaningful access to individuals with limited English proficiency. We have thus revised our cost estimates, for the final rule, as shown below, to reflect our assumption that 50% of the covered entities will choose to develop a language access plan.

Although Title VI does not apply to the Department, Executive Order 13166 ''Improving Access to Services for Persons with Limited English Proficiency'' has applied to HHS for nearly 15 years.[329] This Executive Order requires Federal departments to develop and implement a plan, consistent with the HHS LEP Guidance, to ensure that persons with limited English proficiency can meaningfully access the Department's programs and activities. HHS adopted a Language Access Plan in 2000, and updated it in 2013, to provide individuals with limited English proficiency meaningful access to HHS-conducted programs and activities, including Federally-facilitated Health Insurance Marketplaces.[330] Because the final rule does not impose duties beyond the Department's existing obligation under the Executive Order, the rule imposes no new burden on the Department.

In order to estimate the costs of developing a language access plan for recipients of Federal financial assistance, we assume that developing a plan requires approximately three hours of medical and health service managers staff time for the first year, and then an average of one hour of medical and health service managers staff time per year to update the plan in subsequent years. We based our assumption of three hours on feedback from covered entities included in our pre-award compliance review program. This program reviews civil rights compliance of 2,000 to 3,000 health care provider applicants for Medicare Part A per year.

The health care providers that receive Medicare Part A funds already have to develop a written language access plan as a requirement of participation in the Medicare Part A program. Thus, we can reduce the number of covered entities from having a new burden of developing a language access plan. CMS reports data on Medicare hospital spending per claim which identifies 3,209 unique hospitals, which suggests that at least 3,209 hospitals participate in Medicare Part A. As discussed previously, Census data reports that there are a total of 3,688 hospital firms in the United States. Census data reports that there are 6,741 establishments associated with these firms, which in turn suggests that at least 47.6% (3,209/6,741) participate in Medicare Part A. Census data also reports that there are 8,623 nursing care facility entities in the United States. For the purpose of this analysis, we assume that 47.6% of hospitals and nursing care facilities participate in Medicare Part A. Applying 47.6% to all hospitals and nursing care facilities, we estimate that 5,861 entities (47.6% × 3,688 hospital entities (firms) + 47.6% × 8,623 nursing care facility entities) covered by this rule participate in Medicare Part A. This implies that 269,141 entities (firms) will potentially make changes and develop a language access plan as a response to the rule. We arrived at the 269,141 number by subtracting the number of entities participating in Medicare Part A (5,861) from the total number of entities (275,002). We estimate that 50% of these entities will make these changes. Taken together, these assumptions imply that the total cost of the development of language access plans will be approximately $36.0 million (269,141 entities × 50% of entities × 3 hours per entity × $89.24 per hour) in the first year and approximately $12.0 million (269,141 entities × 50% of entities × 1 hour per entity × $89.24 per hour) per year in subsequent years.

We received a number of comments stating that developing a language access plan imposes a cost burden on covered entities. We revised the proposed rule to include cost estimates, in this final rule, for the development of language access plans, as outlined in the paragraph above. We also received comments that providing interpreters imposes a heavy burden on covered entities. The obligation to provide interpreters as part of taking reasonable steps to provide meaningful communication with individuals with limited English proficiency has been a requirement under Title VI for many years. As a result of developing a language access plan, a covered entity might find increased efficiencies in providing language assistance services. Another covered entity might incur extra costs for the provision of language assistance services on more occasions. We are unable to estimate at this point how many covered entities will incur extra costs or the extent of such costs or the savings realized in increased efficiencies. We anticipate that the potential increased efficiencies and increased costs may offset each other to some degree. Thus, we do not believe this rule will impose a greater burden regarding the costs of language assistance services than exist under Title VI.

E. Nondiscrimination on the Basis of Sex

Section 1557 prohibits discrimination on the basis of sex in certain health programs and activities. When providing services, including access to facilities, covered entities must provide individuals with equal program access on the basis of sex, and covered entities are required to treat individuals in a manner consistent with their gender identity.

Title IX applies to educational institutions. Therefore, medical schools, nursing programs, and other health education programs were already prohibited from discriminating on the basis of sex prior to the enactment of Section 1557. Under Section 1557 and this regulation, health insurance issuers receiving Federal financial assistance, hospitals, clinics and other health facilities, HHS health programs and activities, and Title I entities, along with the staff and practitioners working in these health programs, are now similarly prohibited from discriminating on the basis of sex.[331] This section discusses the costs associated with the prohibition of discrimination on the basis of sex in the rule, taking into account the existing environment, including legal authorities, that addresses equal access on the basis of sex.

Covered entities that provide or administer health services or health insurance coverage are covered by the prohibition of discrimination on the basis of sex. The costs that we anticipate that covered entities would incur relate to: (1) Training; (2) enforcement; (3) the posting of the notice; (4) the revision of policies and procedures; and (5) some costs associated with changes in discriminatory practices. This section discusses costs related to changes in policy and procedures and potential changes in discriminatory practices.

[329] Exec. Order No. 13166, 65 FR 50121 (2000).

[330] U.S. Dep't of Health & Human Servs., Language Access Plan, *supra* note 186.

[331] Consistent with OCR's enforcement of other civil rights authorities, the proposed definition of ''Federal financial assistance'' under the regulation does not include Medicare Part B, which means that physicians receiving only Medicare Part B payments are not covered under the regulation. However, because almost all physicians receive payments from other Department programs such as Medicaid or Medicare meaningful use payments, we believe that there are very few physicians excluded from these provisions. *See supra* pt. I. C. 1.

1. Costs for Entities Providing or Administering Health Services

The rule would not invalidate specialties that focus on men or women, *e.g.,* gynecology, urology, etc. Nor would providers have to fundamentally change the nature of their operations to comply with the regulation. For example, the rule would not require a provider that operates a gynecological practice to add to or change the types of services offered in the practice.

Under the sex discrimination prohibition, however, providers of health services may no longer deny or limit services based on an individual's sex, without a legitimate nondiscriminatory reason. Although a large number of providers may already be subject to state laws or institutional policies that prohibit discrimination on the basis of sex in the provision of health services, the clarification of the prohibition of sex discrimination in this regulation, particularly as it relates to discrimination on the basis of sex stereotyping and gender identity, may be new. We anticipate that a large number of providers may need to develop or revise policies or procedures to incorporate this prohibition. For example, if a hospital or other provider has specific protocols in place for domestic violence victims, but engages that protocol only for women, the provider would have to revise its procedures to require that protocol for all domestic violence victims regardless of sex. A provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to provide the procedure for transgender individuals in the same manner it provides the procedure for other individuals.

a. Developing or Revising Policies and Procedures

We assume that it will take, on average, three to five hours for a provider to develop or modify policies and procedures concerning sex discrimination. We are selecting four hours, or the midpoint of this range, for our analysis. We further assume that an average of three of the hours will be spent by a mid-level manager equivalent to a front-line supervisor (Occupation code 43–1011), at a cost of $48.84 per hour after adjusting for overhead and benefits, and an average of one hour will be spent by executive staff equivalent to a general and operations manager (Occupation code 11–1021), at a cost of $93.54 per hour after adjusting for overhead and benefits. We further assume that 75% of covered entities will need to develop or modify policies and procedures, given that some proportion of health care providers already prohibit sex discrimination based on State law or institutional policies prohibiting discrimination generally. The total cost for the estimated 206,252 covered entities to make their policies and procedures consistent with the regulatory prohibition on discrimination on the basis of sex is estimated to be approximately $49.5 million, which we assume is divided evenly between the first two years of compliance.

The above estimates of time and number of entities that would have to revise their policies under the regulation is an approximate estimate based on general BLS data. Due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices, the above estimates of time and number of entities that would have to revise their policies under the regulation is difficult to calculate.

b. Ending Discriminatory Practices

For providers that discriminate on the basis of sex in violation of the rule, some changes in behavior or action would be necessary to come into compliance. We anticipate some change in the patient population for which a particular provider provides care or the extent of services provided. However, the infrastructure and protocols for providing services or treatment are already in place; providers would simply have to start providing those existing services in a nondiscriminatory manner to individuals regardless of sex. For example, a provider could not refuse to treat a patient for a cold or a broken arm based on the patient's gender identity. Similarly, if the provider is accepting new patients, it must accept a new patient request from a transgender individual and cannot decline to accept a transgender individual in favor of a person who is not transgender.

However, the rule does not impose a burden on covered entities with respect to the number of patients treated. The rule does not require a covered entity to change the total number of patients it sees or to treat more patients than it currently accepts. Providers may continue to treat the same number of patients that were accepted prior to the issuance of this final rule, but they must do so in a nondiscriminatory manner. Thus, for example, if a provider is not accepting new patients, the provider does not have to accept a new patient request from a transgender individual. We anticipate that the costs associated with these types of changes would be de minimis.

Moreover, costs associated with administering care or treating a new patient generally would be offset by the reimbursement received by the provider for providing the care, in the same way the provider gets paid for existing care or treatment of patients. Thus, for example, for the hospital or other provider that needs to revise its protocol for domestic violence to require that protocol for all domestic violence victims regardless of sex, rather than just women, there would be little to no net increase in costs for treating men because the hospital or provider would be paid for its services in the same way it is paid to treat women.

2. Costs for Entities Providing or Administering Health Insurance Coverage

The ACA, including Section 1557, changed the health care landscape for millions of people by instituting protections against sex discrimination in the provision of health care and health insurance coverage. Prior to the ACA, it was standard health insurance practice to treat women differently in premium pricing and coverage of benefits,[332] while transgender individuals frequently experienced discrimination when seeking coverage for treatment.[333]

The ACA addresses inequitable treatment by health plans based on sex in multiple ways. The regulations from CMS implementing the ACA prohibit Title I entities [334] and most health insurance issuers [335] from

[332] *See* Adelle Simmons, Katherine Warren, & Kellyann McClain, U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Planning and Eval., ASPE Issue Brief, The Affordable Care Act: Advancing the Health of Women and Children (Jan. 2015), *https://aspe.hhs.gov/pdf-report/affordable-care-act-advancing-health-women-and-children;* U.S. Dep't of Health & Human Servs., Women and The Affordable Care Act, *http://www.hhs.gov/healthcare/facts-and-features/fact-sheets/women-and-aca/index.html* (last visited May 3, 2016).

[333] *See* Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV (2010), *http://www.lambdalegal.org/publications/when-health-care-isnt-caring.*

[334] 45 CFR 155.120(c)(1)(ii) prohibits a Health Insurance Marketplace℠ from discriminating based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.

[335] 45 CFR 147.104(e) prohibits health insurance issuers in non-grandfathered individual, small and large group markets from employing benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, gender

Continued

discriminating based on sex, sexual orientation, and gender identity, in addition to other bases. These market-wide provisions are applicable to health insurance issuers both on and off the Health Insurance Marketplace SM, which includes qualified health plan issuers [336] and health insurance issuers providing non-grandfathered coverage in the individual and group markets outside of the Health Insurance Marketplace SM.[337]

In addition, the ACA prohibits many health insurance issuers from charging higher premiums based on sex; [338] failing to provide essential health benefits that greatly impact women, such as maternity care; [339] failing to cover preventive services that are necessary for women's health, such as mammograms; [340] and denying benefits based on pre-existing conditions [341] or health factors,[342] many of which affect women's health, such as a history of a Caesarian section or a history of domestic violence.[343] Thus, health insurance issuers and the Health Insurance Marketplaces have already had to expand access to women and lesbian, gay, bisexual and transgender (LGBT) individuals under these health insurance market reforms, independent of Section 1557. The existence of these other provisions circumscribes cost burdens on Health Insurance Marketplaces and issuers in the ACA-compliant individual and small group markets that are recipients of Federal financial assistance that are imposed by the prohibition of sex discrimination in the rule.

Section 92.207 (Nondiscrimination in health insurance and other health coverage) of the rule prohibits discrimination on the basis of sex by a covered entity providing or administering health insurance or other health coverage. As noted, many of the same covered entities subject to Section 1557, including Health Insurance Marketplaces and health insurance issuers in the individual and small group markets that are recipients of Federal financial assistance, are also subject to existing nondiscrimination provisions in CMS regulations. Although the CMS regulations complement and do not replace Section 1557 or this part, the existing nondiscrimination requirements applicable to health insurance issuers and Health Insurance Marketplaces have made these entities aware that they are not permitted to discriminate on the basis of sex, sexual orientation, or gender identity, and thus they are familiar with their nondiscrimination obligations under the law. We assume that these covered entities have already taken steps to comply with CMS regulations and so instituted changes in their policies and actions. To the extent these existing obligations overlap with Section 1557 and covered entities have complied with the CMS regulations that prohibit discrimination on the basis of sex, sexual orientation, and gender identity, this rule will impose little or no burden on health insurance issuers and Title I entities to comply with Section 1557's and this part's prohibition on sex discrimination. However, the rule nonetheless imposes some costs.

a. Developing or Revising Policies and Procedures

There may be some incremental burden on issuers and Title I entities in terms of the additional guidance that this rule provides related to sex discrimination, because, in some circumstances, it provides more detail than CMS regulations or guidance. Therefore, covered entities may have an increased burden when incorporating this rule into their existing nondiscrimination policies and procedures. For example, this rule specifies that a categorical coverage exclusion or limitation for all health care services related to gender transition is discriminatory on its face. If a covered entity had not previously understood sex discrimination on the basis of gender identity in this way, the covered entity would have to revise its policies and procedures to provide coverage consistent with this final rule's parameters, which might include revising policies to include gender transition-related care.

However, we note that the number of major U.S. employers providing transgender-inclusive health care coverage has been increasing, from 0 in 2002, to 49 in 2009, 278 in 2013, 336 in 2014, 418 in 2015, and at least 511 in 2016.[344] This indicates that plans that offer transgender-inclusive health care are becoming readily available as models for issuers that may not offer such care, limiting their costs in developing or revising policies and procedures for compliance.

Similar to the estimate for providers of health services, we assume that it will take, on average, three to five hours for issuers of health insurance coverage to develop or modify policies and procedures concerning sex discrimination. We are selecting four hours, or the midpoint of this range, for our analysis. We further assume that three of the hours will be spent by a mid-level manager, at a salary, with fringe benefits and overhead of $57.60 per hour,[345] and one hour will be spent by executive staff, at a salary, with fringe benefits and overhead of $122.15 per hour. Based on our best estimate of industry compliance with CMS regulations, we further assume that one-third or 33% of health insurance issuers will need to develop or modify policies and procedures. Based on an unduplicated count of issuers, we previously identified 180 issuers in the Marketplaces (including Federally-facilitated Marketplaces). One third of this number equals 60 issuers that we estimate would need to revise policies to address the prohibition of sex discrimination in this regulation. The costs to issuers to revise policies and procedures to provide coverage consistent with this rule's parameters equal 60 issuers multiplied by $295 for a one-time cost of $17,700.

b. Ending Discriminatory Practices

In addition to the cost some covered health insurance providers may have for revising policies and procedures to comply with the rule, such providers may also incur a de minimis cost related to the cost of coverage. In this regard, we note that the April 2012 California

identity, sexual orientation, expected length of life, degree of medical dependency, quality of life, or other health conditions. 45 CFR 156.200(e) prohibits a qualified health plan issuer from discriminating on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation. 45 CFR 156.125(a) prohibits issuers that provide essential health benefits from using benefit designs that discriminate based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. 45 CFR 156.125(b) requires issuers that provide essential health benefits to comply with 45 CFR 156.200(e).

[336] 45 CFR 147.104(e), 156.200(e) and 156.125(a)–(b) are applicable to qualified health plan issuers.

[337] 45 CFR 147.104(e) is applicable to non-grandfathered coverage in the individual, small and large group markets. 45 CFR 147.150(a) incorporates essential health benefits requirements (and implementing regulations at 45 CFR 156.200(e) and 156.125(a)–(b)) for non-grandfathered coverage in the individual and small group markets.

[338] 42 U.S.C.300gg.

[339] *Id.* 18022 (b).

[340] *Id.* 300gg–13 (a)(4).

[341] *Id.* 18001.

[342] *Id.* 300gg–4.

[343] *Id.* 300gg–4(a)(7); ASPE Issue Brief, *supra* note 332.

[344] Human Rights Campaign, Corporate Equality Index, *Rating American Workplaces on Lesbian, Gay, Bisexual and Transgender Equality, http://www.hrc.org/campaigns/corporate-equality-index* (last visited May 3, 2016).

[345] U.S. Dep't of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2015 National Occupational Employment and Wage Estimates by ownership, *http://www.bls.gov/oes/2014/may/oes_nat.htm* (last visited May 3, 2016) (using data for First-Line Supervisors of Office and Administrative Support Workers and General and Operations Managers for the health insurance industry).

Department of Insurance Economic Impact Assessment on Gender Nondiscrimination in Health Insurance found that covering transgender individuals under California's private and public health insurance plans would have an ''insignificant and immaterial'' impact on costs.[346] This conclusion was based on evidence of low utilization and the estimated number of transgender individuals in California. The transgender population of California was estimated to range between 0.0022% and 0.0173%.[347] The study revealed that, contrary to common assumptions, not all transgender individuals seek surgical intervention, and that gender-confirming health care differs according to the needs and pre-existing conditions of each individual.[348] Despite expecting a possible spike in demand for benefits due to former or current unmet demand, the California Insurance Department concluded that any increased utilization that might occur over time is likely to be so low that any resulting costs remain actuarially immaterial.[349] Additionally, issuers in California that established premium surcharges after enactment of California's Gender Nondiscrimination in Health Insurance Law subsequently eliminated them because they found they did not spend the extra funds generated.[350]

Two other studies also support the conclusion that the cost is de minimis for entities providing or administering health insurance coverage to come into compliance with this rule's provision of nondiscrimination on the basis of sex. One is a 2013 Williams Institute study of 34 public and private employers, and the second consists of cost projections of providing transition-related health-care benefits to members of the military.

The first of these two studies, a 2013 study of 34 employers that provided nondiscriminatory health care coverage, found that providing transition-related benefits to treat gender dysphoria had ''zero to very low costs.'' [351]

The second study, published in the *New England Journal of Medicine,* projected that the cost for providing transition-related health care benefits to members of the military would result in an annual increase of 0.012% of health care costs, ''little more than a rounding error in the military's $47.8 billion annual health care budget.'' [352] Based on the California and two other studies discussed above, we estimate that providing transgender individuals nondiscriminatory insurance coverage and treatment will impact a very small segment of the population due to the fact that the number of transgender individuals (and particularly those who seek surgical procedures in connection with their gender transition) in the general population is small, and consequently will have de minimis impact on the overall cost of care and on health insurance premiums.[353]

F. Accessibility of Electronic and Information Technology

Although Section 1557 requires covered entities to ensure that the health programs, services, and activities provided through electronic and information technology are accessible to individuals with disabilities, all covered entities affected by Section 1557 already have these obligations under Section 508, Section 504 or the ADA.

1. HHS Health Programs and Activities, Including the Federally-Facilitated Marketplaces

Section 508 requires that electronic and information technology developed, procured, maintained, or used by Federal agencies be accessible for individuals with disabilities (both members of the public and Federal employees). Section 504 also establishes general obligations for Federal agencies to make their programs that are provided through electronic and information technology accessible to individuals with disabilities. Both Section 504 and Section 508 were in place before the passage of the ACA. There is, therefore, no additional burden under Section 1557 for HHS health programs, including the Federally-facilitated Marketplaces, as the Section 1557 requirements are consistent with the obligations these programs already have under Section 504 and Section 508.

2. Recipients of Federal Financial Assistance From HHS and Title I Entities

Section 504 also establishes general obligations for entities receiving Federal financial assistance to make their programs, services, and activities provided through electronic and information technology accessible to individuals with disabilities. The ADA imposes similar accessibility requirements on covered entities. This rule thus imposes no additional burden on recipients of Federal financial assistance from HHS because Section 1557 is consistent with existing standards these entities are already obligated to meet under the ADA and Section 504. Title I entities have no Section 1557 burden with respect to this proposed requirement, as the Title I entities must already be compliant with the ADA, which is consistent with the Section 1557 accessibility standards.

G. Enforcing the Rule

After grievances are filed with covered entities or complaints are filed with OCR, there are associated costs to investigate and resolve those grievances and complaints. We believe the following costs result from enforcement of the Section 1557 regulation:

- Costs to covered entities for modifying and implementing grievance procedures to cover grievances filed under Section 1557.
- Costs to OCR for reviewing and investigating complaints, monitoring corrective action plans, and taking other enforcement actions against covered entities.

In the analysis below, we estimate the aggregate costs of these enforcement procedures, and analyze the costs to covered entities separately from the costs to OCR.

1. Costs to Covered Entities

Federal civil rights laws that were in place before the enactment of Section 1557 apply to entities that receive Federal financial assistance. Entities subject to those laws are already required to have in place established grievance procedures to address complaints of disability discrimination and complaints of sex discrimination in education programs. We anticipated that additional costs arising from the expansion of the grievance process to cover all bases included in Section 1557, including race, color, national origin, and age, as well as sex discrimination in health care, could impose additional costs on covered entities. We assumed a slight increase in the number of grievances filed, and a

[346] State of Cal., Dep't of Ins., Economic Impact Assessment Gender Nondiscrimination in Health Insurance. (Apr. 13, 2012). *http://translaw.wpengine.com/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf.*

[347] *Id.*

[348] *Id.* at 8.

[349] *Id.* at 9.

[350] *Id.* at 6–7.

[351] The Williams Inst., Cost and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers, at 2 (Sept. 2013), *http://williamsinstitute.law.ucla.edu/wp-content/uploads/Herman-Cost-Benefit-of-Trans-Health-Benefits-Sept-2013.pdf*

[352] A. Belkin, ''Caring for Our Transgender Troops — The Negligible Cost of Transition-Related Care,'' 373 New Eng. J. Med. 1089 (Sept. 15, 2015).

[353] State of Cal., Dep't of Ins., *supra* note 346, at 2, 5. Issuers in California that established a premium surcharge to cover the City of San Francisco's expected claim costs eventually eliminated the additional premium because they found their cost assumptions were 15 times higher than actual claims generated.

corresponding increase in time to investigate and resolve these additional grievances.

To compute the anticipated costs for covered entities to enforce the regulation, we looked to OCR data. The current number of civil rights complaints filed annually with OCR is approximately 3,000. Since the passage of Section 1557, OCR's complaint workload has increased slightly, with approximately 15 to 20 unique Section 1557 cases filed each year. If we include another ten cases per year as a result of the promulgation of the regulation, we calculate an increase of 30 cases per year or 1% of the annual caseload of 3,000. We assume the incremental workload will be similar for affected entities and thus will be approximately 1%. We anticipate that within the first five years following the promulgation of the regulation, complaints will initially increase, but then will eventually drop off as covered entities modify their policies and practices in response to the rule. Due to the likelihood that applicable changes will need to be phased in, we assume one half of the annual projected costs for investigating discrimination complaints will be incurred during the first year and three quarters of the annual projected enforcement costs will be spent in the second year and the full amounts in the third through fifth years. Although we have data on OCR's caseload, we have no data on the caseload of affected covered entities.

We assume that as a result of promulgating the regulation, the 41,250 covered entities with 15 or more employees will require an average of an additional 1% of a Full Time Equivalent (FTE) for designated grievance officials to investigate discrimination grievances in years three through five following publication of the final rule, with costs half as large in the first year and costs three quarters as large in the second year. We assume the grievance official's salary is equivalent to that of medical and health service managers (occupation code 11–9111), who have annual median wages of $103,680. These assumptions imply costs, after adjusting for fringe benefits and overhead, of $42.8 million in the first year, $64.2 million in the second year, and $85.5 million in years three through five following publication of the final rule.

One comment suggested that litigation costs may also rise as a result of issuance. We assume that the costs of litigation are included in the costs listed in the paragraph above.

The same incremental calculations apply to the workloads of State agencies and the officials working in these agencies. If we assume the same increases in workload at each State agency as discussed previously, and the average mid-level State official salary is $94,580 (including fringe benefits and overhead), we must multiply $94,580 by the number of State covered entities.[354] To arrive at the number of State covered entities we make the following assumptions:

- We assume that there are 56 Medicaid State agencies;
- We assume that there are 56 State health departments;
- We assume that there are 1,003 State and local government community hospitals;[355] and
- We assume that each of 3,143 counties has a county health department that provides direct health services (*e.g.,* immunization clinics) and is accountable to the State Health Department. We assume that each of the county health departments has a designated official for handling grievances.

The total number of State covered entities is 4,252. Multiplying $94,580 by 4,252 equals $402.2 million. One percent of this value equals $4.0 million. This implies costs of $2.0 million in the first year, $3.0 million in the second year and $4.0 million in subsequent years following the publication of the final rule.

2. Costs to OCR

We considered the various OCR enforcement costs together, based on OCR average salary data presented in its annual budgets. According to the FY 2016 President's Budget, $28,400,000 and 137 FTEs were requested for Enforcement and Regional Operations, at a cost of approximately $201,000 per FTE. Of the 137 FTEs, approximately 40 FTEs spend 100% of their investigative time enforcing the civil rights laws.[356] If we make the same assumption we did above and assume the same increase in caseload from the issuance of Section 1557 as discussed above, the anticipated increase in number of staff necessary would be approximately 0.4 of an FTE (1% of 40) and would cost approximately $40,200 in the first year, $60,300 in the second year, and $80,400 in subsequent years following the publication of the final rule.

3. Summary of Cost and Phase-In

The table below summarizes the costs attributable to the regulation that covered entities may incur following enactment of the final regulation. We assume that half of the training costs and changes to policies and procedures on the prohibition of discrimination on the basis of sex will be incurred in the first year and the second half will be expended in the second year. For covered entities that will be printing and distributing notices to their patients and policy holders, we assume that all of the estimated printing and distribution costs will be expended in the first year after the effective date of the rule. Familiarization costs, information collection requirements and paperwork burden costs would be incurred within the first year after the effective date of the final regulation. Cost of enforcement, by contrast, will increase over the course of the first five years.

TABLE 5—COST SUMMARY OF THE REGULATION FOLLOWING ENACTMENT OF THIS FINAL RULE

[Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total/ annualized
Training and Familiarization (undiscounted)	234.9	185.8	0.0	0.0	0.0	420.8
Training and Familiarization (3%)	228.1	175.2	0.0	0.0	0.0	88.1
Training and Familiarization (7%)	219.6	162.3	0.0	0.0	0.0	93.1
Enforcement (undiscounted)	44.8	67.2	89.6	89.6	89.6	381.0
Enforcement (3%)	43.5	63.4	82.0	79.6	77.3	75.5
Enforcement (7%)	41.9	58.7	73.2	68.4	63.9	74.6
Notice Publication (undiscounted)	7.2	0.0	0.0	0.0	0.0	7.2

[354] Based on the annual salary of Executive Secretary and Executive Administrative Assistant.

[355] American Hospital Ass'n: Fast Facts on US Hospitals, (Jan. 2016), *http://www.aha.org/research/rc/stat-studies/101207fastfacts.pdf.*

[356] This is based on an informal staff estimate.

TABLE 5—COST SUMMARY OF THE REGULATION FOLLOWING ENACTMENT OF THIS FINAL RULE—Continued

[Discounted 3% and 7% in millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total/ annualized
Notice Publication (3%)	7.0	0.0	0.0	0.0	0.0	1.5
Notice Publication (7%)	6.7	0.0	0.0	0.0	0.0	1.6
Sex discrimination	24.8	24.8	0.0	0.0	0.0	49.5
Policy and Procedure Changes (undiscounted):						
Sex discrimination	24.0	23.3	0.0	0.0	0.0	10.3
Policy and Procedure Changes (3%):						
Sex discrimination	23.1	21.6	0.0	0.0	0.0	10.9
Policy and Procedure Changes (7%):						
Language Access Plan (undiscounted)	36.0	12.0	12.0	12.0	12.0	84.1
Language Access Plan (3%)	35.0	11.3	11.0	10.7	10.4	17.1
Language Access Plan (7%)	33.7	10.5	9.8	9.2	8.6	17.5
Total (undiscounted)	347.7	289.8	101.6	101.6	101.6	942.5
Total (3%)	337.6	273.2	93.0	90.3	87.7	192.5
Total (7%)	325.0	253.2	83.0	77.5	72.5	197.8

Note: Discounted and annualized values take into account the cost of borrowing and paying back funds at hypothetical interest rates to simulate opportunity costs.

This completes our analysis of the costs of the final rule. Next, we examine the benefits that can be expected to accrue as a result of the final rule.

III. Benefits & Transfers

In enacting Section 1557 of the ACA, Congress recognized the benefits of equal access to health services and health insurance that all individuals should have, regardless of their race, color, national origin, age, or disability. Section 1557 brought together the rights to equal access that had been guaranteed under Title VI, the Age Act and Section 504. At the same time, Congress extended these protections and rights to individuals seeking access to health services and health insurance without discrimination on the basis of sex.

This rule implements the provisions of Section 1557. In most respects, the rule clarifies existing obligations under existing authorities, and we have noted in the cost analysis that we do not expect that covered entities will incur costs related to the clarification of those existing obligations in the final rule. As the HHS LEP Guidance [357] and regulation implementing Title VI [358] indicate, recipients are already required to take reasonable steps to ensure meaningful access to their programs and activities by persons with limited English proficiency. We note that the additional provisions related to serving individuals with limited English proficiency in the final rule may create some additional costs but will also create substantial benefits to patients and providers by improving access to quality care.[359]

Studies show that individuals with limited English proficiency experience barriers to receiving regular and adequate health care. However, according to the Institute of Medicine, when reliable language assistance services are utilized, patients experience treatment-related benefits, such as enhanced understanding of physician instruction, shared decision-making, provision of informed consent, adherence with medication regimes, preventive testing, appointment attendance, and follow-up compliance.[360] Additional intangible benefits may include retention of cultural information, exchange of information, greater satisfaction with care,[361] and enhanced privacy and autonomy of individuals with limited English proficiency who may have previously had to rely on family members for language assistance.[362]

Health service providers also benefit from providing language assistance services for individuals with limited English proficiency. Providers can more confidently make diagnoses, prescribe medications, reach treatment decisions, and ensure that treatment plans are understood by patients.[363] ''Language is also an important tool for clinicians to establish an empathic connection with patients[;]'' accordingly, language assistance services benefit both patients and providers alike.[364] One study states that ensuring effective communication can also help providers avoid costs associated with ''damages paid to patients, legal fees, the time lost when defending a lawsuit, the loss of reputation and patients, the fear of possible monetary loss, and the stress and distraction of litigation.'' [365] Another study of malpractice claims found that a malpractice carrier insuring in four states paid over $2 million in damages or settlements as well as over $2 million in legal fees over a four year period for claims arising from failure to use an appropriate interpreter.[366]

We have also noted that we expect that the prohibition of sex discrimination in the final rule will generate certain actions and other changes in behavior by covered entities and that these actions and changes will impose costs. These actions and other

[357] 68 FR 47311, 47313 (Aug. 8, 2003).

[358] 45 CFR 80.3.

[359] Report to Congress. Assessment of the Total Benefits and Costs of Implementing Executive Order No. 13166: Improving Access to Services for Persons with Limited English Proficiency (Mar. 2002), p. 20, *https://www.justice.gov/sites/default/files/crt/legacy/2010/12/14/omb-lepreport.pdf.*

[360] Brian D. Smedley, Adrienne Y. Stith, Alan R. Nelson, eds., Institute of Medicine, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care, Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Board on Health Science Policy,* (2003), pp.142, 191; Report to Congress, *supra* note 359 at 20–22.

[361] *Id.*

[362] Kelvin Quan & Jessica Lynch, *The High Costs of Language Barriers in Medical Malpractice* (2010), p.17, *http://www.healthlaw.org/images/stories/High_Costs_of_Language_Barriers_in_Malpractice.pdf.*

[363] ASPE, *Caring for Immigrants: Health Care Safety Nets in Los Angeles, New York, Miami and Houston,* (2001), *https://aspe.hhs.gov/execsum/caring-immigrants-health-care-safety-nets-los-angeles-new-york-miami-and-houston;* Elizabeth A. Jacobs, Donald S. Shepard, Jose A. Suaya and Esta-Lee Stone, *Overcoming Language Barriers in Health Care: Costs and Benefits of Interpreter Services, Am. J. Public Health (2004), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1448350/;* Unequal Treatment, *supra* note 360 at 141.

[364] *Unequal Treatment, supra* note 360 at 141.

[365] *The High Costs of Language Barriers in Medical Malpractice, supra* note 362 at 15.

[366] Agency for Healthcare Research and Quality, Improving Patient Safety Systems for Patients With Limited English Proficiency: A Guide for Hospitals (2012), *http://www.ahrq.gov/sites/default/files/publications/files/lepguide.pdf.*

changes in behavior will also result in benefits.

The provisions prohibiting sex discrimination in the ACA increase the affordability and accessibility of health care for women and transgender individuals. However, despite the ACA improving access to health services and health insurance, many women and transgender individuals continue to experience discrimination in the health care context, which can lead to denials of adequate health care and increases in existing health disparities in underserved communities. This continued discrimination demonstrates the need for further clarification regarding the prohibition of discrimination on the basis of sex.

Prior to the enactment of the ACA, insurance companies were allowed to impose higher premiums on women or deny women coverage altogether. If issuers did cover women, they frequently did not cover a number of women's health services, including routine preventive services, such as pap smears or mammograms. Insurance premiums previously could differ by sex, and were often higher for females relative to males. The ACA prohibits differential treatment based on sex, includes maternity coverage in essential health benefits, and requires non-grandfathered plans to cover women's preventive services without copays, among other benefits.

For transgender individuals, a major barrier to receiving care is a concern over being refused medical treatment based on bias against them.[367] In a 2010 report, 26.7% of transgender respondents reported that they were refused needed health care.[368] A 2011 survey revealed that 25% of transgender individuals reported being subject to harassment in medical settings, and 50% reported having to teach their medical providers about transgender care.[369] We received many comments expressing anecdotal evidence of these statistics.

Another potential barrier for transgender individuals to care is covered entities' nondiscrimination policies, which often do not include gender identity. The 2014 Human Rights Campaign Healthcare Equality Index, which evaluates health care facilities' LGBT policies and practices, found that among the 640 hospitals it evaluated, 501 had patient nondiscrimination policies but of those only 257 had a patient nondiscrimination policy that included both the terms ''sexual orientation'' and ''gender identity.'' [370]

Yet another barrier to care for transgender individuals is the process of obtaining health insurance coverage. A study by the Center for American Progress found that transgender individuals have often experienced difficulties when seeking insurance coverage.[371] Similarly, in 2014, Out2Enroll, a national campaign that serves as a key link between LGBT communities and the ACA by connecting LGBT people with information about their new coverage options, issued findings in a report entitled *''Key Lessons for LGBT Outreach and Enrollment under the Affordable Care Act.''* [372] The report focuses on the lack of adequate training of Navigator staff when encountering LGBT individuals seeking access to the Health Insurance Marketplaces. A major complaint was that Navigator staff was unaware of the multitude of discriminatory practices and policy restrictions in which issuers engage to deny or restrict coverage of transgender individuals, and that Navigator staff lacked basic knowledge of health issues that are unique to transgender individuals.[373]

Ultimately, transgender individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care, which may lead to negative health consequences.[374] A study by the National Center for Transgender Equality and the National Gay and Lesbian Task Force found that ''one-quarter of the more than 6,400 transgender and gender-nonconforming respondents reported . . . being denied needed treatment[,] . . . being harassed in health care settings[,] . . . [and] postponing medical care because of discrimination by providers.'' [375] We received several comments echoing these statements, both from individuals citing personal experiences and from entities citing data. This kind of discrimination exacerbates health disparities experienced by the LGBT population, including: higher rates of mental health issues, including depression and suicide attempts; higher risk of HIV/AIDS; higher use of tobacco and other drugs; and higher risk of certain cancers, such as breast cancer, with some portion of the differential potentially attributable to barriers to health care.[376]

By prohibiting discrimination on the basis of sex, Section 1557 would result in more women and transgender individuals obtaining coverage and accessing health services. Since 2013, the uninsured rate for women has declined, with nearly 9.5 million women gaining health coverage as of 2016.[377] Similarly, uninsured rates for LGBT individuals dropped from 34% in 2013 to 26% in 2014.[378] While these declines in the rates of the uninsured are attributable to many factors, among these factors may be provisions in the ACA prohibiting discriminatory practices in insurance. We expect that the Section 1557 regulation may contribute to a continued reduction in the number of individuals who are uninsured, although the reduction would be much more modest.

For a representative example, we look to a State of California economic impact assessment of State practices prohibiting gender discrimination in health care, which cites the following benefits: [379]

1. Reduced violence against affected individuals;

2. Reduced depression and suicide attempts among the affected population; and

3. Overall declines in substance abuse, smoking and alcohol abuse rates, and improvements in mental health among treated individuals in LGBT populations who receive appropriate medical treatment.

Moreover, because discrimination contributes to health disparities, the prohibition of sex discrimination in health care under Section 1557 can help

[367] Lambda Legal, *supra* note 333 at 12–13.

[368] *Id.* at 10.

[369] National Center for Transgender Equality and National Gay and Lesbian Task Force, Injustice at Every Turn: A Report of the National Transgender Discrimination Survey, 5–6 (2011), *http://www.thetaskforce.org/.*

[370] Human Rights Campaign, Healthcare Equality Index 2014, *http://www.hrc.org/reports/hei.*

[371] Laura E. Durso, Kellan Baker, and Andrew Cray, Center for American Progress Issue Brief: LGBT Communities and the Affordable Care Act Findings from a National Survey, (Oct. 10, 2013), *http://www.preventionjustice.org/wp-content/uploads/2013/10/CAP–LGBT-Messaging-Research.pdf.*

[372] Out2Enroll, Key Lessons for LGBT Outreach and Enrollment under the Affordable Care Act (July 24, 2014), *http://out2enroll.org/lgbthealthcare/wp-content/uploads/2014/07/O2E_KeyLessons_FINAL.pdf.*

[373] *Id.* at 24.

[374] Kellan E, Baker, Center for American Progress, Open Doors for All, Sexual Orientation and Gender Identity Protections in Health Care (Apr. 30, 2015), *https://www.americanprogress.org/issues/lgbt/report/2015/04/30/112169/open-doors-for-all/.*

[375] *Id.*

[376] *Id.*

[377] U.S. Dep't of Health & Human Servs., Office of the Assistant Secretary for Planning and Eval., ASPE Issue Brief: Health Insurance Coverage and the Affordable Care Act 201–2016, 2 (Mar. 3, 2016) *https://aspe/hhs.gov.*

[378] Kellan Baker, Laura E. Durso, and Andrew Cray, Center for American Progress, Moving the Needle, The Impact of the Affordable Care Act on LGBT Communities, 3 (Nov. 2014), *https://www.americanprogress.org/issues/lgbt/report/2014/11/17/101575/moving-the-needle/.*

[379] California Department of Insurance, *supra* note 346, at 10–12.

reduce health disparities. While it is not possible to quantify the benefits of the reduction in health disparities, the benefits would include more people receiving adequate health care, regardless of their sex, including gender identity.

The health and longevity benefits discussed above as potential effects of this rule assume additional or higher-quality medical services are provided to affected individuals. These services would be associated with costs (which we lack data to estimate). As mentioned in the earlier discussion of actuarial risk, to the extent that changes in insurance premiums do not alter how society uses its resources, the final rule would result in transfers between members of society, rather than social costs or benefits. In addition to women and transgender individuals, health service providers and the Federal government could also be recipients of these transfers. For example, in 2013, $53.3 billion was paid to offset uncompensated care, of which the Federal government paid for approximately $32.8 billion.[380] Based on estimated coverage gains in 2014, uncompensated care costs are expected to continue to fall substantially following continued major insurance coverage expansions, including coverage expansions through the Health Insurance Marketplace℠.[381] While issuance of the Section 1557 regulation is not a factor in this projection, we believe that the Section 1557 regulation will likewise contribute to a decrease in payments by the Federal government for uncompensated care by promoting an increase in the number of individuals who have coverage when they receive care.

Aside from the specific benefits and transfers that women and transgender individuals, and the health care community can be expected to gain from the enactment of the regulation, there are additional benefits that are intangible and unquantifiable that derive from providing equal access to health care for all.

[380] Teresa A. Coughlin, John Holahan, Kyle Caswell, and Megan McGrath, The Henry J. Kaiser Family Foundation, Uncompensated Care for the Uninsured in 2013: A Detailed Examination (May 30, 2014), p. 4. *https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8596-uncompensated-care-for-the-uninsured-in-2013.pdf.*

[381] U.S. Dep't of Health & Human Servs., Office of the Assistant Sec'y for Planning and Eval., Thomas DeLeire, Karen Joynt, and Ruth McDonald, ASPE Issue Brief, Impact of Insurance Expansion on Hospital Uncompensated Care Costs in 2014 (Sept. 24, 2015) *https://aspe.hhs.gov/sites/default/files/pdf/77061/ib_UncompensatedCare.pdf.*

IV. Alternatives Considered

In the course of developing this regulation, OCR considered various alternatives. Some of those alternatives are discussed in the preamble. A discussion of alternatives cannot cover all alternatives considered by OCR. The following alternatives are meant to be a representative sample to show how burden reduction was a major consideration in constructing the standards in this regulation.

The first option is no new regulatory action. We did not select this option because we believe the regulation provides substantial benefits to society, net of the costs. We received a comment suggesting that we consider either writing a more informative than prescriptive regulation or delaying the regulation, based on a possible trend of increased voluntary compliance by health care agencies with nondiscrimination statutes. OCR's current experience, however, points to the importance of and need for a prescriptive regulation. OCR provides education and information on the civil rights statutes and regulations, conducts technical assistance and outreach to promote compliance, and is developing training materials to provide information and technical assistance on this rule. However, OCR has found that providing information and outreach is not sufficient to ensure nondiscrimination in health care programs and activities. OCR continues to receive and resolve many complaints of discrimination and to hear of ongoing discrimination through outreach and communications with stakeholders. The regulation will inform stakeholders of their rights so that affected individuals know that they can seek OCR's assistance, and will provide clarity for covered entities, limiting uncertainty and promoting compliance. In addition, the majority of the comments from the public in response to the proposed rule favored issuance of a regulation.

OCR considered requiring covered entities to provide separate notices, covering separate content, *e.g.,* separate notices on the requirements concerning the provision of meaningful access for individuals with limited English proficiency, requirements concerning effective communication for individuals with disabilities, and policies on nondiscrimination. To reduce the burden on covered entities, OCR rejected this option in favor of a comprehensive single-notice requirement. We are also permitting entities to combine the Section 1557 notice with other notices that the entities may be required to post.

OCR decided to further reduce the burden imposed on covered entities by the notice requirement by making available a sample notice, located in Appendix A. OCR allows covered entities flexibility in complying with the notice requirement by giving covered entities the option of using the sample notice or developing their own notice. Although OCR considered requiring covered entities to post the notice in 15 languages (Spanish (or Spanish Creole), Chinese, Vietnamese, Korean, Tagalog, Russian, Arabic, French Creole, French (including Patois, Cajun), Portuguese (or Portuguese Creole), Polish, Japanese, Italian, German, and Persian (Farsi)), we rejected that option. Instead, we are providing the notice translated into 64 languages, and are allowing covered entities the discretion to post one or more of the translated notices. We believe that making translated notices readily available to covered entities maximizes efficiency and economies of scale, provides flexibility while minimizing burden, and helps provide greater access for beneficiaries and consumers. Additionally, although OCR considered requiring covered entities to create their own taglines in the top 15 national languages spoken by individuals with limited English proficiency, we rejected that option. Instead, OCR is making available to covered entities the taglines in 64 languages. As the tagline requirement for the covered entities only requires the cost of printing and posting, this burden is expected to be minimal.

OCR considered not providing training materials to covered entities on the requirements of the regulation. However, in order to reduce costs and burden, OCR is providing these materials, which will reduce covered entities' costs of developing training materials from $500 per entity to $125 per entity, resulting in a savings of approximately $104 million. Entities are assumed to bear one quarter of the total costs. These costs result from paying the presenters who will run the training sessions, providing classroom space, and supplementing the training materials that OCR is making available (should they choose to do so).

OCR considered remaining silent on covered entities' obligations to comply with Section 1557's prohibition of national origin discrimination as it affects individuals with limited English proficiency. We rejected this approach because we were concerned that OCR's silence would create ambiguity about covered entities' obligations to individuals with limited English proficiency and could jeopardize the access of individuals with limited

English proficiency to covered entities' health programs and activities. Clearly explaining the standards also promotes compliance and reduces enforcement costs. Options for addressing the prohibition of national origin discrimination as it affects individuals with limited English proficiency are discussed in the preamble to the proposed rule.

OCR considered a regulatory scheme requiring covered entities to provide meaningful access to each individual with limited English proficiency by providing effective language assistance services, at no cost, unless such action would result in an undue burden or fundamental alteration. OCR also considered requiring covered entities of a certain type or size to have enhanced obligations to provide language assistance services. Such enhanced obligations would include providing a predetermined range of language assistance services in certain non-English languages that met defined thresholds. A covered entity that was not of a certain type or size still would be required to provide meaningful access to each individual with limited English proficiency in its health programs and activities, but the covered entity would not have to provide a predetermined range of language assistance services in certain non-English languages. OCR also explored applying the threshold requirement to standardized vital documents on a national, State, or county level, as well as specific to a covered entity's geographic service area.

The strengths of these alternate regulatory schemes included limited obligations for small businesses providing health programs or activities and defined standards for larger entities. The costs of these approaches included the complexity of the regulatory scheme and the potential burden on the covered entities of a certain type or size that would have enhanced applications. OCR determined these costs outweigh the benefits.

OCR considered drafting new provisions addressing effective communication (apart from communication through electronic and information technology) with individuals with disabilities, but instead is incorporating provisions of the regulation implementing Title II of the ADA to ensure consistency for covered entities and potentially reduce burden by limiting resources spent on training and modification of policies and procedures.

Options regarding communication through electronic and information technology are discussed in the preamble to the regulation. Regarding the accessibility requirements under the proposed regulation, OCR at first considered a narrower interpretation that the rule applied only to access to health programs and activities provided through covered entities' Web sites. However, we chose a broader interpretation, to include both Web sites and other means of electronic and information technology. While this could potentially increase the burden on recipients of Federal financial assistance and State-based Marketplaces, this would offer clarity to covered entities, increase the benefit of the rule, and help enhance access for individuals with disabilities.

In the area of compliance, OCR considered having one set of procedures for all compliance activities involving recipients of Federal financial assistance and State-based Marketplace℠ entities. Instead, OCR decided to adopt the unique Age Act procedures [382] for age-related compliance activities under Section 1557 because Age Act compliance activities and Section 1557 compliance activities regarding age discrimination are likely to substantially overlap.

With regard to other areas of compliance, OCR considered developing a separate set of procedures for Section 1557 compliance activities involving HHS health programs and activities, but decided to largely adopt the existing procedures for disability compliance activities involving HHS health programs and activities (with some enhancement) to improve efficiencies for OCR and the HHS health programs and activities covered by Section 1557.

V. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately $146 million.

The Unfunded Mandates Reform Act does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from: (1) Imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

Our impact analysis shows that burden associated with training staff working for covered entities will be spread widely across health care entities, State and local governmental entities, and a substantial number of health insurance issuers. The analysis estimates the unfunded burden will be about $422 million in training and familiarization costs. We project that for the first few years following promulgation of the final rule, private sector costs for investigating discrimination complaints may amount to $87 million per year. Within the first five years following the final rule's promulgation, we anticipate complaints will increase, and then eventually drop off as covered entities modify their policies and practices in response to the final rule.

As we explain in the RIA, we believe there will be benefits gained from the promulgation of this regulation in the form of reduction in discrimination based on race, color, national origin, sex, age, and disability, and the corresponding improvement in the quality of care to underserved communities. In response to comments concerning the costs to covered entities, we note that we have not included some changes that would have been beneficial to individuals because we recognize that they would be costly for covered entities.

VI. Executive Order 13132: Federalism

As required by Executive Order 13132 [383] on Federalism, OCR examined the effects of provisions in the regulation on the relationship between the Federal government and the States. OCR has concluded that the regulation does have Federalism implications but preempts State law only where the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.

The regulation attempts to balance State autonomy with the necessity of creating a Federal floor that will provide a uniform level of nondiscrimination protection across the country. The regulation restricts regulatory preemption of State law to the minimum level necessary to achieve the objectives of the underlying Federal statute, Section 1557 of the ACA.

[382] The Age Act procedures, for example, require mediation of all age discrimination complaints, and exhaustion of administrative remedies prior to the filing of a civil lawsuit. 45 CFR 91.43, 91.50.

[383] Exec. Order No. 13132, 64 FR 43255 (1999).

It is recognized that the States generally have laws that relate to nondiscrimination against individuals on a variety of bases. State laws continue to be enforceable, unless they prevent application of the final rule. The final rule explicitly provides that it is not to be construed to supersede State or local laws that provide additional protections against discrimination on any basis articulated under the regulation. Provisions of State law relating to nondiscrimination that is ''more stringent'' than the proposed Federal regulatory requirements or implementation specifications will continue to be enforceable.

Section 3(b) of Executive Order 13132 recognizes that national action limiting the policymaking discretion of States will be imposed only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance. Discrimination issues in relation to health care are of national concern by virtue of the scope of interstate health commerce. The ACA's provisions reflect this position.

Section 3(d)(2) of Executive Order 13132 requires that where possible, the Federal government defer to the States to establish standards. Title I of the ACA authorized the Secretary to promulgate regulations to implement Section 1557, and we have done so accordingly.

Section 4(a) of Executive Order 13132 expressly contemplates preemption when there is a conflict between exercising State and Federal authority under a Federal statute. Section 4(b) of the Executive Order authorizes preemption of State law in the Federal rulemaking context when ''the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.'' The approach in this regulation is consistent with these standards in the Executive Order in superseding State authority only when such authority is inconsistent with standards established pursuant to the grant of Federal authority under the statute.

Section 6(b) of Executive Order 13132 includes some qualitative discussion of substantial direct compliance costs that State and local governments could incur as a result of a proposed regulation. We have determined that the costs of the final rule will not impose substantial direct compliance costs on State or local governments. We have considered the cost burden that this rule will impose on State and local health care and benefit programs, and estimate State and local government costs will be in the order of $17.8 million in the first two years of implementation. The $17.8 million represents the sum of the costs of training State workers and enforcement costs attributable to State agencies analyzed above.

VII. Regulatory Flexibility Act (RFA)

The RFA requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule will have a significant impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as:

(1) A proprietary firm meeting the size standards of the Small Business Administration (SBA);

(2) A nonprofit organization that is not dominant in its field; or

(3) A small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of ''small entity'').

HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3% for 5% or more of affected small entities.

In instances where OCR judged that the final rule would have a significant impact on a substantial number of small entities, we considered alternatives to reduce the burden. To accomplish our task, we first identified all the small entities that may be impacted, and then evaluated whether the economic burden we determined in the RIA represents a significant economic impact.

A. Entities That Will Be Affected

HHS has traditionally classified most health care providers as small entities even though some nonprofit providers would not meet the definition of ''small entity'' were they proprietary firms. Nonprofit entities are small if they are independently owned and operated and are not dominant in their fields.

The CMS Provider of Service file has indicators for profit and nonprofit entities, but these have proven to be unreliable. The Census data identifies firms' tax status by profit and non-profit status but only reports revenues and does not report them by the profit and non-profit status of the entity.

1. Physicians

One class of providers we do not automatically classify as small businesses is physician practices. Physician practices are businesses and therefore are ''small'' if they meet the SBA's definition. The current size standard for physicians (excluding mental health specialists) (North American Industry Classification System code 62111) is annual receipts of less than $11 million.[384] Using the Census data showing the number of firms, employees and payroll, we selected physicians that reported fewer than 20 employees as the top end for small physician offices. This equaled 17,835 entities or 9.6% of all physician offices defined as ''large.'' This left 167,814 offices or 90.4% as ''small.''[385]

2. Pharmacies

Pharmacies also are businesses, and the size standard for them is annual receipts of less than $27.5 million. According to Census Statistics of U.S. Businesses, there are 18,852 pharmacy and drug store firms (North American Industry Classification System code 44611). Because of the lack of revenue or receipt data for pharmacies, we are unable to estimate the number of small pharmacies based on the SBA size standard. However, using the number of employees taken from the Statistics of U.S. Businesses as a proxy for revenues, the data is divided by number of employees per firm and shows the number of employers with fewer than 20 employees and those with more than 20 employees.[386] The number of firms with fewer than 20 employees is 16,520 and represents 88% of the total number of pharmacy firms. It seemed reasonable to assume that firms with fewer than 20 employees satisfy the SBA size standard and thus we accepted that the number of small pharmacy firms equaled 16,520. As with the number of small physician offices, our method can only identify the minimum number of ''small'' pharmacies that meet the SBA size standard. We cannot determine the actual number of ''small'' pharmacies.

3. Health Insurance Issuers

Another class of covered entities that are business enterprises is health insurance issuers. The SBA size standard for health insurance issuers is annual receipts of $38.5 million. Although the Blue Cross/Blue Shield companies that operate in some markets are organized as nonprofit entities, they often are large enough so as to not meet the definition of ''small entity.''

[384] U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes. Small Business Administration, (June, 2016), *https://www.sba.gov/sites/default/files/Size5FStandards5FTable.pdf.*

[385] Physician practices may earn more than $11 million per year and that would reduce the number of ''large'' practices to be excluded from the analysis. But as we will later show, large practices will have proportionally larger workforce staff that must be excluded from the analysis.

[386] U.S. Census Bureau, Statistics of U.S. Businesses, *supra* note 314.

Unfortunately, we cannot use the Census revenue data for estimating the number of small health insurance issuers because the Census data combines life and health insurance. Substituting costs for revenues allows us to obtain a rough estimate of the number of large insurance issuers, realizing that cost will probably be less than revenues, thus giving us a lower count of large issuers. Using the National Health Expenditure for 2013, net cost of health insurance equaled $173.6 billion. However, the 2012 Census data report a total of 815 health insurance issuers. Dividing the $174 billion in costs by the number of insurance issuers reported in the census tables yields average costs of over $213 million, which means that average annual revenues per issuer exceeds $213 million. We concluded, therefore, that there are almost no small insurance issuers. The above analysis comports with the conclusion CMS published in the Health Insurance Web Portal Requirements.[387]

4. Local Government Entities

We also excluded local governmental entities from our count of small entities because we lack the data to classify them by populations of fewer than 50,000. The following table shows the number of small covered entities we estimated could be affected by the proposed rule.

TABLE 6—SMALL COVERED ENTITIES

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
62141	HMO medical centers	104
62142	Kidney dialysis centers	492
62143	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home health care services	21,668
6219	All other ambulatory health care services	6,956
62321	Residential mental retardation facilities	6,225
62199	General medical and surgical hospitals	3,067
621991	Psychiatric and substance abuse hospitals	411
6221	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	16,520
6211	Offices of physicians	167,814
	Navigator grantees	100
	Total small entities	254,998

B. Whether the Rule Will Have a Significant Economic Impact on Covered Small Entities

Total undiscounted costs associated with the final rule are an average of $189 million per year over a five year period. If all of those costs are borne by small entities, this amounts to an average of $739 each year over that five year period. As a result, we believe that fewer than 5% of all small entities will experience a burden of greater than 3% of their revenues. Ambulatory health care services facilities (North American Industry Classification System 621), for example, are small entities with an average of 13 employees and revenue of $1.7 million based on 2012 reported data for employees of 6.4 million and total revenues of $825.7 million for 485,235 firms.[388] In addition, the majority of the costs associated with this final rule are proportional to the size of entities, meaning that even the smallest of the affected entities are unlikely to face a substantial impact. Thus, we would not consider this regulation a significant burden on a substantial number of small entities, and, therefore, the Secretary certifies that the final rule will not have a significant impact on a substantial number of small entities.

VIII. Conclusion

For the most part, because this regulation is consistent with existing standards applicable to the covered entities, the new burdens created by its issuance are minimal. The major impacts are in the areas of voluntary training, posting of notices, enforcement (where increased caseloads pose incremental costs on covered entities), voluntary development of language access plans, and revisions or development of new policies and procedures. The final rule does not include broad expansions of existing civil rights requirements on covered entities, and therefore minimizes the imposition of new burdens. Nevertheless, it is still a major rule with economically significant costs. The annualized cost of this rule over the first five years following its publication is $192.5 million using a discount rate of 3%, and $197.8 million using a discount rate of 7%. This RIA was organized and designed to explain the origin of these cost impacts and to incorporate relevant public comments.

[387] 75 CFR 24481, May 5, 2010.

[388] U.S. Dep't of Labor, Bureau of Labor Statistics, Industries at a Glance, *http://www.bls.gov/iag/tgs/iag621.htm* (last visited Mar. 26, 2016).

TABLE 7—ACCOUNTING STATEMENT

Accounting statement				
Category	Primary estimate	Low estimate	High estimate	Source
BENEFITS				
Qualitative Benefits (02)	• Potential health improvements and longevity extensions as a result of reduced barriers to medical care for transgender individuals.		.....	RIA
COSTS (millions)				
Annualized monetized	Covered entities train 40% of their employees on the new regulations	Covered entities train 60% of their employees on the new regulations	.....	
3%	192.5	177.0	208.1	RIA
7%	197.8	181.4	214.2	RIA
Non-quantified costs (02)	Costs of increased provision of health care services as a result of reduced barriers to access for transgender individuals.		.....	RIA
Transfers (02)	Health insurance premium reductions for affected women, with offsetting increases for other premium payers in affected plans.		.....	RIA
Effects on State and Local Governments (02)	$17.8 million costs in the first 2 years (training + enforcement)		.....	RIA
Effects on Small Entities (02)	Average of less than $1,000 per small entity per year		.....	RFA

List of Subjects in 45 CFR Part 92

Administrative practice and procedure, Civil rights, Discrimination, Elderly, Health care, Health facilities, Health insurance, Health programs and activities, Individuals with disabilities, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Department of Health and Human Services adds 45 CFR part 92 as follows:

PART 92—NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AGE, OR DISABILITY IN HEALTH PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE AND HEALTH PROGRAMS OR ACTIVITIES ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OR ENTITIES ESTABLISHED UNDER TITLE I OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

Subpart A—General Provisions

92.1 Purpose and effective date.
92.2 Application.
92.3 Relationship to other laws.
92.4 Definitions.
92.5 Assurances required.
92.6 Remedial action and voluntary action.
92.7 Designation of responsible employee and adoption of grievance procedures.
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Subpart B—Nondiscrimination Provisions

92.101 Discrimination prohibited.

Subpart C—Specific Applications to Health Programs and Activities

92.201 Meaningful access for individuals with limited English proficiency.
92.202 Effective communication for individuals with disabilities.
92.203 Accessibility standards for buildings and facilities.
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92.205 Requirement to make reasonable modifications.
92.206 Equal program access on the basis of sex.
92.207 Nondiscrimination in health-related insurance and other health-related coverage.
92.208 Employer liability for discrimination in employee health benefit programs.
92.209 Nondiscrimination on the basis of association.

Subpart D—Procedures

92.301 Enforcement mechanisms.
92.302 Procedures for health programs and activities conducted by recipients and State-based Marketplaces.
92.303 Procedures for health programs and activities administered by the Department.
Appendix A to Part 92—Sample Notice Informing Individuals About Nondiscrimination and Accessibility

Requirements and Sample Nondiscrimination Statement
Appendix B to Part 92—Sample Tagline Informing Individuals With Limited English Proficiency of Language Assistance Services
Appendix C to Part 92—Sample Section 1557 of the Affordable Care Act Grievance Procedure

Authority: 42 U.S.C. 18116, 5 U.S.C. 301.

Subpart A—General Provisions

§ 92.1 Purpose and effective date.

The purpose of this part is to implement Section 1557 of the Patient Protection and Affordable Care Act (ACA) (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557 provides that, except as provided in Title I of the ACA, an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA. This part applies to health programs or activities administered by recipients of Federal financial assistance from the Department, Title I entities that administer health programs or activities, and Department-administered health programs or activities. The effective date of this part shall be July 18, 2016, except to the extent that provisions of this part require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

§ 92.2 Application.

(a) Except as provided otherwise in this part, this part applies to every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity.

(b)(1) Exclusions to the application of the Age Discrimination Act of 1975, as set forth at 45 CFR 91.3(b)(1), apply to claims of discrimination based on age under Section 1557 or this part.

(2) Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.

(c) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 92.3 Relationship to other laws.

(a) *Rule of interpretation.* Neither Section 1557 nor this part shall be construed to apply a lesser standard for the protection of individuals from discrimination than the standards applied under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, or the regulations issued pursuant to those laws.

(b) *Other laws.* Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals under Title VI of the Civil Rights Act of 1964, Title VII of the Civil Rights Act of 1964, the Architectural Barriers Act of 1968, Title IX of the Education Amendments of 1972, Sections 504 or 508 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008, or other Federal laws or to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.

§ 92.4 Definitions.

As used in this part, the term—

1991 Standards means the 1991 ADA Standards for Accessible Design, published at Appendix A to 28 CFR part 36 on July 26, 1991, and republished as Appendix D to 28 CFR part 36 on September 15, 2010.

2010 Standards means the 2010 ADA Standards for Accessible Design, as defined at 28 CFR 35.104.

ACA means the Patient Protection and Affordable Care Act (Pub. L. 111–148, 124 Stat. 119 (2010) as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. 111–152, 124 Stat. 1029 (codified in scattered sections of U.S.C.)).

ADA means the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), as amended.

Age means how old an individual is, or the number of elapsed years from the date of an individual's birth.

Age Act means the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), as amended.

Applicant means an individual who applies to participate in a health program or activity.

Auxiliary aids and services include:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.303(b); note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunication products and systems, text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs; large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision;

(3) Acquisition or modification of equipment and devices; and

(4) Other similar services and actions.

Covered entity means:

(1) An entity that operates a health program or activity, any part of which receives Federal financial assistance;

(2) An entity established under Title I of the ACA that administers a health program or activity; and

(3) The Department.

Department means the U.S. Department of Health and Human Services.

Director means the Director of the Office for Civil Rights (OCR) of the Department.

Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the ADA, 42 U.S.C. 12102, as amended. Where this part cross-references regulatory provisions that use the term ''handicap,'' ''handicap'' means ''disability'' as defined in this section.

Electronic and information technology means the same as ''electronic and information technology,'' or any term that replaces ''electronic and information technology,'' as it is defined in 36 CFR 1194.4.

Employee health benefit program means:

(1) Health benefits coverage or health insurance coverage provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to an employer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1191b(a)(1)), third party administrator, or health insurance issuer.

(2) An employer-provided or employer-sponsored wellness program;

(3) An employer-provided health clinic; or

(4) Long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer for the benefit of an employer's employees.

Federal financial assistance. (1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal government provides or otherwise makes available assistance in the form of:

(i) Funds;

(ii) Services of Federal personnel; or

(iii) Real and personal property or any interest in or use of such property, including:

(A) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal government.

(2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including all tax credits under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health-related insurance coverage for payment to or on behalf of an individual obtaining health-related insurance coverage from that entity or extended by the Department directly to such individual for payment to any entity providing health-related insurance coverage.

Federally-facilitated Marketplace℠ means the same as ''Federally-facilitated Exchange'' defined in 45 CFR 155.20.

Gender identity means an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth. The way an individual expresses gender identity is frequently called ''gender expression,'' and may or may not conform to social stereotypes associated with a particular gender. A transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Health Insurance Marketplace℠ means the same as ''Exchange'' defined in 45 CFR 155.20.

Health program or activity means the provision or administration of health-related services, health-related insurance coverage, or other health-related coverage, and the provision of assistance to individuals in obtaining health-related services or health-related insurance coverage. For an entity principally engaged in providing or administering health services or health insurance coverage or other health coverage, all of its operations are considered part of the health program or activity, except as specifically set forth otherwise in this part. Such entities include a hospital, health clinic, group health plan, health insurance issuer, physician's practice, community health center, nursing facility, residential or community-based treatment facility, or other similar entity. A health program or activity also includes all of the operations of a State Medicaid program, a Children's Health Insurance Program, and the Basic Health Program.

HHS means the U.S. Department of Health and Human Services.

Individual with a disability means any individual who has a disability as defined for the purpose of Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 705(20)(B)–(F), as amended. Where this part cross-references regulatory provisions applicable to a ''handicapped individual,'' ''handicapped individual'' means ''individual with a disability'' as defined in this section.

Individual with limited English proficiency means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English.

Language assistance services may include, but are not limited to:

(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;

(2) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English; and

(3) Taglines.

National origin includes, but is not limited to, an individual's, or his or her ancestor's, place of origin (such as country or world region) or an individual's manifestation of the physical, cultural, or linguistic characteristics of a national origin group.

On the basis of sex includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.

Qualified bilingual/multilingual staff means a member of a covered entity's workforce who is designated by the covered entity to provide oral language assistance as part of the individual's current, assigned job responsibilities and who has demonstrated to the covered entity that he or she:

(1) Is proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and

(2) is able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified individual with a disability means, with respect to a health program or activity, an individual with a disability who, with or without reasonable modifications to policies, practices, or procedures, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of aids, benefits, or services offered or provided by the health program or activity.

Qualified interpreter for an individual with a disability. (1) A qualified interpreter for an individual with a disability means an interpreter who via a remote interpreting service or an on-site appearance:

(i) Adheres to generally accepted interpreter ethics principles, including client confidentiality; and

(ii) is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, terminology and phraseology.

(2) For an individual with a disability, qualified interpreters can include, for example, sign language interpreters, oral transliterators (individuals who represent or spell in the characters of another alphabet), and cued language transliterators (individuals who represent or spell by using a small number of handshapes).

Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:

(1) Adheres to generally accepted interpreter ethics principles, including client confidentiality;

(2) has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language; and

(3) is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

Qualified translator means a translator who:

(1) Adheres to generally accepted translator ethics principles, including client confidentiality;

(2) has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language; and

(3) is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

Recipient means any State or its political subdivision, or any instrumentality of a State or its political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, to whom Federal financial assistance is extended directly or through another recipient and which operates a health program or activity, including any subunit, successor, assignee, or transferee of a recipient.

Section 504 means Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112; 29 U.S.C. 794), as amended.

Section 1557 means Section 1557 of the ACA (42 U.S.C. 18116).

Sex stereotypes means stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. These stereotypes can include the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes also include gendered expectations related to the appropriate roles of a certain sex.

State-based Marketplace SM means a Health Insurance Marketplace SM established by a State pursuant to 45 CFR 155.100 and approved by the Department pursuant to 45 CFR 155.105.

Taglines mean short statements written in non-English languages that indicate the availability of language assistance services free of charge.

Title I entity means any entity established under Title I of the ACA, including State-based Marketplaces and Federally-facilitated Marketplaces.

Title VI means Title VI of the Civil Rights Act of 1964 (Pub. L. 88–352; 42 U.S.C. 2000d *et seq.*), as amended.

Title IX means Title IX of the Education Amendments of 1972 (Pub. L. 92–318; 20 U.S.C. 1681 *et seq.*), as amended.

§ 92.5 Assurances required.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies shall, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director, that the entity's health programs and activities will be operated in compliance with Section 1557 and this part. A health insurance issuer seeking certification to participate in a Health Insurance Marketplace SM or a State seeking approval to operate a State-based Marketplace SM to which Section 1557 or this part applies shall, as a condition of certification or approval, submit an assurance, on a form specified by the Director, that the health program or activity will be operated in compliance with Section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in a Health Insurance Marketplace SM or approval to operate a State-based Marketplace SM.

(b) *Duration of obligation.* The duration of the assurances required by this subpart is the same as the duration of the assurances required in the Department's regulations implementing Section 504, 45 CFR 84.5(b).

(c) *Covenants.* When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing Section 504, at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under Section 1557 and this part.

§ 92.6 Remedial action and voluntary action.

(a) *Remedial action.* (1) If the Director finds that a recipient or State-based Marketplace SM has discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, such recipient or State-based Marketplace SM shall take such remedial action as the Director may require to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of Section 1557 or this part, and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both entities to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of Section 1557 or this part, require a recipient or State-based Marketplace SM to take remedial action with respect to:

(i) Individuals who are no longer participants in the recipient's or State-based Marketplace SM's health program or activity but who were participants in the health program or activity when such discrimination occurred; or

(ii) Individuals who would have been participants in the health program or

activity had the discrimination not occurred.

(b) *Voluntary action.* A covered entity may take steps, in addition to any action that is required by Section 1557 or this part, to overcome the effects of conditions that result or resulted in limited participation in the covered entity's health programs or activities by individuals on the basis of race, color, national origin, sex, age, or disability.

§ 92.7 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* Each covered entity that employs 15 or more persons shall designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 and this part, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557 or this part or alleging any action that would be prohibited by Section 1557 or this part. For the Department, including the Federally-facilitated Marketplaces, the Director will be deemed the responsible employee under this section.

(b) *Adoption of grievance procedures.* Each covered entity that employs 15 or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this part. For the Department, including the Federally-facilitated Marketplaces, the procedures for addressing complaints of discrimination on the grounds covered under Section 1557 or this part will be deemed grievance procedures under this section.

§ 92.8 Notice requirement.

(a) Each covered entity shall take appropriate initial and continuing steps to notify beneficiaries, enrollees, applicants, and members of the public of the following:

(1) The covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities;

(2) The covered entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;

(3) The covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;

(4) How to obtain the aids and services in paragraphs (a)(2) and (3) of this section;

(5) An identification of, and contact information for, the responsible employee designated pursuant to § 92.7(a), if applicable;

(6) The availability of the grievance procedure and how to file a grievance, pursuant to § 92.7(b), if applicable; and

(7) How to file a discrimination complaint with OCR in the Department.

(b) Within 90 days of the effective date of this part, each covered entity shall:

(1) As described in paragraph (f)(1) of this section, post a notice that conveys the information in paragraphs (a)(1) through (7) of this section; and

(2) As described in paragraph (g)(1) of this section, if applicable, post a nondiscrimination statement that conveys the information in paragraph (a)(1) of this section.

(c) For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, the content of a sample notice that conveys the information in paragraphs (a)(1) through (7) of this section, and the content of a sample nondiscrimination statement that conveys the information in paragraph (a)(1) of this section, in English and in the languages triggered by the obligation in paragraph (d)(1) of this section.

(d) Within 90 days of the effective date of this part, each covered entity shall:

(1) As described in paragraph (f)(1) of this section, post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States; and

(2) As described in paragraph (g)(2) of this section, if applicable, post taglines in at least the top two languages spoken by individuals with limited English proficiency of the relevant State or States.

(e) For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, taglines in the languages triggered by the obligation in paragraph (d)(1) of this section.

(f)(1) Each covered entity shall post the notice required by paragraph (a) of this section and the taglines required by paragraph (d)(1) of this section in a conspicuously-visible font size:

(i) In significant publications and significant communications targeted to beneficiaries, enrollees, applicants, and members of the public, except for significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures;

(ii) In conspicuous physical locations where the entity interacts with the public; and

(iii) In a conspicuous location on the covered entity's Web site accessible from the home page of the covered entity's Web site.

(2) A covered entity may also post the notice and taglines in additional publications and communications.

(g) Each covered entity shall post, in a conspicuously-visible font size, in significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures:

(1) The nondiscrimination statement required by paragraph (b)(2) of this section; and

(2) The taglines required by paragraph (d)(2) of this section.

(h) A covered entity may combine the content of the notice required in paragraph (a) of this section with the content of other notices if the combined notice clearly informs individuals of their civil rights under Section 1557 and this part.

Subpart B—Nondiscrimination Provisions

§ 92.101 Discrimination prohibited.

(a) *General.* (1) Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies.

(2) This part does not apply to employment, except as provided in § 92.208.

(b) *Specific discriminatory actions prohibited.* Under any health program or activity to which this part applies:

(1)(i) Each covered entity must comply with the regulation implementing Title VI, at § 80.3(b)(1) through (6) of this subchapter.

(ii) No covered entity shall, on the basis of race, color, or national origin, aid or perpetuate discrimination against any person by providing significant assistance to any entity or person that discriminates on the basis of race, color, or national origin in providing any aid, benefit, or service to beneficiaries of the covered entity's health program or activity.

(2)(i) Each recipient and State-based Marketplace℠ must comply with the regulation implementing Section 504, at §§ 84.4(b), 84.21 through 84.23(b), 84.31, 84.34, 84.37, 84.38, and 84.41 through 84.52(c) and 84.53 through 84.55 of this subchapter. Where this paragraph cross-references regulatory provisions that use the term ''recipient,'' the term ''recipient or State-based Marketplace℠'' shall apply in its place.

(ii) The Department, including the Federally-facilitated Marketplaces, must comply with the regulation implementing Section 504, at §§ 85.21(b), 85.41 through 85.42, and 85.44 through 85.51 of this subchapter.

(3)(i) Each covered entity must comply with the regulation implementing Title IX, at § 86.31(b)(1) through (8) of this subchapter. Where this paragraph cross-references regulatory provisions that use the term ''student,'' ''employee,'' or ''applicant,'' these terms shall be replaced with ''individual.''

(ii) A covered entity may not, directly or through contractual or other arrangements, utilize criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals on the basis of sex.

(iii) In determining the site or location of a facility, a covered entity may not make selections that have the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs to which this regulation applies, on the basis of sex; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity on the basis of sex.

(iv) A covered entity may operate a sex-specific health program or activity (a health program or activity that is restricted to members of one sex) only if the covered entity can demonstrate an exceedingly persuasive justification, that is, that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective.

(4)(i) Each covered entity must comply with the regulation implementing the Age Act, at § 91.11(b) of this subchapter.

(ii) No covered entity shall, on the basis of age, aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person that discriminates on the basis of age in providing any aid, benefit, or service to beneficiaries of the covered entity's health program or activity.

(5) The enumeration of specific forms of discrimination in this paragraph does not limit the generality of the prohibition in paragraph (a) of this section.

(c) The exceptions applicable to Title VI apply to discrimination on the basis of race, color, or national origin under this part. The exceptions applicable to Section 504 apply to discrimination on the basis of disability under this part. The exceptions applicable to the Age Act apply to discrimination on the basis of age under this part. These provisions are found at §§ 80.3(d), 84.4(c), 85.21(c), 91.12, 91.15, and 91.17–.18 of this subchapter.

(d) Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), and (b)(4), and paragraph (c) of this section use the term ''recipient,'' the term ''covered entity'' shall apply in its place. Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), and (b)(4) and paragraph (c) of this section use the terms ''program or activity'' or ''program'' or ''education program,'' the term ''health program or activity'' shall apply in their place.

Subpart C—Specific Applications to Health Programs and Activities

§ 92.201 Meaningful access for individuals with limited English proficiency.

(a) *General requirement.* A covered entity shall take reasonable steps to provide meaningful access to each individual with limited English proficiency eligible to be served or likely to be encountered in its health programs and activities.

(b) *Evaluation of compliance.* In evaluating whether a covered entity has met its obligation under paragraph (a) of this section, the Director shall:

(1) Evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the individual with limited English proficiency; and

(2) Take into account other relevant factors, including whether a covered entity has developed and implemented an effective written language access plan, that is appropriate to its particular circumstances, to be prepared to meet its obligations in § 92.201(a).

(c) *Language assistance services requirements.* Language assistance services required under paragraph (a) of this section must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency.

(d) *Specific requirements for interpreter and translation services.* Subject to paragraph (a) of this section:

(1) A covered entity shall offer a qualified interpreter to an individual with limited English proficiency when oral interpretation is a reasonable step to provide meaningful access for that individual with limited English proficiency; and

(2) A covered entity shall use a qualified translator when translating written content in paper or electronic form.

(e) *Restricted use of certain persons to interpret or facilitate communication.* A covered entity shall not:

(1) Require an individual with limited English proficiency to provide his or her own interpreter;

(2) Rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication, except:

(i) In an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(ii) Where the individual with limited English proficiency specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances;

(3) Rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(4) Rely on staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency.

(f) *Video remote interpreting services.* A covered entity that provides a qualified interpreter for an individual with limited English proficiency through video remote interpreting services in the covered entity's health programs and activities shall provide:

(1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(2) A sharply delineated image that is large enough to display the interpreter's

face and the participating individual's face regardless of the individual's body position;

(3) A clear, audible transmission of voices; and

(4) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the video remote interpreting.

(g) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services.

§ 92.202 Effective communication for individuals with disabilities.

(a) A covered entity shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities, in accordance with the standards found at 28 CFR 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term ''public entity,'' the term ''covered entity'' shall apply in its place.

(b) A recipient or State-based Marketplace℠ shall provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

§ 92.203 Accessibility standards for buildings and facilities.

(a) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace℠ shall comply with the 2010 Standards as defined in § 92.4, if the construction or alteration was commenced on or after July 18, 2016, except that if a facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace℠, was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility shall comply with the 2010 Standards, as defined in § 92.4, if the construction was commenced after January 18, 2018. Departures from particular technical and scoping requirements by the use of other methods are permitted where substantially equivalent or greater access to and usability of the facility is provided. All newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a ''public building or facility'' as defined in Section 106.5 of the 2010 Standards.

(b) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace℠ in conformance with the 1991 Standards or the 2010 Standards as defined in § 92.4 shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced on or before July 18, 2016. Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace℠ in conformance with the Uniform Federal Accessibility Standards as defined in § 92.4, shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction was commenced before July 18, 2016 and such facility was not covered by the 1991 Standards or 2010 Standards.

§ 92.204 Accessibility of electronic and information technology.

(a) Covered entities shall ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity shall provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

(b) Recipients and State-based Marketplaces shall ensure that their health programs and activities provided through Web sites comply with the requirements of Title II of the ADA.

§ 92.205 Requirement to make reasonable modifications.

A covered entity shall make reasonable modifications to policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term ''reasonable modifications'' shall be interpreted in a manner consistent with the term as set forth in the ADA Title II regulation at 28 CFR 35.130(b)(7).

§ 92.206 Equal program access on the basis of sex.

A covered entity shall provide individuals equal access to its health programs or activities without discrimination on the basis of sex; and a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.

§ 92.207 Nondiscrimination in health-related insurance and other health-related coverage.

(a) *General.* A covered entity shall not, in providing or administering health-related insurance or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, or disability.

(b) *Discriminatory actions prohibited.* A covered entity shall not, in providing or administering health-related insurance or other health-related coverage:

(1) Deny, cancel, limit, or refuse to issue or renew a health-related insurance plan or policy or other health-related coverage, or deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability;

(2) Have or implement marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy, or other health-related coverage;

(3) Deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other

limitations or restrictions on coverage, for any health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that an individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available;

(4) Have or implement a categorical coverage exclusion or limitation for all health services related to gender transition; or

(5) Otherwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition if such denial, limitation, or restriction results in discrimination against a transgender individual.

(c) The enumeration of specific forms of discrimination in paragraph (b) does not limit the general applicability of the prohibition in paragraph (a) of this section.

(d) Nothing in this section is intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case.

§ 92.208 Employer liability for discrimination in employee health benefit programs.

A covered entity that provides an employee health benefit program to its employees and/or their dependents shall be liable for violations of this part in that employee health benefit program only when:

(a) The entity is principally engaged in providing or administering health services, health insurance coverage, or other health coverage;

(b) The entity receives Federal financial assistance a primary objective of which is to fund the entity's employee health benefit program; or

(c) The entity is not principally engaged in providing or administering health services, health insurance coverage, or other health coverage, but operates a health program or activity, which is not an employee health benefit program, that receives Federal financial assistance; except that the entity is liable under this part with regard to the provision or administration of employee health benefits only with respect to the employees in that health program or activity.

§ 92.209 Nondiscrimination on the basis of association.

A covered entity shall not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs or activities on the basis of the race, color, national origin, sex, age, or disability of an individual with whom the individual or entity is known or believed to have a relationship or association.

Subpart D—Procedures

§ 92.301 Enforcement mechanisms.

(a) The enforcement mechanisms available for and provided under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975 shall apply for purposes of Section 1557 as implemented by this part.

(b) Compensatory damages for violations of Section 1557 are available in appropriate administrative and judicial actions brought under this rule.

§ 92.302 Procedures for health programs and activities conducted by recipients and State-based Marketplaces.

(a) The procedural provisions applicable to Title VI apply with respect to administrative enforcement actions concerning discrimination on the basis of race, color, national, origin, sex, and disability discrimination under Section 1557 or this part. These procedures are found at §§ 80.6 through 80.11 of this subchapter and part 81 of this subchapter.

(b) The procedural provisions applicable to the Age Act apply with respect to enforcement actions concerning age discrimination under Section 1557 or this part. These procedures are found at §§ 91.41 through 91.50 of this subchapter.

(c) When a recipient fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may find noncompliance with Section 1557 and initiate appropriate enforcement procedures, including beginning the process for fund suspension or termination and taking other action authorized by law.

(d) An individual or entity may bring a civil action to challenge a violation of Section 1557 or this part in a United States District Court in which the recipient or State-based Marketplace SM is found or transacts business.

§ 92.303 Procedures for health programs and activities administered by the Department.

(a) This section applies to discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities administered by the Department, including the Federally-facilitated Marketplaces.

(b) The procedural provisions applicable to Section 504 at §§ 85.61 through 85.62 of this subchapter shall apply with respect to enforcement actions against the Department concerning discrimination on the basis of race, color, national origin, sex, age, or disability under Section 1557 or this part. Where this section cross-references regulatory provisions that use the term ''handicap,'' the term ''race, color, national origin, sex, age, or disability'' shall apply in its place.

(c) The Department shall permit access by OCR to its books, records, accounts, other sources of information, and facilities as may be pertinent to ascertain compliance with Section 1557 or this part. Where any information required of the Department is in the exclusive possession of any other agency, institution or individual, and the other agency, institution or individual shall fail or refuse to furnish this information, the Department shall so certify and shall set forth what efforts it has made to obtain the information. Asserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with Section 1557 or this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary under the law.

(d) The Department shall not intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by Section 1557 or this part, or because such individual has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under Section 1557 or this part. The identity of complainants shall be kept confidential by OCR, except to the extent necessary to carry out the purposes of Section 1557 or this part.

Appendix A to Part 92—Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination is Against the Law

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. [Name of covered entity] does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

[Name of covered entity]:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:

○ Qualified sign language interpreters
○ Written information in other formats (large print, audio, accessible electronic formats, other formats)

• Provides free language services to people whose primary language is not English, such as:

○ Qualified interpreters
○ Information written in other languages

If you need these services, contact [Name of Civil Rights Coordinator]

If you believe that [Name of covered entity] has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: [Name and Title of Civil Rights Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email]. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, [Name and Title of Civil Rights Coordinator] is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–868–1019, 800–537–7697 (TDD).

Complaint forms are available at *http://www.hhs.gov/ocr/office/file/index.html.*

Nondiscrimination statement for significant publications and signification communications that are small-size:

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

Appendix B to Part 92—Sample Tagline Informing Individuals With Limited English Proficiency of Language Assistance Services

ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–xxx–xxx–xxxx (TTY: 1–xxx–xxx–xxxx).

Appendix C to Part 92—Sample Section 1557 of the Affordable Care Act Grievance Procedure

It is the policy of [Name of Covered Entity] not to discriminate on the basis of race, color, national origin, sex, age or disability. [Name of Covered Entity] has adopted an internal grievance procedure providing for prompt and equitable resolution of complaints alleging any action prohibited by Section 1557 of the Affordable Care Act (42 U.S.C. 18116) and its implementing regulations at 45 CFR part 92, issued by the U.S. Department of Health and Human Services. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. Section 1557 and its implementing regulations may be examined in the office of [Name and Title of Section 1557 Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email], who has been designated to coordinate the efforts of [Name of Covered Entity] to comply with Section 1557.

Any person who believes someone has been subjected to discrimination on the basis of race, color, national origin, sex, age or disability may file a grievance under this procedure. It is against the law for [Name of Covered Entity] to retaliate against anyone who opposes discrimination, files a grievance, or participates in the investigation of a grievance.

Procedure:

• Grievances must be submitted to the Section 1557 Coordinator within (60 days) of the date the person filing the grievance becomes aware of the alleged discriminatory action.

• A complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.

• The Section 1557 Coordinator (or her/his designee) shall conduct an investigation of the complaint. This investigation may be informal, but it will be thorough, affording all interested persons an opportunity to submit evidence relevant to the complaint. The Section 1557 Coordinator will maintain the files and records of [Name of Covered Entity] relating to such grievances. To the extent possible, and in accordance with applicable law, the Section 1557 Coordinator will take appropriate steps to preserve the confidentiality of files and records relating to grievances and will share them only with those who have a need to know.

• The Section 1557 Coordinator will issue a written decision on the grievance, based on a preponderance of the evidence, no later than 30 days after its filing, including a notice to the complainant of their right to pursue further administrative or legal remedies.

• The person filing the grievance may appeal the decision of the Section 1557 Coordinator by writing to the (Administrator/Chief Executive Officer/Board of Directors/etc.) within 15 days of receiving the Section 1557 Coordinator's decision. The (Administrator/Chief Executive Officer/Board of Directors/etc.) shall issue a written decision in response to the appeal no later than 30 days after its filing.

The availability and use of this grievance procedure does not prevent a person from pursuing other legal or administrative remedies, including filing a complaint of discrimination on the basis of race, color, national origin, sex, age or disability in court or with the U.S. Department of Health and Human Services, Office for Civil Rights. A person can file a complaint of discrimination electronically through the Office for Civil Rights Complaint Portal, which is available at: *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201.

Complaint forms are available at: *http://www.hhs.gov/ocr/office/file/index.html.* Such complaints must be filed within 180 days of the date of the alleged discrimination.

[Name of covered entity] will make appropriate arrangements to ensure that individuals with disabilities and individuals with limited English proficiency are provided auxiliary aids and services or language assistance services, respectively, if needed to participate in this grievance process. Such arrangements may include, but are not limited to, providing qualified interpreters, providing taped cassettes of material for individuals with low vision, or assuring a barrier-free location for the proceedings. The Section 1557 Coordinator will be responsible for such arrangements.

Dated: May 11, 2016.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2016–11458 Filed 5–13–16; 11:15 am]

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§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.
16 CA ADC § 1707.5
BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS

Barclays Official California Code of Regulations Currentness
Title 16. Professional and Vocational Regulations
Division 17. California State Board of Pharmacy
Article 2. Pharmacies (Refs & Annos)

16 CCR § 1707.5

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.

HISTORY

1. New section filed 11-17-2010; operative 1-1-2011 pursuant to Government Code section 11343.4(b) (Register 2010, No. 47).

2. Amendment of subsection (a)(1) filed 1-8-2015; operative 4-1-2015 (Register 2015, No. 2).

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16 CCR § 1707.5, 16 CA ADC § 1707.5

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§ 1707.6. Notice to Consumers.
16 CA ADC § 1707.6
BARCLAYS OFFICIAL CALIFORNIA CODE OF REGULATIONS

Barclays Official California Code of Regulations Currentness
Title 16. Professional and Vocational Regulations
Division 17. California State Board of Pharmacy
Article 2. Pharmacies (Refs & Annos)

16 CCR § 1707.6

§ 1707.6. Notice to Consumers.

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:
Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

HISTORY

1. New section filed 1-17-2012; operative 2-16-2012 (Register 2012, No. 3).

This database is current through 8/12/16 Register 2016, No. 33

16 CCR § 1707.6, 16 CA ADC § 1707.6

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Summary of Best Practices for Making Prescription Drug Labels Accessible To Patients Who are Blind, Visually Impaired or Elderly

Federal best practices for prescription drug containers have been developed to make it easier for people who are blind, visually impaired or elderly to access label information.

The recommended best practices were developed by a working group of consumer and drug industry advocates convened by the United States Access Board under the Food and Drug Administration Safety and Innovation Act (Public Law 112-144, 126 Stat. 993).

The working group stated that people who cannot read printed prescription labels because of visual impairment "all too often take the wrong medication, the wrong amount, at the wrong time and under the wrong instructions." The group also noted that most people who become blind or visually impaired do so after age 60 – a time when many take multiple medications and have physical and cognitive conditions that increase the need for "safe, consistent, reliable and independent access" to drug label information.

Recommendations of the federal working group include:

- Encourage patients to communicate their needs to pharmacists.
- Follow universal patient-centered prescription drug container label standards.
- Make container labels available in audible, braille and large-print formats. Explain the choices and provide the format selected by the patient.
- Ensure that duplicate accessible labels preserve the integrity of the print prescription label.
- Subject accessible prescription labels to the same quality control processes used for print labels to ensure accuracy and patient safety.
- Maintain patient privacy (HIPPA rules) when preparing accessible drug labels.
- Keep a sufficient inventory of supplies to provide accessible labels.
- Provide drugs with an accessible label within the same time frame as would be provided to patients without visual impairments.
- Don't impose an extra fee to cover the cost of providing an accessible drug label.
- Ensure durability of accessible label formats until the prescription expiration date.
- Select a container that best supports the type of accessible label provided.
- Ensure all required information contained on the print prescription drug label is provided in the same sequence on the accessible label.
- Include in accessible labels the information on warning labels added to the container at the pharmacist's discretion.

A variety of methods and technologies exist to enable blind, visually impaired and elderly people to access information on prescription labels, including:

- Hard copy labels printed in large type or braille.
- Digital voice or text-to-speech recorders – "Talking bottles" that use a small electronic device attached to a drug container to read the label information aloud.
- Radio Frequency Identification Device (RFID) tags – Attaching RFID tags to drug containers that enable a dedicated device used by the patient to read the label aloud.
- Smart devices and computers equipped with electronic braille, large text and audio technology to access electronic text.

A brochure listing the best practices was issued in June 2016 by the National Council on Disability. The brochure is available at http://www.ncd.gov/sites/default/files/ADLP_508.pdf.

Additional information about the recommended best practices and a link to the working group's full report is available at https://www.access-board.gov/guidelines-and-standards/health-care/about-prescription-drug-container-labels.

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To: Board Members

Subject: VIII. Discussion and Consideration of a Proposal Regarding Ambulances Restocking Medications Using Automated Drug Delivery Systems

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Background

For approximately four years, board staff have been meeting periodically with the LA County Fire Department headquarters staff on a proposal to allow the Fire Department to establish automated drug delivery systems in certain fire stations from which the department's ambulances can restock their ambulances. This system would be in addition to other methods already in place that permit the restocking of ambulances.

The general provisions would be that medications would be owned by LA County Fire, and initially purchased and stored centrally in a licensed wholesaler premises licensed by the board that is owned and operated by the Fire Department.

Distribution of medications from the wholesaler premises would be to the fire stations with automated drug delivery systems. A fire station with an automated drug delivery system would be licensed (requiring a new license type). Restocking of the automated drug delivery systems done under the supervision of a pharmacist. The automated dispensing machine would then be available for access by ambulance staff, where the tracking system for the automated drug delivery system would track the signatures of the two staff who removed medications from the automated drug delivery system to replenish the stock of medications on the ambulance.

The resultant system would provide increased flexibility to fire departments and to EMS agencies on methods to restock medications carried on ambulances.

During this meeting Clayton Kazan, MD, Medical Director, LA County Fire Department will be available to answer questions from the board.

According to Dr. Kazan, other ambulance service providers in other counties are restocking ambulances through similar procedures, although there is no specific authority board staff can identify to permit this function.

The restocking of ambulances is necessary for public health. Board staff suggest that the board work with interested parties to secure the enactment of this additional option for the restocking of ambulances.

Existing Law

Business and Professions Code Section 4119 (b) provides:

4119. Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies

(a) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Public Health set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to 24.

(b) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years. The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances Act.