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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Licensing Committee Report

Members:
Greg Lippe, Public Member, Chairperson
Ryan Brooks, Public Member
Rosalyn Hackworth, Public Member
Debbie Veale, PharmD

LICENSING COMMITTEE REPORT AND ACTION

The Licensing Committee met on September 26, 2011.

a. FOR DISCUSSION and POSSIBLE ACTION: <u>Review of Requests and Possible Board Action to Become a Board of Pharmacy Approved Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies</u>

Attachment 1

<u>Relevant Statutes</u>
California Business and Professions Code section 4127.1 establishes a specialized category of pharmacy licensure for pharmacies that compound injectable sterile drug products and sets forth the requirements for licensure including:

1. Licensure as a pharmacy
2. Inspection by the board prior to issuance of a license and prior to renewal of a license

B&PC Section 4127.1(d) creates an exemption in existing law from this specialty category of board licensure for pharmacies if the pharmacy is:

- licensed by the board or the Department of Public Health
  AND
- currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

Note: an exemption from the specialty license, does not exempt the pharmacy from complying with all board laws and regulations surrounding the compounding of sterile injectable products. Rather, such entities must comply with all CA laws, including the compounding regulations established by the board in 2010.

<u>Background</u>
The board has over 240 such licensed facilities in California, and approximately 90 nonresident pharmacies with such permits.

Consistent with the statute, the board has approved three accreditation agencies:

1. Accreditation Commission for Health Care, Inc (ACHC)
2. Community Health Accreditation Program (CHAP)
3. Det Norske Veritas (DNV).

In 2003, the Licensing Committee developed criteria for approval of accreditation agencies for sterile injectable compounding pharmacies under Business and Professions Code section 4127.1, and generally that these criteria should assess the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors:

1. **Periodic inspection** -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years. ***(Note during 2011 discussions with the accrediting agencies, the board urged annual inspections during the review process.)***
2. **Documented accreditation standards** -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. **Evaluation of surveyor's qualifications** -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. **Acceptance by major California payers** -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. **Unannounced inspection of California accredited sites** -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. **Board access to accreditor's report on individual pharmacies.**
7. **Length of time the accrediting agency has been operating.**
8. **Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

<u>Licensing Committee Meeting Discussion</u>

During the meeting, the committee heard presentations from representatives of the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) and representative from Pharmacy Compounding Accreditation Board (PCAB). Supervising Inspector Janice Dang provided the results of her evaluation of the applications submitted by the two agencies as well as the outcomes of her inspections of pharmacies accredited by these two agencies.

Both organizations were asked to respond to the following requirements:

<u>Survey teams will include a pharmacist.</u>

HFAP would need to restructure its survey teams to include a pharmacist.

PCAB surveyor teams consist of all pharmacists.

<u>Agency agrees to provide the board access to accreditation reports.</u>

HFAP will report deficiencies, serious noncompliance and denial or withdrawals of accreditation to the board.

PCAB will notify the board regarding noncompliance and situations where a pharmacy's accreditation is denied or revoked.

Agency agrees to conduct an annual inspection of each pharmacy.

HFAP will conduct annual inspections if required by the board but that routine inspections will impact efficiency and lead to additional costs for the pharmacies.

PCAB annual inspections would increase costs for accreditation and suggested that the board consider random inspection of ten percent of the pharmacies each year.

The committee requested clarification regarding these requirements and the commitments agreed to by other accreditation agencies recognized by the board.

Committee Recommendations
MOTION: Direct board staff to develop a comparison of the current accreditation agencies and HFAP and PCAB to review and compare all criteria assessed during the application review and the requirements agreed to prior to recognition to be reviewed by the board at the October 2011 Board Meeting.

MOTION: Recommend to the board to conditionally approve HFAP and PCAB as accreditation agencies pending confirmation that they meet the requirements of other accreditation agencies recognized by the board and the guidelines established for all accreditation agencies to follow at the October 2011 Board Meeting.

Recent Update
Board staff prepared the comparison chart detailing the commitments by accreditation agencies recognized by the board. This information is provided in **Attachment 1** along with applications submitted by HFAP and PCAB and Dr. Dang's findings.

b. Discussion and Possible Action: Statutory Amendment to Business and Professions Code Section 4209 to allow for the Reporting of Intern Hours to the Board of Pharmacy by Other State Boards of Pharmacy

Relevant Statutes
Business and Professions Code section 4209 specifies that an intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination. This section also specifies that an intern pharmacist shall submit proof of his or her experience on a board-approved affidavit and established the criteria for submission.

Background
Until last year, the board accepted intern hours earned in another state, if the hours were either:
1. Verified by the state board of pharmacy in which the hours were earned or
2. Accepted board affidavits.

After further review of this policy, it was noted that acceptance of intern hour verification was contrary to legal requirements established in B&PC section 4209(b). The result is a

significant increase in staff resources to complete the necessary license verifications, not only on the out of state intern, but also each pharmacist providing verification of the experience earned.

Licensing Committee Meeting Discussion
The committee discussed the issue regarding the importance of training and experience earned in a pharmacy.

Committee Recommendation
MOTION: Sponsor legislation to modify Business and Professions Code section 4209 as provided below.

> 4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam
>
> (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.
>
> (2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.
>
> (b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of such hours.
>
> (c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

c. FOR DISCUSSION: Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Relevant Statutes
Business and Professions Code section 4231 requires a pharmacist to earn 30 hours of approved continuing education credit every two years as a condition of renewal.

Business and Professions Code section 4232 specifies that content of courses that will be acceptable including the following:

- Pharmacology

- Biochemistry
- Physiology
- Pharmaceutical chemistry
- Pharmacy Administration
- Pharmacy Jurisprudence
- Public health and communicable diseases
- Professional practice management
- Anatomy
- Histology

Background

At several prior meetings of the board or its committees, there has been general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. To establish such a requirement would take either a legislative or regulation change.

Prior discussions have included possible mandatory CE in emergency/disaster response, patient consultation, drug abuse or in maintaining control of a pharmacy's drug inventory. Any topic the board determines as appropriate for mandatory CE should have generally broad-based applicability for pharmacists.

At the February 2011 Board Meeting, the board directed that the committee continue its discussion about such a requirement and specified that if the recommendation is approved, authorize staff to investigate implementation.

Suggested topics considered by the committee included:

- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Patient Consultation
- Ethics
- Drug Abuse
- Defined Content Areas
- Certification in a pharmacist specialty by a accreditation agency

The committee also has heard comments about content specific course mandates and CE in general, and whether a portion of CE should be obtained in specific manner (e.g. lives, web-based, journal, etc.).

Committee Discussion

The committee discussed that any topic identified by the board should have generally broad-based applicability for pharmacists.

The committee discussed possible implementation of this policy including:

- Statutory changes
- Regulation changes
- Preferential credit for completing courses in specified areas
- Encouraging completion of certain courses in *The Script*

Committee Recommendation: Direct staff to research implementing incentives for licensees who earn CE in specific content areas including ethics, substance abuse, emergency/disaster response and patient consultation. Recommend that the board reconsider and possibly decrease the amount of CE a licensee can earn by attending meetings of the board.

d. FOR DISCUSSION: DCA's Focus on Continuing Competency

Attachment 2

Background

The Department of Consumer Affairs has asked all boards to evaluate how they can ensure the continued competency of their practitioners and this item has been discussed at several Board and Licensing Committee Meetings over the last year.

During the July 2011 Board Meeting, the National Association of Boards of Pharmacy provided a presentation on a new self-assessment exam that they are developing - - The Pharmacist Assessment for Remediation and Evaluation (PARE). The PARE provides a multidimensional assessment that the boards of pharmacy may use as a contributory factor when making decisions regarding pharmacist practice deficiencies that result from disregarding pharmacy practice standards, non-compliance with laws and regulations, and/or threats to patient safety. Ms. Russell discussed that the PARE can be used as a tool to evaluate pharmacist's competence when reactivating or reinstating a license. She advised that the exam is internet based and should be administered in a monitored or proctored setting.

The PARE will be psychometrically validated and will be updated regularly to address current drug therapies. The exam will be available for use in 2012 and will cost $250. Board Member Veale and former Member Ken Schell have agreed to take the examination as a pre-tester (to help calibrate the exam). No date has yet been set for this.

Committee Discussion

The committee briefly discussed the issue. It was the consensus of the committee to defer this item to be discussed during the October 2011 Board Meeting.

Attachment 2 contains a DCA document on the topic as well as information prepared by the Citizen Advocacy Center

e. FOR DISCUSSION: Office of Statewide Health Planning and Development's Manpower Assessment and Survey of Licensees

Attachment 3

Background

As part of Senate Bill 139 (Chapter 522, Statutes of 2007) the Office of Statewide Health Planning and Development (OSHPD) was directed to establish the California Healthcare Workforce Clearinghouse (Clearinghouse) to serve as the central source for collection, analysis, and distribution of information on the healthcare workforce employment and educational data trends for the state.

Specifically the bill included a provision that OSHPD work with the Employment Development Department's Labor Market Information Division, state licensing boards, and state higher education entities to collect, to the extent available, all of the following data:

(a) The current supply of health care workers, by specialty.
(b) The geographical distribution of health care workers, by specialty.
(c) The diversity of the health care workforce, by specialty, including, but not necessarily limited to, data on race, ethnicity, and languages spoken.
(d) The current and forecasted demand for health care workers, by specialty.
(e) The educational capacity to produce trained, certified, and licensed health care workers, by specialty and by geographical distribution, including, but not necessarily limited to, the number of educational slots, the number of enrollments, the attrition rate, and wait time to enter the program of study.

Acting Director Brian Stiger is encouraging all boards to collect the necessary information to assist OSHPD in their charge to, among other items, serve as the repository for comprehensive data and standardize data collection tools and methods. In addition, as part of the board's Sunset Report, the board needs to discuss its efforts to collect the information and provide it to OSHPD.

As the board has neither a statutory or regulatory mandate to collect this data, nor are licensees required to provide this information as a condition of licensure or renewal, implementation efforts are limited. Previously members were advised that the department was working with OSHPD on the development of a survey and that the board could provide a link via our website however board staff was later advised that the department is no longer moving towards such implementation.

Committee Discussion

The committee discussed the information that is required to be collected and use of on-line resource such as Survey Monkey that could serve as an easy collection method that would have minimal impact on board staff as well as possible ways to incentivize completion of the survey.

The committee requested that the survey include language indicating that participation is voluntary and counsel offered to provide possible disclosure language.

Recent Update

Provided in **Attachment 3** is an updated draft survey incorporating counsel's language.

f. FOR DISCUSSION: Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).

The board instituted a quality assurance review of the CPJE effective August 8, 2011. This process is done periodically to ensure the reliability of the examination. On September 27, 2011, the quality assurance review was removed and results have been released.

CPJE Statistics
CPJE statistics for all candidates who took the CPJE examination between 4/1/11 – 9/30/11, inclusive, will be available for distribution at the board meeting.

Examination Development
Each Competency Committee workgroup met this fall to continue for examination development activities.

g. FOR INFORMATION: Licensing Statistics for 2011/12

Attachment 4

Attachment 4 includes the licensing statistics for the first quarter of 2011/12.

h. FOR INFORMATION: Minutes of the Meeting Held September 26, 2011

Attachment 5

Attachment 5 contains the minutes from the meeting.

i. FOR INFORMATION: First Quarterly Report on the Committee's Goals for 2011/12

Attachment 6

The first quarterly report on the Licensing Committee's goals is provided at the back of the tab section in **Attachment 6.**

Attachment 1

Table 2: Comparison of Inspections of Approved Accreditation Organizations To PCAB and HFAP

Criteria	Accreditation Commission for Health Care Inc. (ACHC)	Community Health Accreditation Program (CHAP)	Det Norske Veritas (DNV)	The Joint Commission (JCAHO)	Pharmacy Compounding Accreditation Board (PCAB)	American Osteopathic Association Healthcare Facility Program (HFAP)
Record keeping (CCR 1751.1, 1735.2, 1735.3)	Pharmacy #1 • Reviewed.	Pharmacy #1 • **Add to compounding sheet equipment used.** • **Unable to retrieve electronic data for temperature monitoring**.	Pharmacy #1 • Reviewed.	Pharmacy #1 •**Supplies invoices not on premise for 3 years.** •**Add to compounding sheet equipment used.**	Pharmacy #1 • Accredited period 10/21/2010 to 10/20/2013. • Review of previous inspection correction issued to complete compounding self-assessment. • Reviewed. • **Discussion: print CSOS and document qty and date received.** • Compound sterile to sterile, nonsterile to sterile and nonsterile products	Pharmacy #1 • Review last inspection with one correction to complete self assessment. • Accredited 2009 to 2012 • Hospital pharmacy. • **Correction: interviewed housekeeping and PIC, weekly cleaning of floors, ceiling, walls but document as daily**. • **Correction: unable to locate Power of Attorney form to execute DEA 222 order forms for second pharmacist.**
	Pharmacy #2 • Reviewed. • **Document cleaning of TPN Compounder**. • **No c/s DEA inventory.**	Pharmacy #2 • Reviewed.		Pharmacy #2 • **Compounding records missing expiration date of final product.** • **Require record of manufacturer or supplier of each component.** • **Add to compounding sheet equipment used.**	Pharmacy #2 • Last LSC inspection with no corrections issued.. • Accredited from 2/9/11 to 2/18/13. • Compounds sterile to sterile, nonsterile to sterile and nonsterile products. • **Correction issued: to maintain all invoices on licensed premise.**	Pharmacy #2 • Reviewed last inspection with no corrections issued. • **Correction: No master formulas**. • **Correction: No compounding logs.**
Labeling (CCR 1751.2, 1735.4)	Pharmacy #1 • New labeling implemented identifying products that are compounded.	Pharmacy #1 • **Add statement the drug was compounded by pharmacy.** • Label needs to contain generic name of drug.	Pharmacy #1 • **Label on container missing name of prescriber.** • **Add statement the drug was compounded by pharmacy**.	Pharmacy #1 •**Add statement the drug was compounded by pharmacy**.	Pharmacy #1 •Reviewed.	Pharmacy #1 • Reviewed.
	Pharmacy #2 • **Add Chemo – Dispose properly label.** • Add statement the drug was compounded by the pharmacy.	Pharmacy #2 • **Add statement the drug was compounded by pharmacy**		Pharmacy #2 • **Add generic name to label .** • **Add statement the drug was compounded by pharmacy**.	Pharmacy #2 • Reviewed.	Pharmacy #2 • Reviewed.

Criteria	Accreditation Commission for Health Care Inc. (ACHC)	Community Health Accreditation Program (CHAP)	Det Norske Veritas (DNV)	The Joint Commission (JCAHO)	Pharmacy Compounding Accreditation Board (PCAB)	American Osteopathic Association Healthcare Facility Program (HFAP)
Policy and procedures (CCR 1751.3, 1735.5)	Pharmacy #1 • **Need p/p for QA program regarding potency, strength, integrity and quality.**	Pharmacy #1 •. **Revise p/p to weekly cleaning of surfaces: walls, ceilings, workbench surfaces** • **Need p/p for QA program regarding integrity, potency, quality and strength.**	Pharmacy #1 • **Need to update p/p to reflect new changes in compound laws.** • **Revise p/p to weekly cleaning of surfaces: walls, ceiling, workbench surfaces**.	Pharmacy #1 •**Need p/p for QA program regarding integrity, potency, quality and strength.** • **Need p/p for use of equipment, including cleaning, maintenance, calibration, training**.	Pharmacy #1 • Reviewed. • **Recommend adding to current p/p to check BOP website to verify license prior to conducting business with a new vendor (reliable supplier**).	Pharmacy #1 •Reviewed.
	Pharmacy #2 • **Add Chemo p/p.** • **Revise p/p to weekly cleaning of surfaces, walls, ceiling, workbench**.	Pharmacy #2 • **Update p/p to reflect training of staff on new p/p.** • **Revise p/p to weekly cleaning of surfaces: walls, ceiling, workbench surfaces**.		Pharmacy #2 • **P/P overdue for annual review.** • **Unable to locate recall p/p.** • **Change p/p to weekly cleaning of surfaces: walls, ceiling, workbench surfaces.** • **Need p/p for QA program regarding integrity, potency, quality and strength.**	Pharmacy #2 • Reviewed.	Pharmacy #2 • **Presented a p/p from another pharmacy that this pharmacy was going to adopt**.
Facility equipment (CCR 1751.4)	Pharmacy #1 • Reviewed.	Pharmacy #1 • **Refrigerator/Freezer requiring defrosting.** • **Expired frozen drugs need to be quarantined and properly disposed.**	Pharmacy #1 • Reviewed.	Pharmacy #1 •**Temperature logs unavailable**	Pharmacy #1 •Reviewed.	Pharmacy #1 •Reviewed
	Pharmacy #2	Pharmacy #2 • **Card board boxes in cleanroom.** • **4 refrigerators with only 1 being monitored; no thermometers. All containing drugs.**		Pharmacy #2	Pharmacy #2 • Reviewed.	Pharmacy #2 •**Discussion: Remove corrugated boxes near iso-barrier**. • **Discussion: Documenting weekly cleaning of floors, ceiling and walls.** • **Use an iso-barrier hood.**
Attire (CCR 1751.5)	Pharmacy #1 • Reviewed.	Pharmacy #1 • Reviewed.	Pharmacy #1 • Reviewed.	Pharmacy #1 •Reviewed.	Pharmacy #1 •Reviewed.	Pharmacy #1 •Reviewed.
	Pharmacy #2 • **Need to order chemo spill kit and chemo gown/gloves**	Pharmacy #2 • Reviewed.		Pharmacy #2 • Reviewed	Pharmacy #2 •Reviewed.	Pharmacy #2 • Reviewed.

Criteria	Accreditation Commission for Health Care Inc. (ACHC)	Community Health Accreditation Program (CHAP)	Det Norske Veritas (DNV)	The Joint Commission (JCAHO)	Pharmacy Compounding Accreditation Board (PCAB)	American Osteopathic Association Healthcare Facility Program (HFAP)
Training staff, patient, caregiver (CCR 1751.6)	Pharmacy #1 • Reviewed.	Pharmacy #1 • **Competency testing due**.	Pharmacy #1 • Reviewed.	Pharmacy #1 •Reviewed.	Pharmacy #1 •Reviewed	Pharmacy #1 •Reviewed
	Pharmacy #2 • Reviewed.	Pharmacy #2 • **Annual Competency testing overdue.**		Pharmacy #2 • **Add testing of terminology.** • **Annual restesting of competency overdue**.	Pharmacy #2 •Reviewed.	Pharmacy #2 • **Discussion: Written competency incomplete; also self testing d/t only one rph; recommended having an outside RPH test staff (self) competency**.
Quality assurance and process validation (CCR 1751.7)	Pharmacy #1 • Does end product testing for sterility, pyrogen testing only. • Conduct QA testing on products mailed, temperature of drug when sent to cold and hot places.	Pharmacy #1 • **Only sterility testing and end product testing conducted.**	Pharmacy #1 • Reviewed.	Pharmacy #1 •Reviewed.	Pharmacy #1 •Reviewed. • Did in house testing and contracted with outside lab.	Pharmacy #1 • **Discussion: in process of revising QA to test for integrity, quality, strength and potency**.
	Pharmacy #2 • Reviewed.	Pharmacy #2 • **Not documenting corrective actions when QA testing on personnel performance, equipment and facility fails.**		Pharmacy #2 • Reviewed.	Pharmacy #2 • Did in house testing and contracted with outside lab.	Pharmacy #2 • **Correction: Was only testing sterility and not integrity, potency and strength.**
Reference materials (CCR 1751.8)	Pharmacy #1 • Reviewed.	Pharmacy #1 • Reviewed .		Pharmacy #1 •Reviewed.	Pharmacy #1 •Reviewed.	Pharmacy #1 •Reviewed.
	Pharmacy #2 • Reviewed.	Pharmacy #2 • Reviewed.		Pharmacy #2 • Reviewed.	Pharmacy #2 • Reviewed.	Pharmacy #2 • Reviewed.

Table 1. Comparison of Approved Accreditation Organizations to PCAB and HFAP

Criteria	Accreditation Commission for Health Care Inc. (ACHC)	Community Health Accreditation Program (CHAP)	Det Norske Veritas (DNV)	The Joint Commission (TJC aka JCAHO)	Pharmacy Compounding Accreditation Board (PCAB)	American Osteopathic Association, Healthcare Facilities Accreditation Program (HFAP)
Discussion of organization at licensing and board meetings	**Dec 2, 2010 Licensing Committee Meeting** • Tim Safley representing ACHC. • Dr. Dang indicated two pharmacies accredited by ACHC passed inspection. • Response to conducting random and unscheduled inspections: ACHC visits are unannounced. • Ms. Herold requested ACHC provide information to the board by 1/10/11 regarding how many sterile injectable compounding pharmacies have been accredited, reaccredited, placed on provisional status, withdrawn and denied within the last 5 years. The numbers to reflect both national and CA statistics and include nonresident pharmacies that are shipping into CA. • Response to request for validation information: ACHC is certified by the International Organization for Standardization and agreed to provide this information to the board. • Response to how ACHC would respond if they received similar findings of pharmacies accredited by ACHC not in compliance as a result of an inspection by the BOP: ACHC would conduct an investigation to validate	**Dec 2, 2010 Licensing Committee Meeting** • Terry Duncome representing CHAP. • Dr. Dang expressed concerns of pharmacies "ramp up" for the survey process after inspecting 2 pharmacies accredited by CHAP. • Response to conducting random and unscheduled inspection: CHAP does not conduct unannounced visits of facilities seeking exemption from licensure. • Response to concerns of board's inspection of two pharmacies accredited by CHAP: Expressed results are a concern; requested information regarding the two pharmacies; discussed pharmacies with identified deficiencies must complete a plan of correction and are subject to a subsequent visit. She indicated the minimum number of visits for a facility is once every three years; but annual inspections may be necessary based on a facility's performance. • Response to how many organizations CHAP accredits annually: CHAP accredits several hundred entities a year for all the 10 services accredited; accredits 13 pharmacies in CA.	**June 16, 2010 Licensing Committee Meeting** • Patrick Horine representing DNV. • Mr. Horine provided an overview of DNV; indicated the national Integrated Accreditation for Healthcare Organization (NIAHO) standards are integrated requirements based on the CMS Conditions of Participation (CoPs) with the internationally recognized ISO 9001 Standards for the formation and implementation of the Quality Management System. The model standards are consistent with California pharmacy law. • Dr. Dang expressed concerns that the surveyors may not be adequately familiar with California pharmacy law and may not be compliant with the new compounding laws that will go into effect July 2010. **7/28/2010 Board Meeting** • DNV has indicated pharmacists will conduct the inspection if requested by the Board.	**Oct 5, 2010 Licensing Committee Meeting** • Mark Crafton representing The Joint Commission. • Overview of process: a survey can be conducted in 4 to 6 weeks of opening on a new facility, but depends on nature of the change. • If service is being provided by a current accredited facility "original hospital" then the inspection would be completed as part of the next regular triennial survey. Also depend on the type of service being provided at the new site. • When asked if JCAHO may extend an accreditation to a new satellite pharmacy if the services provided were similar to the already accredited hospital without doing an inspection; the response was "YES." • JCAHO indicated they now perform a periodic performance review similar to the board's self-assessment program. The results are filed with JCAHO. • JCAHO completes a 5% random surveys annually as well as completes "for cause" survey where they believe the quality and safety is compromised.	**Oct 18 and 19, 2011 Board Meeting** (To be discussed)	**Oct 18 and 19, 2011 Board Meeting** (To be discussed)

	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	whether the accreditation should be revoked; stated the pharmacy would be required to complete a plan of correction and the accreditation would be contingent on a follow-up inspection known as a "dependent survey." • Ms. Veale asked if the board has the ability to provide investigation information to accreditation agencies. Ms. Shellan advised providing this information would make it public. • Ms. Herold asked ACHC has been approved accreditation agencies in CA since 2003, why has neither agency reported a substandard report to the board. Response: ACHC responded pharmacies are given 30 days to come into compliance; pharmacies found to be deficient with a state regulation will be reported to the board immediately. • Ms. Herold asked minor violations were found with the 2 pharmacies inspected by the board, how will ACHC ensure compliance in these areas. Response: A plan of correction is required for minor violations; pharmacies will be placed on a "dependant status" for more significant violations and will be subject to a focus visit. Any pharmacy requiring a second or third visit for a compliance issue will most likely be placed on revocation status.	• Response to if CHAP has identified critical finding in the past that have jeopardized licensure: Findings are not typical of the pharmacy program; indicated CHAP accredits 467 pharmacies in the U.S. • Ms. Herold asked for statistics regarding the amount of provisional statuses issued as well as decline rates within the past 5 years. • Ms. Duncome discussed a deferred status indicates a facility has deficiencies that must be corrected prior to accreditation; accreditation can be denied or withdrawn; denial rates for CHAP accreditation are increasing. • Ms. Herold requested CHAP provide information to the board by 1/10/11 regarding how many sterile injectable compounding pharmacies have been accredited, reaccredited, placed on provisional status, withdrawn and denied within the last 5 years. The numbers to reflect both national and CA statistics and include nonresident pharmacies that are shipping into CA. • Response to if the board's findings will initiate a review of other CA pharmacies accredited by CHAP: CHAP will be requiring that all CA pharmacies be reviewed. • Ms. Duncome provided this is the first occurrence during her nine years as president of CHAP; advised CHAP has o deficiencies upon validation visits by CMS	• DNV would comply with the requirement of having a pharmacist surveyor and would expect this requirement be imposed on the other agencies. • All accreditation teams will include a physician or nurse as well as a "generalist" which could be a pharmacist. • Approved Det Norske Veritas to serve as an accreditation agency for three years.	• Ms. Herold inquired if the committee felt a pharmacist should participate in the JCAHO survey. Committee discussed and was in support of this requirement. • Motion: Request JCAHO have a pharmacist participate in surveys when possible and if not, then the best candidate should complete the survey. • Vote: Support. **Oct 20 and 21, 2010 Board Meeting:** • Discussed concerns regarding no pharmacist on survey team. Response: given the large number of entities JCAHO accredits, it would be a challenge to have pharmacist in all surveys. Will try to include a pharmacist when possible. • Committee recommendation was to request pharmacist participate in the surveys when possible and if not, the next best candidate should complete the survey. • Response by JCAHO: Best candidate would be a registered nurse with infusion therapy experience who has been trained by a pharmacist on the JCAHO standards and has been evaluated for competency of these standards.		

	(ACHC) • Motion: Recommend to the board ACHC be reapproved as accreditation agency for three years pending receipt of the requested information. • Vote: Support **Feb 1 and 2, 2011** **Public Board Meeting** • Dr. Dang indicated ACHC submitted the information regarding the number of pharmacies accredited in CA and the U.S. but the information did not specify which pharmacies were compounding pharmacies and specialty pharmacies. • Dr. Dang discussed concerns regarding pharmacies "ramp up" their standard for the accreditation process (survey) and pharmacies licensed in CA for sterile compounding are subjected to annual inspections. • Response to whether ACHC utilizes pharmacists as part of the survey team: ACHC provided all surveys of a pharmacy are done by a pharmacist.; the program includes four pharmacy services including 1)infusion pharmacy, 2) ambulatory infusion center, 3) infusion nursing services, and 4) specialty pharmacy.	(CHAP) • Ms. Duncome provided pharmacies will be placed on a warning status if deficiencies are not corrected by the second visit; accreditation will be revoked if the correction is not made by the third visit; explained the initial accreditation will be denied if deficiencies identified during the initial review are not corrected by the second visit. • Motion: Recommend to the board to reapproved CHAP as accreditation agencies for three years pending receipt of the requested information. • Vote: Support **Feb 1 and 2, 2011** **Public Board Meeting** • ACHC indicated all pharmacies are surveyed by a pharmacist. • Dr. Dang highlighted the two CHAP accredited pharmacies had several areas of noncompliance and appeared to "ramp up" their standards for the accreditation process. • Ms. Duncombe provided that CHAP has submitte copies of reports for the last CHAP surveys of the pharmacies assessed by the board. Both pharmacies were required to complete plan of corrections for deficiencies and were subject to follow up visits. Ms. Duncombe advised CHAP accredited pharmacies are always subject to follow up visits within the 3 year accreditation period.	(DNV)	(JCAHO) • Response to type of pharmacist surveyors: consist of 6 pharmacist consisting of both community and hospital pharmacist, all with knowledge on infusion therapy. • Response to concerns not having a commitment to have a pharmacist survey: JCAHO can prioritize that community based pharmacies have a pharmacist surveyor; however it is unlikely for the surveying hospitals. • Response to comparing survey results when a pharmacist is on the survey team and when a pharmacist is not on the team: No analysis available. Info can be provided to the Board. • Response to is it typical to have a licensed sterile injectable compounding area in the hospital surveyed: Is dependent on the size and complexity of the services of the hospital. • Response to whether surveyors are aware they will be surveying for a specific function prior to the inspection: Surveyors will not know this; the application does not require the entity disclose the depth and breadth of their pharmacy services.	(PCAB)	(HFAP)

	(ACHC) • Response to whether there is a formal mechanism in the survey process to address issues and concerns: ACHC utilizes an investigative committee for both compliance and complaint issues. There is a mechanism in place for reporting to the board. • Response to whether ACHC has revoked accreditation: ACHC has revoked about 218 accreditations for all its services. The data regarding the reapplication of a revoked entity is not maintained. • Ms. Herold indicated the board should be notified of any complaints regarding the safety of drugs or the safety of the procedures being used by the accredited pharmacies. The board will work with ACHC to help facilitate this information. • ACHC requested they be notified regarding any complaints submitted to the board against an ACHC accredited pharmacy. • Response to whether ACHC is paid by the entities that it accredits: ACHC is paid by these entities. •Dr. Castellblanch discussed the board needs to be vigilant in the review of these pharmacies as they are paying for ACHC accreditation.	(CHAP) • Dr. Castellblanch discussed the assessment results were alarming from the perspective of a non-pharmacist. • Mr. Badlani asked whether the accredited pharmacies are also licensed by the board. Ms. Herold provided that accredited pharmacies are required to follow CA pharmacy law, but are not required to have a special sterile compounding license. DA Room provided these accredited pharmacies do not have a special license in addition to their general pharmacy license. • Dr. Schell expressed concerns that these pharmacies should be visited again to ensure compliance. • Ms. Herold provided deficiencies regarding expiration dates and refrigeration would warrant a strong warning or citation. Egregious cases of noncompliance in this area would be referred to the Attorney General's office. • Dr. Castellblanch confirmed, if approved, the agencies will be re-evaluated for accreditation in 3 years. • Ms. Veale stated the committed felt comfortable that both agencies (ACHC and CHAP) had the right processes in place to ensure the standards were being met. Advised CHAP will have pharmacist on the surveying team which represents an enhancement of the current standard in this area.	(DNV)	(JCAHO) • Ms. Herold request board to require annual inspections for licensed sterile injectable compounding pharmacies because of the importance of having a pharmacist with adequate knowledge of sterile compounding involved in these inspections. EO offered to work with JCAHO to ensure its accredited facilities meet the board's requirements. • JCAHO indicated they monitor regulatory changes and request for notification regarding changes in California pharmacy law to ensure JCAHO surveyors are aware. • Ms. Veale recommend Licensing Committee revisit the issue of surveyors qualifications at its next meeting. • Response to whether JCAHO would be able to comply if the board required a pharmacist participate in every survey: JCAHO accredits a larger volume of organizations than others; it would make it difficult for JCAHO to comply. • Ms. Veale comment on all accrediting bodies, regardless of size, should adhere to the same requirements.	(PCAB)	(HFAP)

	(ACHC) • Ms. Herold discussed the assessment of the two pharmacies accredited by ACHC were identified as minor corrections and no major areas of noncompliance. • Ms. Veale stated the committed felt comfortable that both agencies (ACHC and CHAP) had the right processes in place to ensure the standards were being met. Advised ACHC will have pharmacist on the surveying team which represents an enhancement of the current standard in this area. • Dr. Schell commented to support recommendation for approval and the board has the right to readdress this issue an any time before the 3 year period. • Ms. Herold provided the board will continue to conduct random inspections of the accredited pharmacies. • Motion: Recommend to the board that ACHC be reapproved as accreditation agencies for three years pending receipt of the requested nformaion. • Vote: Support	(CHAP) • Dr. Schell commented to support recommendation for approval and the board has the right to readdress this issue an any time before the 3 year period. • Ms. Herold provided the board will continue to conduct random inspections of the accredited pharmacies. • Motion: Recommend to the board that CHAP be reapproved as accreditation agencies for three years pending receipt of the requested nformaion. • Vote: Support	(DNV)	(JCAHO) • Dr. Schell: while it is preferred a pharmacist participate in the surveys, the board could consider whether it should require an additional survey by an agency that does not include a pharmacist for facilities accredited by JCAHO. • Motion: Request JCAHO have a pharmacist participate in surveys when possible and if not possible, then the best candidate should complete the survey. • Vote: Support	(PCAB)	(HFAP)

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
1. Periodic Inspections	Accreditation is valid for 3 years, requiring a full site inspection.	Site visit with a minimum of every 3 years. Site visit conducted after the submission of a completed self-study report. Visit is scheduled.	Triennial inspection for accreditation with annual ISO periodic inspections.	Accreditation award is continuous until the organization has its next full survey, which will be between 18 and 39 months after its previous full survey, unless accreditation is revoked for cause. The additional 3 months at the end of the survey window ensures that the surveys are not only unannounced, but unexpected. The vast majority of surveys are conducted by the three year anniversary date. However, if requested by the CA BOP, The Joint Commission will modify this time frame for pharmacies subject to these regulations to ensure resurveys are performed no more than 36 months after the previous full survey.	Surveys every 3 years. • Onsite survey lasting a minimum of one day with one surveyor; busier pharmacies may last two days with two surveyors. • Includes: personnel interviews, observation of compounding, record review, SOP reviewed, and evaluation of facility compliance to USP and PCAB standards. • A registered pharmacist generates the written report; is provided to the pharmacy; any corrective action is given a time frame to make corrections; corrective actions are required to be submitted to PCAB. • Once corrective actions are submitted, the accreditation committee makes the final decision to award accreditation. • Committee consists of 5 pharmacists: 1-USP, 1-NABP, 3-qualified experts in compounding. • If PCAB receives a complaint with probable cause or requires a call for action, PCAB will conduct a random inspection.	Surveys every 3 years. Will require pharmacies provide HFAP with a copy of the California State Board of Pharmacy, Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self Assessment.

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
2. Comparison of standards	Copy of pharmacy standards submitted.	Copy of pharmacy standards submitted.	Comparison table of standards to regulations was submitted.	Refer to crosswalk comparison submitted.	Standards are developed with the participation of various authorities in the field of pharmaceutical compounding. PCAB Board of Directors includes 7 organizations. American College of Apothecaries; American Pharmacist Association, International Academy of Compounding Pharmacies; National Association of Boards of Pharmacy; National Alliance of State Pharmacy Association, National Home Infusion Association; United States Pharmacopeia. Standards were submitted and compared to California compounding laws.	Standards were submitted and compared to California compounding laws. Submitted HFAP hospital Chapter 25 Pharmacy Services/medication use – compounding sterile preparations (Supplement for California Hospitals), Sections 25.04 and 25.05.)

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
3. Surveyor's qualifications.	•Maintain a current pharmacist license in one of the 50 states or territories of the U.S. •Required to have a minimum of 5 years managerial experience in homecare and/or pharmacy market. A PharmD is preferred. •Must complete the initial two day surveyor training and a minimum of two preceptorships; prior to conducting their initial survey. •Must attend an annual full day training session. •Must maintain current knowledge of industry standards, licensure regulations and changes that impact accreditation and/or licensure standards. •Are evaluated annually for their ability to perform surveys in accordance with ACHC p/p.	•CHAP site visitors are required to have at least 5 years middle senior management experience in the service line in which they perform site visits. •Only a pharmacist would be assigned to survey a pharmacy. •All new staff receives a 5-day classroom orientation and 4 to 6 site visits where they are assigned an experienced pharmacy site visitor preceptor. •Job description provided.	•Will make every effort to ensure a pharmacist participates as a member of the survey team when a hospital seeks to demonstrate compliance to sterile compounding requirements. •Must complete NIAHO surveyor didactic training and ISO 9001 lead auditor didactic training. •All surveyors are evaluated in terms of their interpersonal skills. •Must complete 45 hours of continuing education in their discipline within every 3 year period. •Must participate in annual surveyor training	•In general, surveyors reviewing pharmacies are pharmacists or licensed registered nurses with infusion experience. •Pharmacist must have a Doctor of Pharmacy degree or equivalent. •Nurses must have graduated from an approved school of nursing and have a Master's degree in an appropriate discipline. •All surveyors must have five years of recent experience, including three year of direct clinical experience in the appropriate health care setting and two years of senior management experience. •All surveyors participate in a training and competency assessment process. •New surveyors begins with a 1-week classroom educational program tailored to their setting. •New surveyors complete a minimum of three surveys with a preceptor in the field, and must pass the Surveyor Certification Examination. New surveyors are terminated if they fail the exam after three attempts. •Surveyors must pass a re-certification exam every five years. •Continuing/ongoing surveyor education includes annual on-site training conference each January. Surveyors participate in a Quarterly educational conference call. Every other week,, surveyors receive an email addressing topics of interest.	Surveyors are all registered pharmacists with extensive sterile and non-sterile compounding experience. Receives initial and ongoing training on conducting on-site surveys, standards interpretation, and use of survey tools. Training on CA compounding regulations and determining compliance with CA pharmacy laws. If approved by BOP, will also conduct training on CA laws where there is no PCAB standard.	Surveyors are registered nurses. Surveyors engaged in surveys of hospitals in CA will receive additional training related to surveying against the standards. Current plan is to conduct a surveyor training webcast for HFAP Hospital Chapter 25, Pharmacy Service /Medication Use with special focus on the additional Section 25.04 and 25.05, Supplement for California Hospitals. Primary instructor is Andrew Lowe, Pharm.D. Director of Pharmacy for Arrowhead Regional Medical Center.

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
(continue surveyors qualifications)				•All surveyors receive official newletters with updates on new standards. •All surveyors receive an annual performance evaluation.		
4. Acceptance by major California payors	ACHC is recognized by most major payors. In CA, Accordia of Northern CA, Aetna, BCBS, CCN managed care, California Care Plus, InsurNational California and the California Department of Health.	•Is accepted by major payors everywhere. Works effectively and ongoing with all payors to educate them about CHAP, and the robustness of the accreditation process. (List of specific payor sources not provided). •CMS (Medicaid and Medi-Care)	Medi-Caid and Medi-Care (CMS) approval 9/26/2008.	Joint Commission accreditation is recognized by several California payor organizations. Example: Blue Cross of California.	Accredits compounding pharmacies only. • The only acceptance as an accrediting agency PCAB has or needs is the fact the pharmacy has a contract for prescription services with a payor. • Somewhat different than other accreditation services who accredit healthcare services in addition to pharmacy services. PCAB only accredits pharmacy services. • Pharmacist's Mutual, an insurance company for pharmacies, has recognized PCAB's standards; however, they do not sell into CA. • The American Medical Association policy 120.95 recognizes PCAB as a means to identify compounding pharmacies that adhere to quality and practice standards.	HFAP is accepted by the following healthcare payors among others: Medicare, Medicaid, Blue Cross of CA, Blue Shield of CA, Medi-Cal, Intervalley Health Plan (Senior HMO), HealthNet Health Plan (Senior HMO) and Care First Health Plan (Senior HMO). Also recognized by California Statute CA Welfare and Institution Code section 14043.26.
5. Subjected to Unannounced inspections by BOP	ACHC welcomes feedback from the CA BOP on any ACHC accredited organization that is licensed by the Board.	•CHAP agreement with pharmacies include oversight visits for organizations who monitor CHAP performance. CHAP welcomes oversight and opportunity for learning, continuous improvement and accountability.	•Currently DNV has accredited one hospital in California who is maintaining their LSC license with the BOP until DNV is approved.	Pharmacies subjected to the compounding regulations are accredited under The Joint Commission's Comprehensive Accreditation Manual for Home Care – Pharmacy standards. List of accredited pharmacies was provided.	Accredits pharmacies that compound non-sterile compounded drug products and sterile injectable compounded drug products. 12 pharmacies accredited by PCAB in CA of which 5 pharmacies have LSC licenses with BOP.	New standards for California pharmacies were written, but have not been implemented. Current pharmacies were surveyed on HFAP basic standards. • 25 hospital pharmacies HFAP accredited in CA.

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
(Continued #5 unannounced inspections by BOP)					• 2 of the 5 pharmacies with an LSC license were inspected.	• 7 of 25 hospitals do not have an LSC license in CA. 1 of 25 hospitals has a delinquent LSC license in CA
6. Access to accreditor's reports on individual pharmacies.	•ACHC will make available to CA BOP any provider's summary of findings as requested. •The Board can access current accredited provider by visiting ACHC website.	•CHAP agreements allow CHAP to disclose accreditation reports to certain authority, which include the CA BOP. •CHAP standards also required accredited organizations to disclose this information with a copy of the written report available on site. A process for providing reports on demand can be established.	Will adhere to the requirements and oversight of the BOP, including DNV findings of noncompliance and corrective actions required.	Joint Commission official accreditation reports are provided to accredited organizations. These organizations are authorized and encouraged to share the accreditation report with regulatory agencies as required under state law. Should the Board of Pharmacy ask The Joint Commission to provide the accreditation report of a pharmacy subject to these regulations, The Joint Commission will contact the pharmacy and seek to obtain an authorization from the pharmacy to release the report to the Board. Once authorization is received from the pharmacy, The Joint Commission will provide the accreditation report to the Board.	• Will need to check with legal dept if the report can be made available to the board upon request. A copy is provided to the pharmacy. • A copy is not available online. Will inform the Board when the PCAB accreditation committee notes noncompliance with PCAB standard or other practices documented by the surveyor places the public at harm. Will notify the Board of situations where PCAB denies or revokes a pharmacy's accreditation.	HFAP requires responses to all deficiencies cited indicating the corrective action taken by the facility. Following CMS national protocols, HFAP conducts resurveys of facilities that have deficiencies cited at a full Medicare Conditions of Participation during a HFAP survey. HFAP will notify the board of any serious noncompliance requiring the board to follow up with an inspection. We would use the full condition level of CCR 1735 and 1751 et al as the criteria for serious noncompliance. We would notify the Board if HFAP denies or withdraws an accreditation from a pharmacy.
7. Length of time accrediting agency has been operating as an accrediting agency.	ACHC is an independent, private, not for profit corporation established in 1986.	•CHAP was founded in 1965 as the first organization in the U.S. to accredit community based health care organizations. •CHAP is authorized by CMS to provide accreditation for home health, hospice, durable medical equipment and pharmacy.	•Established in 1864 in Oslo, Norway with 15 offices in the U.S. •In U.S. since 1898. •DNVHS offices in Houston Texas and Cincinnati, Ohio. •300 offices in over 100 countries.	The Joint Commission has been in operations as an accrediting agency since 1951. The Joint Commission's Home Care Accreditation – Pharmacy program was established in 1988.	Incorporated in 2004 with the first pharmacy licensed in 2006.	HFAP has been accrediting hospitals and other health types of healthcare facilities since 1945 and under Medicare since 1965.

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
8. Ability to accredit out-of-state pharmacies.	ACHC accredits both resident and non-resident pharmacies that have businesses in any of the 50 states or territories of the U.S.	As a national organization and provider of accreditation services, CHAP is able to accredit pharmacies in all 50 states and US territories.	•Refer to #7	The Joint Commission can and does accredit pharmacies throughout the United States.	Currently 132 pharmacies are PCAB accredited throughout the United States; no pharmacies accredited in Puerto Rico.	HFAP accredits pharmacies in its hospitals across the United States.
9. Annual submission of list of accredited board of licensed facilities.	List received.	•CHAP has 6 currently accredited pharmacy sites in CA. •Current list submitted 6/4/2010.	Currently, Hoag Medical Center is the only pharmacy accredited by DNV in CA. Hoag also maintains an LSC license until DNV is approved by the BOP.	List received. Also an internet search is available on The Joint Commission website to verify accreditation.	Is willing to provide the board annually a list of PCAB accredited pharmacies in CA. To verify if a pharmacy outside of CA is PCAB accredited, the Board will be able to contact PCAB for verification.	Will provide annually, no later than July 1, a list of board licensed facilities that are accredited during the past 12 months.

AMERICAN OSTEOPATHIC ASSOCIATION

BUREAU OF HEALTHCARE FACILITIES ACCREDITATION
HEALTHCARE FACILITIES ACCREDITATION PROGRAM (HFAP)

142 E. Ontario St., Chicago, IL 60611-2864 (312) 202-8258 , (800) 621-1773 x8258

June 30, 2011

2011 JUL -1 PM 4:18

Janice Dang, Pharm. D.
Supervising Inspector
California State Board of Pharmacy
1625 N. Market Blvd; Ste N219
Sacramento, California95834

Dear Ms. Dang,

Thank you for your email of June 8, 2011 in which you acknowledged receipt of the HFAP application for recognition as an accreditation organization for pharmacies compounding sterile drug products in California. You requested additional information from the HFAP related to that application. Your questions and the HFAP response to each are listed below. Additional documents are included with this response as indicated in the related HFAP response.

1. Periodic inspections: The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.

   HFAP Response: Accreditation surveys by the Healthcare Facilities Accreditation Program (HFAP) occur every three years.

2. Documented accreditation standards: The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California Law and sound professional practice as established by nationally recognized professional or standard setting organizations.

   - In addition, submit a comparison of HFAP's sterile compounding standards with each of the components listed in the new compounding regulations and changes that went into effect July 6, 2010, Division 17 of Title 16 California Code of Regulations sections 1735 and 1735.1 to 1735.8, Division 17 of Title 16 California Code of Regulations sections 1751 and 1751.1 to 1751.8 and other California laws regarding sterile injectable compounding (CCR 1751.9 to 1791.12, etc.) A copy of the California Pharmacy Law can be obtained from the board's website at www.pharmacy.ca.gov. Your request will not be processed unless the comparison demonstrates HFAP standards are in compliance with California Pharmacy Law. Attached is a copy of the board's compounding self-assessments required to be completed by all pharmacies compounding any drug products. It references the rules and regulations related to compounding of drug products. In review of the documents you already provided, the comparison table addressed the regulation changes related to CCR 1751 et al. but did not address CCR 1735 et al.

     HFAP Response: We have included an update HFAP hospital Chapter 25, Section 25.04.00 through 25.04.29 address 16 CCR 1735(a) through 1735.8(d). Section 25.05.00 through 25.05.26 address 16 CCR 1751(a) through 1751.12(b). **(See enclosed HFAP hospital Chapter 25 *PHARMACY SERVICES/MEDICATON USE – COMPOUNDING STERILE PREPARATIONS (Supplement for California Hospitals), Sections 25.04 and 25.05)***

***NOTE! Please use this enclosure as a replacement for the original Chapter 25 PHARMACY SERVICES/MEDICATION USE – Compounding Sterile Preparations* originally submitted with our application.**

In addition I have enclosed the balance of HFAP Hospital Chapter 25 PHARMACY SERVICES/MEDICATION USE as a demonstration of our use of professional practice as established by nationally recognized professional or standard setting organizations. These standards crosswalk to the Medicare Conditions of Participation for Pharmaceutical Services 482.25(a)(1-3) and 482.25(b)(1-9). **(See enclosed HFAP hospital Chapter 25 *PHARMACY SERVICE/MEDICATION USE* , Sections 25.00, 25.01, 25.02, and 25.03)**

3. Evaluation of surveyor's qualification: The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.

   HFAP Response: Surveyor Qualifications are included. **(See enclosed: *Administrator Surveyor Participation Guidelines, Registered Nurse Surveyor Participation Guidelines, Team Captain Physician Surveyor Participation Guidelines*)**

   - Include how the surveyors are trained on California's compounding regulations and would they be able to determine if the pharmacy is compliant with California laws.

     HFAP Response: Surveyors engaged in survey of hospitals in California will receive additional training related to surveying against these standards. The current plan is to conduct a surveyor training webcast for HFAP Hospital Chapter 25, Pharmacy Service/Medication Use with special focus on the additional Sections 25.04 and 25.05, Supplement for California Hospitals. The primary instructor will be the Andrew G. Lowe, Pharm.D., Director of Pharmacy for Arrowhead Regional Medical Center, Colton California, one of the HFAP accredited hospitals in California. Dr. Lowe was also engaged in development and review of the supplemental sections.

   - Include whether the surveyors are pharmacists, nurses, or other. If other, please specify.

     HFAP Response: The surveyors conducting review of the pharmacies are registered nurses.

4. Acceptance by major California payors: Recognition of the accrediting agency by at least one California healthcare payors (e.g. HMO's, PPO's, PBGH, CalPERS).

   HFAP Response: HFAP is accepted by the following healthcare payors among others: Medicare and Medicaid, Blue Cross of California, Blue Shield of California, Medi-CAL, InterValley Health Plan (senior HMO), Healthnet Health Plan (Senior HMO), and Care First Health Plan (senior HMO). The program is also recognized in California State Statute CAL WEL & Inst Code 14043.26.

5. Unannounced inspection of California accredited sites – The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.

   - Thank you for your list of pharmacies presently accredited by the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP). As part of the evaluation, the board will be conducting random unannounced inspections from your list of accredited pharmacies.

     HFAP Response: Please note that HFAP has not surveyed under the enclosed Supplement for

California Hospitals HFAP hospital chapter 25.04.00 through 25.04.29 and 25.00.00 through 25.05.26. These will be incorporated upon acceptance by the California Board of Pharmacy. We have surveyed under our basic chapter 25.00.00 through 25.03.06.

6. Board access to accreditor's report on individual pharmacies.

   - Include whether HFAP will notify the board of any serious noncompliance requiring the board to follow up with an inspection.

     HFAP Response: HFAP requires responses to all deficiencies cited indicating the corrective action taken by the facility to correct each deficiency cited.

     Following CMS national protocols, HFAP conducts resurveys of facilities that have deficiencies cited at a full Medicare Conditions of Participation during an HFAP survey.

     HFAP will notify the board of any serious noncompliance requiring the board to follow up with an inspection. We would use the full condition level of the California Code of Regulations (CCR) i.e., 16 CCR 1735 or 16 CCR 1751 as the criteria for serious noncompliance. We would also notify the California State Board of Pharmacy if we denied or withdrew accreditation of a pharmacy.

7. Length of time the accrediting agency has been operating as an accrediting agency.

   HFAP Response: HFAP has been accrediting hospitals and other health types of healthcare facilities since 1945 and under Medicare since its inception in 1965.

   - Include how HFAP can assure the accredited pharmacies are in compliance with California laws pertaining to sterile compounding and are continuously maintaining adherence to HFAP standards. Does HFAP require a self-assessment to be submitted or conduct unannounced surveys during the accreditation period?

     HFAP Response: HFAP will require that pharmacies provide HFAP with a copy of the California State Board of Pharmacy, Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment.

8. Ability to accredit out-of-state pharmacies: Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

   HFAP Response: HFAP accredits pharmacies in its hospitals across the United States. A copy of the related standards was provided with our initial application. HFAP hospital Chapter 25, *PHARMACY SERVICES/MEDICATION USE*.

9. Annual submission of list of accredited board licensed facilities: On an annual basis, no later than July 1 of each year, an approved accrediting agency shall submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months.

   HFAP Response: HFAP will provide a list of facilities that have been accredited during the past 12 months, on an annual basis, no later than July 1 of each year.

HFAP understands that if approved, the approval will be good for a period of three years. The approval process will include submission of our responses to the Licensing Committee Meeting who will make their

recommendations at the board meeting. Currently, the date and location for the next licensing committee meeting has not been set. Please keep me informed when this date is determined.

If you have questions about the HFAP application for recognition, or any on this additional material I may be reached via phone at 312-202-8060 or via email at greuther@hfap.org.

Sincerely,

George A. Reuther

George A. Reuther
Chief Operating Officer

Enclosures

C: Michael J. Zarski, JD, Chief Executive Officer, HFAP
Lawrence U. Haspel, DO, Chair, Bureau of Healthcare Facilities Accreditation, American Osteopathic Association

PHARMACY SERVICES/MEDICATION USE - COMPOUNDING STERILE PREPARATIONS
(Supplement for California Hospitals)

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
25.04.00 – Introduction. These HFAP standards for Compounding Sterile Preparations are cross referenced to the California Code of Regulations (CCR) Section 16, Article 4.5 Compounding. 1735 Compounding in Licensed Pharmacies through 1735.8 Compounding Quality Assurance.	Self-explanatory.	These standards are scored below through review of HFAP standards 25.04.01 through 20.04.29	
25.04.01 Compounding in Licensed Pharmacies. (Effective 07/06/10) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription: 16 CCR 1735(a) (1)Altering the dosage form or delivery system of a drug. 16 CCR 1735(a)(1) (2)Altering the strength of a drug. 16 CCR 1735(a)(2) (3)Combing components or active ingredients. 16 CCR 1735(a)(3) (4)Preparing a drug product from chemicals or bulk drug substances. 16 CCR 1735(a)(4) Exceptions: "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability. 16 CCR 1735(b)	Self-explanatory.	**Documents and Observations** 1. Verify that the pharmacy is licensed. 2. Verify that compounding, as defined, occurs under the supervision of a licensed pharmacist. 3. Verify that the facility policy for compounding has all elements required,	1 [illegible] 4 NA 1 = Full compliance 4 = Non-compliance. NA = Compounding not performed at the facility.

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"Compounding" does not include, except in small quantities under limited circumstances as justified by a specific documented medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace. 16 CCR 1735(c) The parameters and requirements stated by this Article 4.5(Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1735 et seq). 16 CCR 1735(d)			
25.04.02 <u>Compounding Definitions.</u> (Effective 07/06/10) The following definitions apply to the compounding activities: (a)"Integrity" means retention of potency until the expiration date noted on the label. 16 CCR 1735.1 (a) (b)"Potency" means active ingredient strength within +/- 10% of the labeled amount. 16 CCR 1735.1(b) (c)"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label. 16 CCR 1735.1(c)	Self-explanatory.	**Documents and Observations** 1.Verify that the pharmacy is using these definitions in their policy for compounding.	1 2 3 4 NA 1 - Full compliance 4 - Non-compliance. NA - Compounding not performed at the facility.

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(d)"Strength" means amount of active ingredient per unit of a compounded drug product. 16 CCR 1735.1(d)			
25.04.03 Compounding Limitations and Requirements. (Effective 07/06/10) Except as specified in 25.04.01 Exceptions, no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding. 16 CCR 1735.2(a) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population. 16 CCR 1735.2(b)	Self-explanatory.	**Documents and Observations** 1. Verify that no drug product is compounded prior to receipt of a valid prescription. 2. Verify that if limited quantities of a compounded drug product is prepared in advance of receipt of a patient-specific prescription that the quantity is based on a documented history of prescriptions for that a specific patient population	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.
25.04.04 Provision of Compounded Drug Products to a Prescriber for Office Use. (Effective 07/06/10) A "reasonable quantity" of a compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:	Self-explanatory.	**Documents and Observations** 1. Verify that if a compounded drug product is furnished to a prescriber for office use that it: a. Is sufficient in quantity for the patient(s) b. Is reasonable considering the	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility. ed at the facility.

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(1)Is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and (2)Is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and (3)For any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounding drug product. 16 CCR 1735.2(c)(1)(2)(3)		intended use of the medication c. Is within the capabilities of the pharmacy following pharmaceutical standards	
25.04.05 <u>Written Master Formula Record</u>. (Effective 07/06/10) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements: (1)Active ingredients to be used. (2)Inactive ingredients to be used. (3)Process and/or procedure used to prepare the drug. (4)Quality reviews required at each step in preparation of the drug (5)Post-compounding process or procedures required, if any. (6)Expiration dating requirements. 16 CCR 1735.2(d)(1-6)	Self-explanatory.	**Documents and Observations** 1. Verify that a written master formula record is prepared prior to drug products being compounded that includes at a minimum elements 1-6.	1 2 4 NA 1 - Full compliance 4 Non-compliance. NA Compounding not performed at the facility.

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25.04.06 Master Formula Record on Prescription. (Effective 07/06/10) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself. 16 CCR 1735.2(e)	Self-explanatory.	**Documents and Observations** 1. Verify whether the pharmacy has occasions to record the master formula on the prescription document itself.	1 2 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.
25.04.06 Responsibilities of the Pharmacist. (Effective 07/06/10) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed. 16 CCR 1735.2(f)	Self-explanatory.	**Documents and Observations** 1. Verify that there is a pharmacist identified for all shifts of the pharmacy.	1 2 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.
25.04.07 Storage of Compounding Components. (effective 07/06/10) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength. 16 CCR 1735.2(g)	Self-explanatory.	**Documents and Observations** 1. Verify that compounding components are stored and used as appropriate.	1 2 4 NA 1 = Full compliance 4 = Non-compliance. NA = Compounding not performed at the facility.
25.04.08 Drug Expiration Date. (Effective 07/06/10) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest	Self-explanatory.	**Documents and Observations** 1. Verify that all compounded drug product is given an expiration date 2. Verify that date does not exceed 180 days unless supported by stability studies.	1 2 4 NA 1 = Full compliance 4 = Non-compliance. NA = Compounding not performed at the facility.

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expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. 16 CCR 1735.2(h)			
25.04.09 <u>Responsibilities of Pharmacist.</u> (Effective 07/06/10) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product. 16 CCR 1735.2(i)	Self-explanatory.	**Documents and Observations** 1. Verify that the there is an identified responsible pharmacist.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Compounding not performed at the facility.
25.04.10 <u>Pharmacist Self-assessment Form.</u> (Effective 07/06/10) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board of pharmacy (form 17m-39rev. 10/07). 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 sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1of odd-numbered each year, within 30 days of the start of a new	Self-explanatory.	**Documents and Observations** 1. Verify that a self-assessment form has been completed for each pharmacist-in-charge. 2. Verify that a self-assessment form has been completed thereafter each odd numbered year.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed

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pharmacist-in-charge, 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 16 CCR 1735.2(j) (Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professional Code.)			
25.04.11 <u>Recordkeeping of Compounded Drug Products.</u> (Effective 07/06/10) For each compounded drug product, the pharmacy records shall include: (1) The master formula record. (2) The date the drug product was compounded. (3) The identity of the pharmacy personnel who compounded the drug product. (4) The identity of the pharmacist reviewing the final drug product. (5) The quantity of each component used in compounding the drug product. (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. (7) The equipment used in compounding the drug product.	Self-explanatory.	**Documents and Observations** 1. Verify that for each compounded drug product the pharmacy records include the ten (10) items listed.	1 [illegible] 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.

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(8)A pharmacy assigned reference or lot number for the compounded drug product. (9)The expiration date of the final compounded drug product. (10)The quantity of amount of drug product compounded. 16 CCR 1735.3(a)(1-10)			
25.04.12 <u>Records of Compounding Components.</u> (Effective 07/06/10) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding. 16 CCR 1735.3(b)	Self-explanatory.	**Documents and Observations** 1. Verify the pharmacy maintains records of the acquisition, storage, and destruction of compounding components as listed.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.04.13 <u>Compounding Components Obtained from Reliable Suppliers.</u> (Effective 07/06/10) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration. 16 CCR 1735.3(c)	Self-explanatory.	**Documents and Observations** 1. As how the pharmacy verifies it obtains compounding components from reliable suppliers.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.04.14 <u>Record Retention.</u> (Effective 07/06/10) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at	Self-explanatory.	**Documents and Observations** 1. Verify that retention records are maintained in a readily retrievable form for at least	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not

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least three years from the date the record was created. 16 CCR 1735.3(d) (Authority cited: Sections 4005 and 412, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.)		three years from the date the record was created.	performed
25.04.15 <u>Labeling of Compounded Drug Products.</u> (Effective 07/06/10) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s). 16 CCR 1735.4(a)	Self-explanatory.	**Documents and Observations** 1. Verify that labels contain the generic name(s) of the principal active ingredient(s).	1 2 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.04.16 <u>Responsible Pharmacy Listed.</u> (Effective 07/06/10) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient. 16 CCR 1735.4(b)	Self-explanatory.	**Documents and Observations** 1. Verify that a statement is included on the container or on the receipt provided to the patient.	1 2 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.04.17 <u>Minimum Labeling of Small Containers.</u> (Effective 07/06/10) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with 15.04.15 (subdivisions (a) and (b) of 16 CCR 1735.4(a)) shall be labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date. 16 CCR 1735.4(c)	Self-explanatory.	**Documents and Observations** 1. Verify small containers 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 expiration date.	1 2 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.

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(Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 5036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.)			
25.04.18 Compounding Policies and Procedures. (Effective 07/06/10) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes 1) procurement procedures, 2) methodologies for the formulation and compounding of drugs, 3) facilities and 4) equipment cleaning, 5) maintenance, 6) operation, and 7) other standard operating procedures related to compounding. 16 CCR 1735.5(a)	Self-explanatory.	**Documents and Observations** 1. Verify there is a written policy and procedure manual that contains at least the six (6) basic required elements.	1 3 4 NA 1 = Full compliance 3 = one of the elements missing 4 = Two of more of the elements missing. NA = Sterile compounding not performed
25.04.19 Policy and Procedure Manual – Review. (Effective 07/06/10) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented. 16 CCR 1735.5(b)	Self-explanatory.	**Documents and Observations** 1. Verify that the policy and procedure manual is reviewed at least on an annual basis and updated as necessary.	1 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.04.20 Policy and Procedure Manual – Contents. (Effective 07/06/10) The policy and procedure manual shall include the following: (1)Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.	Self-explanatory.	**Documents and Observations** 1. Verify the policy and procedure manual includes the five (5) required elements.	1 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.

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(2)Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product. (3)The 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. (4)Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products. (5)Documentation of the methodology used to determine appropriate expiration dates for compounded drug products. 16 CCR 1735.5(e)(1-5) (Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.)			
25.04.21 <u>Compounding Facilities and Equipment.</u> (Effective 07/06/10) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.	Self-explanatory.	**Documents and Observations** 1. Verify there is written documentation regarding the facilities and equipment being maintained for safe and accurate compounding of drug products.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed

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16 CCR 1735.6(a)			
25.04.22 Maintenance of Equipment. (Effective 07/06/10) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specification. 16 CRR 1735.6(b) (Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.)	Self explanatory.	**Documents and Observations** 1. Verify that equipment used to compound drug products is stored, used, and maintained in accordance with manufacturers' specifications.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.04.23 Training of Compounding Staff. (Effective 07/06/10) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. 16 CCR 1735.7(a)	Self-explanatory.	**Documents and Observations** 1. Verify the pharmacy has records of staff skills and training related to their job responsibilities	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.04.24 Competency Evaluation Process. (Effective 07/06/10) The pharmacy shall develop and maintain an on-going 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. 16 CCR 1735.7(b)	Self-explanatory.	**Documents and Observations** 1. Verify the pharmacy has an ongoing competency evaluation process. 2. Verify that the pharmacy has documentation of any and all training related to compounding.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed

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25.04.25 Personnel Demonstrated Knowledge. (Effective 07/06/10) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding any drug product. 16 CCR 1735.7(c) (Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and professions Code.)	Self explanatory.	**Documents and Observations** 1. Verify that records are maintained regarding staff demonstration of knowledge about process and procedures for compounding any drug product.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.04.26 Compounding Quality Assurance. (Effective 07/06/10) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products. 16 CCR 1735.8(a)	Self-explanatory.	**Documents and Observations** 1. Verify the pharmacy has a written quality assurance plan designed to monitor and ensure integrity, potency, quality, and labeled strength of compounded drug products. 2. Verify that pharmacy QAPI is incorporated into the hospital-wide QAPI program.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.04.27 Quality Assurance - Written Procedures and Documentation. (Effective 07/06/10) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel. 16 CCR 1735.8(b)	Self-explanatory.	**Documents and Observations** 1. Verify the QA plan includes written procedures for verification, monitoring, and review of the adequacy of the compounding processes. 2. Verify the QA plan includes review of the processes by qualified pharmacy personnel.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.

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25.04.28 Qualitative and Quantitative Analysis and Reports. (Effective 07/06/10) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula. 16 CCR 1735.8(c)	Self-explanatory.	**Documents and Observations** 1. Verify the QA plan includes written standards for qualitative and quantitative analysis of integrity, potency, quality, and labeled strength of compounded drug products. 2. Verify that the related reports are retained and collated with the compounding record and master formula.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.
25.04.29 Quality Assurance – Written Procedures if Products Below Minimum Standards are Identified. (Effective 07/06/10) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength. 16 CCR 1735.8(d)	Self-explanatory.	**Documents and Observations** 1. Verify the QA plan includes a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.05.00 – Introduction. These HFAP standards for Compounding Sterile Preparations are cross referenced to the California Code of Regulations (CCR) Section 16, Article 7. Sterile Injectable Compounding, 1751 Sterile Injectable Compounding Area for Parenteral Solutions through 1751.12 Obligations of a Pharmacy Furnishing Portable Containers. Also	Self-explanatory.	These standards are scored below through review of HFAP standards 25.05.01 through 25.05.27	

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referenced are Title 24 Regulations Sec. 490A.3 Compounding Area for Parenteral Solutions, Sec. 505.12 Pharmacies: Compounding Area for Parenteral Solutions, and 505.12.1 Pharmacies: Laminar Flow Biological Safety Cabinet. Any pharmacy engaged in compounding sterile injectable drug products shall conform 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 Article 7 (section 1751 et seq.), applicable solely to sterile injectable compounding.			
25.05.01 <u>Sterile Injectable Compounding area for Parenteral Solutions.</u> The pharmacy shall have a designated area for the preparation of sterile injectable products which shall meet the following standards 16 CCR 1751(a): (1) Clean Room and Work Station Requirements, shall be in accordance with Section 490A.3.1 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. 16 CCR 1751(a)(1) (2) Walls, ceilings and floors shall be constructed in accordance with Section 490A.31 of Title 24, Part 2, Chapter 4A of the California Code of regulations. 16 CCR 1751(a)(2) (3) Be ventilated in a manner in accordance	**Sec. 490A.3 CA Code of Regulation <u>Compounding Area for Parenteral Solutions.</u>** The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall: 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. 2. Have non-porous and cleanable surfaces, walls, floor and floor coverings.	**DOCUMENTS AND OBSERVATIONS** 1. Verify that compounding area is a clean room. 2. Verify that walls, ceilings and floors made of non-porous, cleanable surfaces. 3. Verify that the area well ventilated. 4. Verify that laminar air flow hoods and clean room are certified annually. 5. Verify that supplies are stored in a manner which maintains integrity of an aseptic environment. 6. Verify that there is a sink with hot and cold running water is located in the	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.

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with section 505.12 Title 24, Part 4, Chapter 5 of the California Code of Regulations. 16 CCR 1751(a)(3) (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years. 16 CCR 1751(a)(4) (5) The pharmacy shall be arranged in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment. 16 CCR 1751(a)(5) (6) A sink shall be included in accordance with Section 490A.3.4 Title 24, Part 2, Chapter 4A of the California Code of Regulations. 16 CCR 1751(a)(6) (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration. 16 CCR 1751(a)(7) (Authority cited: Section 4005, Business and Professional Code; and Section 13944(a), Health and Safety Code.)	3. The pharmacy shall be arranged in such a manner that the laminar-flow hood 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 solutions. There shall be sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials. 4. A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it. **Sec. 505.12 CA Code of Regulation Pharmacies: Compounding Area for Parenteral Solutions.** The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall: 1. Be ventilated in a manner not interfering with laminar air flow. **Sec. 505.12.1 CA Code of Regulation Pharmacies: Laminar Flow Biological Safety Cabinet.** In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be 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 must ensure that contaminated clean room.	7. Verify that there is a refrigerator of sufficient capacity to meet the storage requirements for all materials requiring refrigeration present in the clean room. 8. Verify that there is an ISO class 5 (class 100) laminar air flow hood within a ISO class 7 (10,000) clean room (with a positive air pressure differential relative to adjacent areas **OR** There is an ISO class 5 (class 100) clean room with positive air pressure differential relative to adjacent areas **OR** There is a barrier isolator that provides an ISO class 5 (class 100) environment for compounding.	

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	air plenums that are under positive air pressure are leak tight.		
25.05.02 <u>Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients.</u> (a) No sterile injectable product shall be prepared 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 injectable drug products. 16 CCR 1751.01(a) (b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired. 16 CCR 1751.01(b) (c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected. 16 CCR 1751.01(c) (d) Exterior workbench surfaces and other hard surfaces in the designated area such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination. 16 CCR 1751.01(d) (Authority cited: section 4005, Business and Professional Code. Reference: Section	Self Explanatory	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that no sterile injectable product is prepared if it is known or reasonably should have been known that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products. 2. Verify that access to the designated area or clean room is limited to those individuals who are properly attired. 3. Verify that all equipment used in the designated area or clean room is made of material that can be easily cleaned and disinfected. 4. Verify that exterior workbench surfaces and other hard surfaces in the designated area such as walls, floors, ceilings, shelves, tables and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination.	1 2 3 4 NA 1 Full compliance 4 – Non-compliance. NA Compounding not performed at the facility.

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4005, Business and Professions Code and Section 18944(a), Health and Safety Code.)			
25.05.03 Written Policies and Procedures (P/P). Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to: (1) Compounding filling and labeling of sterile injectable compounds. 16 CCR 1751.02(a)(1) (2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration. 16 CCR 1751.02(a)(2) (3) Equipment and supplies. 16 CCR 1751.02(a)(3) (4) Training of staff in the preparation of sterile injectable products. 16 CCR 1751.02(a)(4) (5) Procedures for handling cytotoxic agents.16 CCR 1751.02(a)(5) (6) Quality assurance program. 16 CCR 1751.02(a)(6) (7) Record keeping requirements. 16 CCR 1751.02(a)(7) (Authority cited: Section 4005, Business and Professions Code. Reference: Section	Self Explanatory	**DOCUMENTS** Verify that policies and procedures for at least the following areas exist and are being followed: (A) Compounding, filling, and labeling of sterile injectable compounds. (B) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration. (C) Equipment and supplies. (D) Training of staff in the preparation of sterile injectable products. (E) Procedures for handling cytotoxic agents. (F)Quality Assurance Performance Improvement program. (G) Record keeping requirements.	1 [illegible] 4 NA 1 - Full compliance 4 – Non-compliance. NA Compounding not performed at the facility.

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4005, Business and Professions Code.)			
25.05.04 P/P Ingredients and Compounding Process. (b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist. 16 CCR 1751.02(b) (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that there is a policy for compounding process. 2. Verify that the ingredients and the compounding process for each preparation are determined in writing before compounding begins and reviewed by a pharmacist.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed
25.05.05 P/P Injectable Products from Non-Sterile Ingredients. Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have a written policies and procedures that comply with the following: (1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors. 16 CCR 1751.02(c)(1) (2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.	Self Explanatory.	DOCUMENTS 1. Verify that written policies are available to all personnel involved in these activities. 2. Verify that all staff have read the policies and procedures before compounding sterile injectable products, Verify that any additions, revisions, and deletions to the written policies and procedures have been communicated to all personnel involved in sterile compounding. 3. Verify policies and procedures must address at least the following: (A) Staff competency evaluations. (B) Storage and handling of products and supplies.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.

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16 CCR 1751.02(e)(2)			
(3) Policies and procedures must address at least the following: (A) Competency evaluation. (B) Storage and handling of products and supplies. (C) Storage and delivery of final products. (D) Process validation. (E) Personnel access and movement of materials into and near the controlled area. (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations). (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision. (H) Disposal of packaging material, used syringes, contains, and needles to enhance sanitation and avoid accumulation in the controlled area. (I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for		(C) Storage and delivery of final product. (D) Process validation. (E) Personnel access and movement of materials into and near the compounding area. (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g. laminar air flow workstations, biological safety cabinet, class 100 clean room, and barrier isolation workstations). (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants (pharmacies subject to an institutional infection control policy may follow that policy. (H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area. (I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation. (J) Sterilization procedures exist	

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appropriate documentation. (J) Sterilization. (K) End-product evaluation and testing. 16 CCR 1751.02(c)(3) (Authority cited: section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)		(including documentation of sterilization results). (K) End-product evaluation and testing occurs.	
25.05.06 Labeling Requirements. In addition to existing labeling requirements, a pharmacy which compounds sterile products shall include the following information on the labels for those products: (a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy. 16 CCR 1751.2(a) (b) Name and concentrations of ingredients contained in the sterile injectable product. 16 CCR 1751.2(b) (c) Instructions for storage and handling. 16 CCR 1751.2(c) (d) All cytotoxic agents shall bear a special label which states "Chemotherapy-Dispose of Properly." 16 CCR 1751.2(d) (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that labels include telephone number of pharmacy (exemption: sterile injectable products dispensed for inpatients of a hospital). 2. Verify that labels include the name and concentration of ingredients contained in the product. 3. Verify that instructions exist for storage and handling of products. 4. Verify that cytotoxic agents bear a special label which states "Chemotherapy-dispose of Properly."	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.

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25.05.07 Recordkeeping Compounding Sterile Injectables for Future Use. (a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1 shall, in addition to those records required by section 1716.2, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber. 16 CCR 1751.3(a)	Sef explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that pharmacies compounding sterile injectable products for future use shall also have records indicating the name, lot number, amount, and date on which the products were provided to the prescriber.	1 2 3 4 NA 1 = Full compliance 4 = Non compliance. NA = Sterile compounding not performed
25.05.08 Records to be Maintained for at Least Three Years. The following records must be maintained for at least three years: 16 CCR 1751.3(b) (1) The training and competency evaluation of employees in sterile product procedures. (2) Refrigerator and freezer temperatures. (3) Certification of the sterile compounding environment. (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipments). (5) Inspection for expired or recalled pharmaceutical products or raw ingredients. (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results. (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)	These records are required in addition to the requirements of 25.05.07 (16 CCR 1751.39a).	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that maintenance of records for three years include: (A) Training and competency evaluation of employees in sterile product procedures. (B) Refrigerator and freezer temperatures monitored and documented. (C) Certification of the sterile compounding environment occurs on a regularly scheduled basis according to written policies and procedures. (D) Other facility qualify control logs specific to the pharmacy's policies and procedures are maintained (e.g. cleaning logs for facilities and equipment).	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed

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		(D) Inspection records for expired or recalled pharmaceutical products or raw ingredients. (E) Preparation records including the master work sheet, the preparation work sheet and records of end product evaluation.	
25.05.09 <u>Record Keeping Requirements (cont'd)</u> Pharmacies shall maintain records of validation processes as required by Section 1751.7(b) for three years. 16 CCR 1751.3(c) (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)	See standards 25.04.13 and 25.04.14.	**DOCUMENTS** **OBSERVATIONS** 1. Verify that records of validation process as described in 25.04.13 and 25.04.14 are maintained for at least three years.	1 2 3 4 NA 1 - Full compliance 4 - Non-compliance. NA - Sterile compounding not performed.
25.05.10 <u>Attire.</u> (a) When preparing cytotoxic agents, gowns and gloves shall be worn. 16 CCR 1751.4(a) (b) When compounding sterile products from one or more non sterile ingredients the following standards must be met: 16 CCR 1751.4(b) (1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be work inside the designated area at all times. (2) Cleanroom garb must be donned and removed outside the designated areas. (3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that when preparing cytotoxic agents, gowns and gloves are worn. <u>For compounding sterile products from one or more non-sterile ingredients:</u> 2. Verify that clean room garb consists of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times. 3. Verify that clean room garb is donned and removed outside the designated area.	1 2 3 4 NA 1 - Full compliance 4 - Non-compliance. NA Compounding not performed at the facility.

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then it must be thoroughly cleaned and covered with a sterile glove. (4) Head and facial hair must be kept out of the critical area or be covered. (5) Gloves made of low-shedding materials are required. (c) The requirements of this subdivision do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients. 16 CCR 1751.4(c) (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)		4. Verify that hand, finger, and wrist jewelry must be removed. If jewelry cannot be removed, the jewelry must be thoroughly cleaned and covered with a sterile glove. 5. Verify that head and facial hair is kept out of the critical area or is covered. 6. Verify that protective gloves made of low-shedding materials are required. 7. Review policy on attire for preparation of cytotoxic agents.	
25.05.11 <u>Training of Staff, Patient, and Caregiver.</u> (a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. 16 CCR 1751.5(a) (b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, Parenteral solutions including cytotoxic agents if the pharmacy compounds products with cytotoxic agents. 16 CCR 1751(b) (c) Records of training and demonstrated	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. 2. Verify that the pharmacist in charge ensures that all personnel engaging in compounding sterile injectable drug products have been trained and demonstrate on-going competence in the safe handling and compounding of sterile injectable drug products including cytotoxic agents 3. Verify that records of training and	1 2 3 4 NA 1 – Full compliance 4 Non-compliance. NA Compounding not performed at the facility.

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competence shall be available for each individual and shall be retained for three years beyond the period of employment. 16 CCR 1751.5(c) (d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. 16 CCR 1751(d) (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)		demonstrated competence are available for each individual and are retained for three years beyond the period of employment.	
25.05.12 Training of Staff RE: Knowledge and Skills. (e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements: (1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that 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: (A) Aseptic technique. (B) Pharmaceutical calculations and terminology. (C) Sterile product compounding documentation	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that pharmacies have an established and follow a written program of training performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. 2. Verify that the program of training and evaluation addresses the following: aseptic technique, pharmaceutical calculations/terminology, sterile product compounding documentation, quality assurance procedures, aseptic preparation procedures, proper gowning and gloving techniques, general conduct in the controlled area, cleaning/sanitizing and maintaining	1 [illegible] 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.

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(D) Quality assurance procedures. (E) Aseptic preparation procedures. (F) Proper gowning and gloving technique. (G) General conduct in the controlled area. (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area. (I) Sterilization techniques. (J) Container, equipment, and closure system selection. (2) Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. 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 every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years. 16 CCR 1751.5(a)(1)(A-J)and (2) (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)		equipment used in the controlled area, sterilization techniques, container, equipment and closure system selection. 3. Verify that each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. 4. Verify that evaluations include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. 5. Verify that each person's proficiency and continuing training needs is reassessed every 12 months. 6. Verify that results of staff assessments are documented and retained in the pharmacy for three years.	
25.05.13 <u>Disposal of Waste Material.</u> Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that pharmacies compounding sterile injectable products have written policies and procedures for the disposal of infectious materials and/or materials	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA = Sterile compounding not performed

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16 CCR 1751.6 (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.) **25.05.14 Quality Assurance and Process Validation for Personnel, Equipment and Facilities (QAPI).** There shall be a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following: (1) Cleaning and sanitization of the parenteral medication preparation area. (2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature. (3) Actions to be taken in the event of a drug recall. (4) Written justification of the chosen expiration dates for compounded sterile injectable products. 16 CCR 1751.7(a)(1-4) (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)		containing cytotoxic residue. 2. Verify that procedures include cleanup of spills and are in conformance with local health jurisdiction. **DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that the pharmacy has a documented, ongoing quality assurance program that monitors personnel, performance, equipment and facilities. Verify that the pharmacy QAPI program is incorporated into the hospital wide QAPI program. 2. Verify that the end product is examined on a periodic sampling basis as determined by the pharmacist in charge to assure that it meets required specifications. 3. Verify that the quality assurance program includes: (a) Cleaning and sanitization of the parenteral medication preparation area. (b) The storage of compounded parenteral products in the pharmacy and periodic documentation of refrigerator/freezer temperature. (c) Steps taken in the event of a drug	1 2 3 4 NA 1 = Full compliance 4 Non compliance. NA Compounding not performed at the facility.	

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		recall. (d) Written justification of the chosen expiration dates for compounded sterile injectable drug products.	
25.05.15 QAPI Personnel Validation Process (cont'd) Each individual involved in the preparation of sterile injectable products must successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be reevaluated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that each individual involved in the preparation of sterile injectable products has successfully completed a validation process on techniques for preparing sterile injectable products. 2. Verify that the process is carried out in the same manner as normal production. 3. Verify that the validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. 4. Verify that the same personnel, procedures, equipment, and materials are involved. 5. Verify that medium samples are incubated. 6. Verify that if microbial growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated.	1 [illegible] 4 NA 1 – Full compliance 4 – Non-compliance. NA Compounding not performed at the facility.

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aseptic techniques are observed. Revalidation must be documented. 1751.7(b) 16 CCR 1751.7(b) (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)		7. Verify that personnel competency is reevaluated at least every twelve months, when ever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. 8. Verify that the reevaluations are documented.	
25.05.16 <u>QAPI Products Testing for Sterility and Pyrogens (cont'd)</u> Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. 16 CCR 1751.7(c) (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that batched produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end produced testing for sterility and pyrogens. 2. Verify each batch is quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.
25.05.17 <u>Compounding Sterile Products Purchased from Specialty Compounding Pharmacies.</u> If the facility purchased sterile compounded products from a specialty compounding pharmacy, the facility must obtain and keep QA records including, but not limited to,	Self explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that the pharmacy obtained and retains quality assurance testing from the specialty compounding pharmacy (ies)	1 2 3 4 NA 1 = Full compliance 4 = Non compliance NA = The facility does not purchase sterile products from specialty

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sterility and pyrogen testing from the compounding pharmacy. Such records must be kept on file for a minimum of three years.		for sterility and pyrogens.	compounding pharmacies.
25.05.18 Reference Materials. There shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy. 16 CCR 1751.9 (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code)	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** Verify that there are current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.
25.05.19 Furnishing to Parenteral Patient at Home. Subject to the following conditions , a licensed pharmacy may furnish to a home health agency licensed under provision of Chapter 8 (commencing with section 1725 or Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice. 16 CCR 1751.10 (Authority cited: Section 4005, Business and Professions Code. Reference: Section	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Determine whether the pharmacy furnishes dangerous drugs for parenteral therapy other than controlled substances, to home health agencies or hospices. 2. If yes above, determine if the drugs are transported in portable containers.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility. NA = Facility does not provide compounded sterile preparations for home use by the patient.

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4005, Business and Professions Code.)			
25.05.20 Furnishing to Parenteral Patient at Home – Portable Container Preparation and Handling, (cont'd) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is: (1) furnished by a registered pharmacist; (2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs; (3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy; (4) labeled on the outside of the container with a list of the contents; (5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995,23rd Revision), and protected at all times from extreme temperatures that could damage the contents. 16 CCR 1751.11(a)(1-5) (Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.)	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** Verify that each portable container is: 1. furnished by a registered pharmacist; 2. sealed in such a manner that a tamperproof seal must be broken to gain access to the drugs; 3. under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy; 4. labeled on the outside of the container with a list of the contents; and 5. maintained at an appropriate temperature.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility. NA Facility does not provide compounded sterile preparations for home use by the patient.
25.05.21 Furnishing to Home Health Agencies and Licensed Hospices – Portable Container Content Volume. The portable container may contain up to: (1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** Verify that the portable containers meet the volume limits described in the standard.	1 2 3 4 NA 1 = Full compliance 4 = Non-compliance. NA Compounding not performed at the facility. NA Facility does

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determined by the pharmacy; (2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy; (3) two vials of urokinase 5000 units; 16 CCR 1751.11(b)(1-3) (Authority cited: Section 4005 and 4057, Business and Professions Code. Reference: Section 4040, 4057, 4081 and 4332, Business and Professions Code.)			not provide compounded sterile preparations for home use by the patient.
25.05.22 <u>Furnishing to Home Health Agencies and Licensed Hospices - Portable Container Medications (cont'd)</u> Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed portable container: (A) heparin sodium lock flush 100 units/mL; (B) heparin sodium lock flush 10 units/mL; (C) epinephrine HCL solution 1:1000; (D) epinephrine HCL solution 1:10,000; (E) diphenhydramine HCL 50mg/mL; (F) methylprednisolone 125mg/2mL; (G) normal saline, preserved, up to 30 mL vials; (H) naloxone 1mg/mL, 2 mL; (I) droperidol 5mg/2 mL; (J) prochlorperazine 10mg/mL; (K) promethazine 25mg/mL; (L) dextrose 25gms/50mL; (M) glucagon 1mg/mL;	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that the items listed in the standard, if used, are limited to five dosage units per portable container. 2. Determine if the pharmacy verified that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policy and procedures.	1 2 3 4 NA 1 – Full compliance 4 – Non-compliance. NA Compounding not performed at the facility. NA – Facility does not provide compounded sterile preparations for home use by the patient.

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(N) insulin (human) 100 units/mL; (o) bumetanide 0.5mg/2mL; (P) furosemide 10mg/mL; (Q) EMLA Cream 5gm tube; (R) Lidocaine 1 percent 30mL vials. 16 CCR 1751.11(b)(4)(A-R) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policy and procedures. 16 CCR 1751.11(b)(5) (Authority cited: Section 4005 and 4052, Business and Professions Code. Reference: Section 4040, 4057, 4081 and 4332, Business and Professions Code.)			
25.05.23 <u>Furnishing to Home Health Agencies and Licensed Hospices – Portable Container Restrictions (cont'd) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not: (1) implement and maintain policies and procedures for: (A) the storage, temperature stability and transportation of the portable container; (B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and (C) a specific treatment protocol for the administration of each medication contained in the portable container.	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that the home health agency or hospice utilizing a portable container has the appropriate policies/procedures addressing the elements of the standard. 2. Verify that the P/P are reviewed at least annually and revised as appropriate by the appropriate individuals.	1 [illegible] 4 NA 1 Full compliance 4 Non-compliance. NA Compounding not performed at the facility. NA – Facility does not provide compounded sterile preparations for home use by the patient

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16 CCR 1751.11(c)(1)(A-C). (2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse. 16 CCR 1751.11(c)(2) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers. 16 CCR 1751.11(d) (Authority cited: Section 4005 and 4057, Business and Professions Code. Reference: Section 4040, 4057, 4081 and 4332, Business and Professions Code.)			
25.05.24 <u>Furnishing to Home Health Agencies and Licensed Hospices – Policies and Procedures that HHA or Hospice must Have in Place (cont'd)</u> In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by a registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days. 16 CCR 1751.11(e)	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** 1. Verify that oral orders for medication are immediately written down by a nurse or a pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days. 2. Verify that within seven days (168 hours) after the seal has been broken on	1 2 3 4 NA 1 – Full compliance 4 – Non-compliance. NA Compounding not performed at the facility. NA – Facility does not provide compounded sterile preparations for home use by the patient.

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The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice. 16 CCR 1751.11(f) (Authority cited: Section 4005 and 4057, Business and Professions Code. Reference: Section 4040, 4057, 4081 and 4332, Business and Professions Code.)		the portable container, the home health agency's director of nursing service or registered nurse employed by the home health agency or licensed hospital returns the container to the furnishing pharmacy. 3. Verify that the furnishing pharmacy then performs an inventory of the drugs used from the container, and if the container will be reused, restocks and reseals the container before it is again furnished to the home health agency or licensed hospice.	
25.05.25 <u>Furnishing to Home Health Agencies and Licensed Hospices – Policies and Procedures that Furnishing Pharmacy must Have in Place (cont'd)</u> The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container. 16 CCR 1751.11(g) (Authority cited: Section 4005 and 4057, Business and Professions Code. Reference: Section 4040, 4057, 4081 and 4332, Business and Professions Code.)	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** Verify that the pharmacy has written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable containers.	1 2 3 4 NA 1 – Full compliance 4 – Non compliance. NA Compounding not performed at the facility. NA – Facility does not provide compounded sterile preparations for home use by the patient.
25.05.26 <u>Furnishing to Home Health</u>	Self-explanatory.	**DOCUMENTS**	1 [illegible] 4 NA

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Agencies and Licensed Hospices - Return of Portable Containers (cont'd) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken. 16 CCR 1751.11(h) (Authority cited: Section 4005 and 4057, Business and Professions Code. Reference: Section 4040, 4057, 4081 and 4332, Business and Professions Code.)		**INTERVIEWS** **OBSERVATIONS** Verify that the pharmacy ensures that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.	1 -Full Compliance 4 Non compliant NA = Facility does not provide compounded sterile preparations for home use by the patient
25.05.27 Furnishing to Home Health Agencies and Licensed Hospices - Inventory and Records the Furnishing Pharmacy must Have in Place. (cont'd) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container. 16 CCR 1751.11(i) (Authority cited: Section 4005 and 4057, Business and Professions Code. Reference: Section 4040, 4057, 4081 and 4332, Business and Professions Code.)	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** Verify that the furnishing pharmacy maintains current inventory and record of all items placed into and furnished from the portable container.	1 [illegible] 4 NA 1=Full Compliance 4 Non-compliant NA = Facility does not provide compounded sterile preparations for home use by the patient.
25.05.28 Obligations of a Pharmacy Furnishing Portable Containers (a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with the provisions of section	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** Verify that the licensed pharmacy does not issue portable containers to any home health agency or licensed hospice	1 [illegible] 4 NA 1 - Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.

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Agencies and Licensed Hospices – Return of Portable Containers (cont'd) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken. 16 CCR 1751.11(h) (Authority cited: Section 4005 and 4057, Business and Professions Code. Reference: Section 4040, 4057, 4081 and 4332, Business and Professions Code.)		**INTERVIEWS** **OBSERVATIONS** Verify that the pharmacy ensures that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.	1 Full Compliance 4 = Non-compliant NA Facility does not provide compounded sterile preparations for home use by the patient.
25.05.27 Furnishing to Home Health Agencies and Licensed Hospices – Inventory and Records the Furnishing Pharmacy must Have in Place. (cont'd) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container. 16 CCR 1751.11(i) (Authority cited: Section 4005 and 4057, Business and Professions Code. Reference: Section 4040, 4057, 4081 and 4332, Business and Professions Code.)	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** Verify that the furnishing pharmacy maintains current inventory and record of all items placed into and furnished from the portable container	1 [illegible] 4 NA 1=Full Compliance 4 = Non-compliant NA – Facility does not provide compounded sterile preparations for home use by the patient.
25.05.28 Obligations of a Pharmacy Furnishing Portable Containers (a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with the provisions of section	Self-explanatory.	**DOCUMENTS** **INTERVIEWS** **OBSERVATIONS** Verify that the licensed pharmacy does not issue portable containers to any home health agency or licensed hospice	1 [illegible] 4 NA 1 Full compliance 4 = Non-compliance. NA Compounding not performed at the facility.

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16 CCR 1751.12(a) (b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section 16 CCR 1751.12(b) (Authority cited: Section 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.)		unless the home health agency or licensed hospice complies with the provisions of: 16 CCR 1751.12(a), and 16 CCR 1751.12(b)	

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25.00.00 Pharmaceutical Services. *The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.* 482.25 **Medication errors are a substantial source of morbidity and mortality in the hospitalized setting. Therefore, the development of policies and procedures to minimize medication errors must be based on accepted professional principles; external alerts and proactive review of facility reported and reviewed adverse drug events. It is important to flag new types of mistakes and continually improve and refine processes, based on the analysis of what went wrong** 1. High-alert medications—dosing limits, administration guidelines, packaging, labeling and storage 2. Limiting the variety of medication-related devices and equipment 3. Availability of current medication information 4. Availability of pharmacy expertise. Pharmacist availability on-call when pharmacy does not operate 24/7. 5. Standardization of prescribing and	Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, doses, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment. The hospital's pharmacy must be directed by a registered pharmacist. **Pharmaceutical services would include:** • **The procuring, manufacturing, compounding, packaging, dispensing, ordering, distributing, disposition, use, and administration of all medications, biologicals, chemicals and the use of medication related devices.** • **Provision of medication-related information to hospital health care professionals and patients necessary to optimize therapeutic outcomes.** • **Provision of pharmaceutical care. Pharmaceutical care is defined as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life while minimizing patient risk.**	**INTERVIEW, OBSERVATION, DOCUMENT REVIEW, FILE REVIEW & CHART REVIEW** Interview the Chief Pharmacist or the individual delegated to fulfill the functions. Review policies and procedures, the formulary, minutes of the meeting where pharmacy issues are discussed and the pharmacy QAPI plan. Observe for compliance with pharmacy-related policies and procedures. Interview staff to determine their familiarity with pharmacy-related policies and procedures. Verify: 1. Either the Medical Staff or pharmacy has developed policies and procedures. 2. The purpose of pharmaceutical policies and procedures is to minimize drug errors. 3. Policies address all 13 issues defined in the standard. 4. Pharmacy is responsible for medication administration throughout the organization, in inpatient and outpatient care. 5. The hospital's pharmacy services are integrated into its hospital-wide QAPI program.	1 2 3 4 NA 1 = Full compliance 2 = Acceptable Compliance 3 = Minimal Compliance. 4 = Non compliance.

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communication practices to include • Avoidance of dangerous abbreviations • Elements of a complete order-dose, strength, units, route, frequency, and rate. • Alert systems for look-alike and sound-alike drug names • Use of facility approved pre-printed order sheets whenever possible 6. Orders to "resume previous orders" are prohibited 7. A voluntary, non-punitive reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions) 8. The preparation, distribution, administration and proper disposal of hazardous medications 9. Drug recalls and external alerts 10. That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. 11. Identification of when weight-based dosing for pediatric populations is required 12. Requirements for review and revision based on facility-generated reports of adverse drug events and QAPI activities. **13. The hospital must have a pharmacist leader that has an active role on the**	**Functions of Pharmaceutical Care are the:** a. **Collection and organization of patient-specific information** b. **Determination of the presence of medication-therapy problems both potential and actual** c. **Summary of the patient's medication related health care needs** d. **Identification and specification of pharmacotherapeutic goals** e. **Development of a pharmacotherapeutic regimen** f. **Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health care professionals** g. **Monitoring the effects of the pharmacotherapeutic regimen** h. **Redesigning the regimen and monitoring plan as indicated.** The hospital may utilize a unit dose system individual prescription, floor stock system or a combination of these systems, properly stored. Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles includes compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical	6. Drugs and biologicals are stored in accordance with manufacturers directions and State and Federal requirements 7. Records have sufficient detail to follow the flow of control from entry through dispensation 8. Employees provide pharmaceutical services within their scope of license and education 9. The hospital has a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and policy and procedure revision. 10. Policies are consistent in application throughout the hospital. 11. The pharmacy director periodically monitors implementation of policies and procedures 12. Policies and procedures are current 13. The pharmacy is responsible for the procurement, distribution and control of all medication products used in the hospital (including medication-related devices) for inpatient and outpatient care. This includes ALL hospital departments and locations. Upon review of patient clinical records, are issues with regard to provision of pharmaceutical services identified? • Is the facility aware of the	

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administration leadership team. **The pharmacy leader should report to the CEO or COO (CNO if on the same organizational level as the CFO/COO), have a title consistent with others reporting to that organizational level.**	services, as well as, standards or recommendations promoted by nationally recognized professional organizations. Agencies and organizations could include FDA, NIH, American Society of Health-System Pharmacists, etc. The hospital pharmacy service must be integrated into the hospital-wide QAPI program. **The pharmacy leader must be appropriately positioned within the organization to ensure the best utilization of his or her expertise in all decisions regarding medication use.** **When the pharmacy leader reports directly to the CEO or COO rather than multiple layers of management, the quality and timeliness of information exchange improve significantly. Pharmacy leaders can be more actively engaged in critical decision making and more effective in helping the organization address rapid change.** **Note: Each organization may have a slightly different leadership structure. The intent of this standard is to eliminate reporting layers between the pharmacy director and the CEO.**	issues? • Was there a failure to implement a policy and procedure? **DOCUMENT REVIEW** 1. **Review Organizational Chart.** 2. **Review policy and procedures to determine pharmacist role and responsibilities.** 3. **Review Job Description** 4. **Minutes from Leadership meetings for attendance and discussion.**	

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	The hospital should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include direct observation of medication administration, review of patient's clinical records, identification of patient signals that would warrant immediate review of patient's medication therapy and implementation of medication use evaluation studies. **The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision considerations.**		
25.00.01 Licensure. Each pharmacy location is licensed as required by State law. If the pharmacy provides retail outpatient dispensing it is also licensed for this activity, if required.	Most states require hospital pharmacies to be licensed separately from the facility. Some states require retail pharmacy licenses for outpatient dispensing even if this is limited to employee prescriptions.	**OBSERVATION** Verify that the license(s) is/are current and prominently posted. (Often, states require reissue in the event of a change in pharmacy director.) If required by the state, license(s) is posted.	1 2 3 4 NA 1 – Full compliance. 2 – License current but not posted in all locations. 4 – License not current in all locations.
25.00.02 Permits & Certifications. Permits and certifications required by law are current for all pharmacy locations. These are located within the pharmacy area and posted, if required by law.	Permits may include but are not limited to: • Drug Enforcement Agency; • State controlled substance; • Tax free alcohol; • Pharmacist preceptor for intern practitioners.	**OBSERVATION** Verify: 1. Permits and certifications are current and posted for all pharmacy locations. 2. Permits exist for all required activities.	1 2 3 4 NA 1 – Full compliance. 2 – Met, but not all posted if required 4 – A permit is not current / available.

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		3. If required by the state, permits are posted.	
25.00.03 Scope of Service. The hospital **provides** pharmaceutical services appropriate to the scope of service of the facility.	The patient mix and acuity drive the scope of services.	**DOCUMENT REVIEW & OBSERVATION** Observe physical space, equipment. Review the scope of service statement Verify: 1. **The scope of service statement identifies the needs of the patients served.** 2. Pharmaceutical services are appropriate **to meet the needs of patients.**	1 2 3 4 NA 1 = Services match the scope of service identified needs. 4 = Services do not meet the scope of service identified needs.
25.00.04 Management. *A full time, part time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all of the activities of the pharmacy services.* 482.25(a)(1)	Depending on the size and complexity of the service the pharmacy director may be less than full time. In any event, the pharmacy director is a state licensed pharmacist with thorough knowledge of hospital pharmacy practice and management. A single pharmacist must be responsible for the overall administration of the pharmacy service. The job description **of the pharmacist** shall clearly state **the** responsibilities **of this individual** which include: • developing, • supervising, and • coordinating all the activities of pharmacy services.	**FILE REVIEW, DOCUMENTATION REVIEW, & INTERVIEW** Review the implementation of the chief pharmacist's responsibilities through review of meeting minutes, schedules and logs, the job description, and the evaluation/competency validation process. Verify: 1. Current state licensure for all pharmacists, including the director, serving the facility. 2. All pharmacy staff function within an appropriate, approved scope of practice.	1 2 3 4 NA 1 = Fully compliant 4 = One license is not current / available. OR 4 = Pharmacy staff are functioning outside of an appropriate approved scope of practice, OR 4 = Chief pharmacist defined responsibilities do not meet standard OR 4 = Pharmacy director is not involved in all committees where medication related policies and procedures are being developed.

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	The pharmacy director will be actively involved in those committees responsible for establishing medication-related policies and procedures. Pharmacists and pharmacy technicians must perform their duties within the scope of their license and education.	3. The pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.	
25.00.05 Staffing. *The pharmacy service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.* 482.25(a)(2)	Professional criteria, Federal and State regulations (and licensing acts) guide the facility requirements for staff. There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served. The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff. The number of pharmacists and/or the number of hours of services provided by pharmacists at the hospital, or at each location of the hospital that provides pharmaceutical services, must meet and be in accordance with the needs of its patients and accepted professional principles (as previously defined), and reflect the scope and complexity of the	**DOCUMENT REVIEW, INTERVIEW, & OBSERVATION** Determine: 1. The staffing mix and number is adequate to provide the level of service appropriate to the institution, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff. 2. There are sufficient personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.	1 2 3 4 NA 1 - Full compliance. 4 – Non compliance.

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	hospital's pharmaceutical services. There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.		
25.00.06 Scheduled Drugs. *Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.* 482.25(a)(3). Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs include: 1. Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs 2. Records of the receipt and disposition of all scheduled drugs must be current and must be accurate 3. Records trace the movement of scheduled drugs throughout the service 4. The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled. 5. The record system, delineated in	A "perpetual" inventory is maintained. Distribution and movement of scheduled drugs throughout the facility is controlled and records are maintained and reconciled. Destruction and waste records are maintained and monitored.	**DOCUMENT REVIEW, INTERVIEW & OBSERVATION** Review a sample of (6) narcotic balance sheets representative of anesthesia, ER, GI lab, pharmacy, and from nursing care units. Observe for witnessed waste / destruction and balanced inventory. Select two drugs from the inventory and complete a drug count with a registered nurse or pharmacist. Verify: 1. The perpetual inventory is maintained. 2. There is a record system in place that provides information on controlled substances in a readily retrievable manner, and review records to determine they effectively trace movement throughout the	1 2 3 4 NA 1 = Narcotic control exists. 2 = 1 instance of inventory not balanced 3 = All locations are not included in the scheduled drug maintenance process 3 = A process is in place, but records are not readily retrievable 4 = Multiple locations are not included in the maintenance process, or, 4 = Multiple instances of unreconciled stock or identified diversion-process does not effectively control receipt and distribution

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policies and procedures, tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs. 6. All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly 7. The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion. 8. Facility policies and procedures should minimize scheduled drug diversion.		hospital. 3. There is an effective process for reconciliation and disposal. 4. The pharmacist is accountable for maintenance of all drug records and reconciliation. 5. Facility policy and procedures minimize scheduled drug diversion.	
25.00.07 Space Requirements. There is adequate space allocated to enhance the security of inventories.	Sufficient space permits the orderly storage of inventories. Separate storage for Schedule II drugs exists.	**OBSERVATION** Interview staff to determine their familiarity with pharmacy-related policies and procedures. **Verify:** 1. **Space allocation allows for orderly storage of inventory.** 2. **Schedule II inventory is stored**	1 2 3 4 NA 1 = Full compliance. 3 = Space inadequate. 4 = Scheduled drugs not secure.

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		separately and double locked.	
25.01.01 Medication Control & Distribution. *In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice consistent with Federal and State law.* 482.25(b)	The pharmacist, in consultation with appropriate hospital staff and committees, develops and implements guidelines, protocols, policies and procedures for the provision of pharmaceutical services that ensure patient safety through the appropriate control and distribution of medications, medication-related devices and biologicals. **High-Risk Medications / Patients** For high-risk medications and high-risk patients (pediatric, geriatric, or patients with renal or hepatic impairment) there should be systems in place to minimize adverse drug events. Such systems could include but are not limited to checklists, dose limits, pre-printed orders, special packaging, special labeling, double-checks and written guidelines. "High risk medications" are those medications involved in a high percentage of medication errors and or critical events and medications that carry a higher risk for abuse, errors, or other adverse outcomes. Lists of high-risk or high-alert drugs are available from such organizations as the	**DOCUMENT REVIEW & OBSERVATION** Verify: There processes in place to: 1. Limit drug concentrations, particularly high-alert drugs like Morphine and heparin, 2. Limit access to concentrated solutions (potassium chloride, sodium chloride concentrations greater than 0.9%), 3. Monitor medication therapy, 4. Report serious adverse drug reactions, 5. Prevent unauthorized usage and distribution of medication, 6. Retrieve and remove a drug recall, including notification of patients that have been impacted as well as those that would order dispense or administer the medication. Are these policies being implemented? Identify and assess the quality assurance procedures for the preparation of sterile products. Determine: 1. The pharmacy is involved in the evaluation, use and monitoring of drug delivery systems,	1 2 3 4 NA 1 – Full compliance 3 – Policies are in place but there is inconsistent implementation 4 – Control and distribution of medication does not meet acceptable standards.

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	Institute for Safe Medication Practices (ISMP) and the United States Pharmacopoeia (USP). Examples of high-risk drugs may include: • Investigational drugs, • Controlled medications, • Medications not on the approved FDA list, • Medications with a narrow therapeutic range, • Psychotherapeutic medications and look-alike/sound-alike medications and • Those new to the market or new to the hospital. **Review of Orders** All medication orders are reviewed for appropriateness by a pharmacist before the order is dispensed, except in emergencies. The review should include: 1. Appropriateness, 2. Therapeutic duplication, 3. Appropriateness of drug, dose, frequency, route and method of administration, 4. Potential interactions, 5. Real or potential allergies or sensitivities, 6. Variation from criteria for use and 7. Other contraindications.	administration devices and automated drug dispensing machines. 2. The evaluation and monitoring should include the potential for medication errors, 3. Medication storage areas are periodically inspected to make sure medications are properly stored.	

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	Monitor Effects of Medications The effects of medications must be monitored to minimize adverse events and assure appropriateness. The monitoring process includes: a. Clinical and laboratory data to evaluate efficacy and anticipate or evaluate toxicity and adverse effects b. Physical signs and clinical symptoms relevant to the patient's medication therapy c. Assessing the patients' own perceptions about side effects, and perceived efficacy.		
	Sterile Preparation Sterile products should be prepared and labeled in a suitable environment by appropriately trained and qualified personnel.		
	Emergency Medication Kits The pharmacy should participate in hospital decisions about emergency medication kits. The supply and provision of emergency medications stored in the kits must be consistent with standards of practice and appropriate for a specified age group or disease treatment as well as consistent with applicable Federal and State laws.		
	Automated Drug Dispensing Machines		

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	The pharmacy should be involved in the evaluation, use and monitoring of drug delivery systems, administration devices and automated drug- dispensing machines. The evaluation and monitoring should include the potential for medication errors. **Report Adverse Reactions** There must be a process to report serious adverse drug reactions to the FDA in accordance with the Med Watch program. **Medications From Home** There is a policy that addresses the use of medications brought into the hospital by patients or their families. **Investigational Medications** There is a process and policy to ensure that investigational medications include the following: * A written process for reviewing, approving, supervising, and monitoring investigational medications specifying that when pharmacy services are provided, the pharmacy controls the storage dispensing, labeling, and distribution of the investigational medication. The hospital pharmacy must ensure that medication orders are accurate and that		

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	medications are administered as ordered. The pharmacy should have a system to reconcile medications that are not administered, that remain in the patient's medication drawer, slot, etc, when the pharmacy inventories patient medications or restocks patient medications. The pharmacy should determine the reason the medications were not used.		
25.01.02 <u>Supervision of Pharmacy Activities.</u> *All compounding, packaging and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with Federal and State laws.* 482.25(b)(1)	1. Medications must be prepared safely. Safe preparation procedures must include: a. Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when the product's stability is short) b. Safety materials and equipment are used when preparing hazardous medications, in all locations c. Wherever medications are prepared, staff use techniques to assure accuracy in medication preparation d. Staff use appropriate techniques to avoid contamination during preparation including using clean or sterile technique as appropriate, maintaining clean, uncluttered, and functionally	**<u>OBSERVATION, INTERVIEW & DOCUMENT REVIEW</u>** A. Review policies and procedures; B. Interview pharmacy and hospital staff to determine how drugs and biologicals are prepared and dispensed; C. Observe on site dispensing and compounding operations; D. Review records of drugs and biologicals removed from the pharmacy by non-pharmacy personnel; and E. Inspect drug storage areas. Verify: 1. Only pharmacists or pharmacy supervised personnel compound, label and dispense drugs or biologicals in accordance with State and Federal laws and regulations and as accepted national principles.	1 2 3 4 NA 1 – Full compliance 4 – Processes do not support safe compounding and dispensing of medications

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	separate areas for product preparation to minimize potential contamination, using a laminar airflow hood or other appropriate environment while preparing any intravenous admixture in the pharmacy, any sterile product made from non-sterile ingredients, or any sterile product that will not be used within 24 hours, and visually inspecting the integrity of the medications.	2. Policies and procedures are consistently implemented.	
	2. Medications must be dispensed safely as well as meet the needs of the patient. a. Quantities are dispensed which minimize diversion and potential adverse events while meeting the needs of patients. b. Medications are dispensed in a timely manner. The hospital must have a system that ensures that orders are received and medications are delivered promptly for timely distribution to patients. c. Medication is dispensed in the most ready to administer form available. d. A consistent packing system is utilized e. All concerns, issues or questions are clarified with the		

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	individual prescriber before dispensing. **Supervision of Non-Pharmacists** A pharmacist verifies the work of a non-pharmacist prior to the drug / biological leaving the pharmacy / drug room. Mechanisms are in place to assure that a registered pharmacist is accountable for all medications leaving the pharmacy service. A Pharmacist reviews medication orders prior to delivery to the patient floor / unit.		
25.01.03 **Security of Medications.** Consistent with state and federal requirements, in the pharmacy and throughout the facility: 1. *All drugs and biologicals must be kept in a secure area, and locked when appropriate. 482.25(b)(2)(i)* 2. *Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area. 482.25(b)(2)(ii)* 3. *Only authorized personnel may have access to locked areas. 482.25(b)(2)(iii)*	The security of drugs and biologicals is essential to patient safety. Thus, all drugs and biologicals must be stored in a manner to prevent access by unauthorized individuals. Only authorized personnel may have access to locked areas. All drugs and biologicals must be kept in a secure area and locked when appropriate. Hospitals have the flexibility to determine the most effective way to safe guard non-controlled drugs and biologicals when they are not locked. The term "locked when appropriate" applies to: a. Schedule II, III, IV, and V drugs:	**DOCUMENT REVIEW** Determine all required policies are in place. **OBSERVATION** While touring each patient care area including the Emergency Department, Critical Care units, Pediatrics, Operating Room, Labor and Delivery, and outpatient services, determine by inspection whether all medications are stored in a manner that prevents unauthorized access. **INTERVIEW** Determine if the facility identifies what personnel may have access to medications.	1 2 3 4 NA 1 – Secure. 4 – Not secure.

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	1) These categories of drugs must be locked within a secured area, regardless of whether the patient care area is staffed. 2) These drugs must be in a locked storage cabinet, cart, etc., located within a secured or locked area. 3) Schedule II, III, IV, and V drugs cannot be left on a shelf or left in an unlocked cabinet / cart within a locked operating room. b. Non-controlled substances: This category drug must be secured at all times and locked when a patient care area is not staffed. <u>Secured Areas</u> a. A medication is considered secure when unauthorized persons are prevented from obtaining access. b. An area would generally be considered a "secure area" when staff are actively providing patient care or preparing to receive patients, e.g., setting up for a surgical procedure in advance of patient arrival. **<u>Policies</u>** Hospital policies are in place for the following: a. Procedures for storage of non-		

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	controlled drugs and biologicals when delivering patient care. b. Measures for safe guarding drugs and biologicals to prevent tampering and minimize diversion. c. Storage and monitoring of drugs, biologicals, and carts (locked and unlocked) in all patient areas to ensure patient safety. d. Identification of the "secure" areas of the hospital, e.g., operating room, labor and deliver. e. Identification of authorized individuals that have access to locked and secured areas, based on need and State and local law. Policy also defines those individuals that require supervision during performance of routine duties, e.g., housekeepers. f. Safeguarding, transferring and availability of keys to the locked storage area. Operating Rooms and Suites a. The operating room suite would be considered: 1) Secure when the suite is staffed and the staff are actively providing patient care.		

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	2) NOT secured when the entire suite is not operational or otherwise not in use (e.g., during weekends, after hours). b. When the OR suite is closed or otherwise not in use, it is expected that all drugs and biologicals be locked. The hospital must lock the entire suite and: 1) Lock non-mobile carts containing drugs and biologicals, or 2) Lock mobile carts containing drugs and biologicals within a locked room, or, 3) Lock drugs and biologicals within a secure area. c. When individual operating rooms are closed or not in use, hospitals are expected to: 1) Lock non-mobile carts containing drugs and biologicals, and 2) Lock mobile carts containing drugs and biologicals within a locked room. d. Schedule II, III, IV, and V drugs must be in a locked storage cabinet, cart, etc., located within a secured or locked area. These drugs cannot be left on a shelf or left in an unlocked cabinet / cart within a		

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	locked operating room. e. Schedule II, III, IV, and V drugs must be locked within a secured area, regardless of whether the patient care area is staffed. Authorized Persons a. Only authorized personnel may have access to the locked area. b. Persons without legal access to drugs or biologicals: 1) Cannot have unmonitored access to drugs or biologicals. 2) Cannot have keys to medication storage rooms, cards, cabinets, or containers. c. Whenever persons without legal access to the drugs or biologicals have unmonitored access to or could gain access to the drugs or biologicals stored in an area, the hospital in not in compliance. **Medication / Anesthesia Carts** a. When not in use, nursing medication carts, anesthesia carts, and other medication carts containing drugs or biologicals must be locked and stored in a locked storage room or secured location, per hospital policy.		

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	b. If a cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart. That person could be a nurse, a physician or other individual who in accordance with State and Federal law and hospital policy has legal access to the drugs and biologicals in the cart. That person must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart. c. When not in use, medication containers that are mobile or readily portable must be stored in a locked room, monitored location, or secured location that will ensure the security of the drugs or biologicals. **Patient Self-Administration of Medications** Hospital policies describe the processes for ensuring safe and accurate self-administration of medications, as allowed by State and local law. Bedside medications (e.g., nitroglycerine, inhalers) must be secured to prevent other patients or visitors from tampering or removing these drugs from		

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	the bedside. Policies are in place for the safe and accurate administration of medications, including processes to: 1. Secure bedside medications 2. Ensure patient competence with self-administration of medication.		
25.01.04 Pharmacy Security. At a minimum, the pharmacy is equipped with locking entries.	The pharmacy is locked when not staffed. Key inventories or access codes are strictly controlled. If "unusual" risk is perceived, measures are taken to respond.	**OBSERVATION & INTERVIEW** Evaluate the security of the pharmacy. 1. The area is secure from unauthorized entry. 2. Keys, security codes, and carts are secure.	1 2 3 4 NA 1 = Secure. 4 = Not secure
25.01.05 Inventory Management System. *Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.* 482.25(b)(3) The pharmacy director is responsible for establishing mechanisms for routine review of all drug inventories in the building and for logging inventory sequestered related to these issues. The destruction and / or return of recalled or unusable drugs is the responsibility of the pharmacist.	The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patent use. Mechanisms exist to identify products due to expire. All drug inventories, including those in "crash carts", etc. are inspected at least monthly for products ready to outdate. Recalled drugs are pulled from inventory immediately and handled according to FDA and manufacturer requirements.	**INTERVIEW** Discuss with the pharmacist the methods for dealing with aging dated products. **OBSERVATION** Observe several storage areas for manufacturer's outdates. (Refrigerators and freezers are often "overlooked" by staff.) Verify: 1. The inspection procedure for **checking outdated / unusable drugs and medications is consistent with policy.** 2. Outdated or recalled products are	1 2 3 4 NA 1 = Full compliance. 3 One outdate or improperly labeled drug found. 4 - Non compliance.

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		sequestered from general inventories to prevent reissue. Outdated Schedule II and III drugs are sequestered separately from nonscheduled drugs. 3. Each patient's medication is appropriately labeled with full name, prescriber's name, strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date. 4. Floor stock medications are labeled with name and strength of the drug, lot and control number or equivalent, and expiration date. 5. If the unit dose system is utilized, verify that each single unit dose package bears: • Name and strength of the drug, • Lot and control number equivalent, and • Expiration date.	
25.01.06 <u>Pharmacy Access.</u> *When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.* 482.25(b)(4)	Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-	**<u>OBSERVATION</u>** **<u>&</u>** **<u>DOCUMENT REVIEW</u>** **Review policies relative to after-hours access to pharmacy.** View the **"after-hours" medication** withdrawal log for at least three different	1 2 3 4 NA 1 – All elements met. 2 – Policies & procedures are in place per standard, but drug removal is not consistently documented 3 – Policies are in place but staff have not been educated or processes are

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	pharmacist staff to enter the pharmacy. Policies and procedures must be consistent with federal and State Law. When non-pharmacist health care professionals are allowed by law and regulation to obtain medications after the pharmacy is closed, the following safeguards are applied: 1. Access is limited to those medications approved by the hospital 2. Only trained, designated prescribers and nurses are permitted access 3. A quality control process is in place to prevent medication retrieval errors. 4. A qualified pharmacist is available on-call or at another location to answer questions or provide medications beyond those accessible to non-pharmacy staff 5. The process is evaluated regarding access issues and 6. Change is implemented to reduce access frequency Medication removals from the pharmacy or drug cabinet: • Are recorded and • Are in quantities sufficient only to dose until a pharmacist can review the order and the removal record. (This activity is to be in	nights. Verify: 1. The policy **limits** access **into the Pharmacy** by **anyone** other than RN or physician. 2. **Entries in the "after-hours" medication** withdrawal log should **indicate the patient's name** and not "to stock supply". 3. The quantity removed is **not** greater than that needed for immediate use. 4. The name of the "pharmacist on call" is readily identified. 5. A retrieval accuracy validation process is in place; unit staff are able to articulate that process. 6. A pharmacist routinely reviews the removal activity and correlates the removal with current medication orders in the patient medication profile. 7. The pharmacist routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital.	not consistently implemented. 4 – Unauthorized staff accessing the pharmacy after hours OR 4 – Off-hours pharmacy access is routine. Effective efforts have not been implemented to reduce access needs. OR 4 – Pharmacy access is not restricted to approved drugs only.	

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	"preparation for immediate dosing only"; dispensing by non-pharmacists is not permitted.) Some states prohibit entry into the pharmacy proper unless a pharmacist is present thus requiring use of "night" closets or drug cupboards for after hours supply. • All after-hour withdrawals are logged.		
25.01.07 <u>Automatic Stop Medication Orders.</u> *Drugs and biologicals not specifically prescribed as to time and / or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.* 482.25(b)(5) The Professional Medical Staff, via Policy and / or Rules and Regulations, establishes time frames for "time limiting" of medication orders. There are mechanisms for automatically discontinuing medications which are written as a "time limited" order.	Drugs and biologicals ordered as single dose, or as a specific number, are dispensed and administered as ordered. Suggested "maximal" time frames for specific groups of drugs are identified which require review prior to renewal <u>or</u> automatic stop. The practitioner is to be notified prior to such automatic stop. Drugs usually included with **the automatic stop procedure** include: • Antibiotics, • DEA Schedules II, IIN, III, IIIN, and IV, • Oxytocics, • Anticoagulant, • Corticosteroids, and • Anti-neoplastics.	**<u>DOCUMENT REVIEW</u>** Review pharmacy policies and procedures and **Medical** Staff Rules / Regulations that address these issues. **<u>OBSERVATION</u>** Observe the mechanism employed by the pharmacy and nursing service to alert practitioners of impending automatic stop orders. Verify: 1. **Pharmacy / medical staff policies are in place that address automatic stop medication orders.** 2. Medication orders are automatically reviewed and renewal is requested or an automatic stop is instituted in accordance with the time frame approved by the Professional Medical Staff. 3. **Practitioners are notified before the drug is automatically stopped.**	1 2 3 4 NA 1 – All issues in policy /procedures are met in practice. 3 = Notifications not done consistently 4 = Automatic stop orders not addressed.

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	A maximal time frame (such as 21 - 30 days) for all other drugs, not written in a time / dose limited fashion, is determined by the **Medical Staff**.		
25.01.08 <u>Drug Reactions & Administration Errors & Incompatibilities.</u> *Drug administration errors, adverse drug reactions and incompatibilities must be immediately reported to the attending physician and if appropriate, to the hospital wide quality assurance* performance improvement *program.* 482.25(b)(6) *There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.* 482.23 (c)(4)	The facility must adopt a medication error and adverse drug reaction (ADR) definition that is broad enough in scope to capture "near misses" and suspected ADRs as well as actual medication errors and ADRs. The program classifies Adverse Drug Reactions (ADR's) in terms of <u>probability, severity, mechanism, and dosing location</u>. The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error meets the inclusive broad criteria required. The facility must proactively identify medication errors and adverse drug reactions. Proactive identification includes: • observation of medication passes, • concurrent and retrospective review of patient clinical records, • ADR surveillance team, • Implementation of medication usage evaluations for high-alert drugs and identification of indicator drugs or "patient signals" that, when ordered or noted automatically generate a	**<u>DOCUMENT REVIEW, CHART REVIEW & INTERVIEW</u>** Review QAPI reports on medication errors, adverse reaction reports, and transfusion reactions. Review records of medication errors, adverse drug reactions, and transfusion reactions to determine that the reporting system is followed. Interview facility staff to ascertain awareness of the facility's policy on reporting and documentation of medication errors, ADRs, and transfusion reactions. Verify: 1. The medication error/drug reactions reporting program has been in existence for the past twelve months and that sufficient data have been reported to result in risk reduction. 2. The process is effective in ensuring reporting and communication to the attending physician. 3. Medication error reporting includes all areas where medication is	1 2 3 4 NA 1 = Full compliance. 2 = Processes are in place but staff awareness is weak or non-existent in some locations 3 = The scope of reporting is narrow and doesn't capture near misses OR 3 = The reporting process is perceived as punitive by staff. 4 = Proactive surveillance is not in place OR 4 = Policies are not implemented OR 4 = The system as designed does not accurately capture required data.

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	drug regimen review for a potential adverse drug event. The facility must have a method by which to measure the effectiveness of their reporting system so as to identify whether or not their system is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-review journals. To improve incident reporting the facility must adopt a non-punitive system with the focus on the system and not the involved health care professionals. The **hospital must report drug administrative errors, drug reactions and drug incompatibilities** to the facility Quality Assessment-Performance Improvement (QAPI) and Risk Management programs. Significant ADR's are reported to appropriate regulator or licensing authority per state and/or federal laws agencies. The definition of an ADR may be that	prepared and administered. (e.g. pharmacy, radiology, anesthesia, respiratory therapy). 4. Corrective actions are identified and implemented. 5. Staff **are knowledgeable** of the facility's policy on reporting and documentation of medication errors, ADRs, and transfusion reactions. Evidence of education is documented.	

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	suggested by the World Health Organization or from other professional groups. Clinical staff are knowledgeable of the definitions, ADR signs / symptoms, and reporting. Evidence of education is documented.		
25.01.09 <u>Reporting of Controlled Drug Loss and/or Abuse.</u> *Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.* 482.25(b)(7)	The tracking system for Scheduled drugs is capable of detecting and reporting such abuses and losses.	**<u>DOCUMENT REVIEW, OBSERVATION, & INTERVIEW</u>** **Review** the policy / procedure regarding abuse / loss of controlled substances. Interview staff to determine their understanding of the controlled drug policies. Review reports to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation. Verify: 1. The **policy addresses the reporting of abuse and losses to** DEA, CEO, and appropriate State Boards. 2. **Problems with controlled drugs, if any, have been reported to the authorities, according to policy.**	1 2 3 4 NA 1 = Full compliance 3 = Procedure excludes an entity. 4 = Non compliance.

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25.01.10 Informational Resources. *Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.* 482.25(b)(8)	The facility has immediately available sufficient texts and other resources on drug therapy. The pharmacist also should be readily available by telephone or other means to discuss drug therapy, interactions, side effects, dosage, etc., with practitioners to assist in drug selection and with nursing personnel to assist in the identification of drug-induced problems. The reference materials include the State Pharmacy Practice Act / Rules and Regulations, Drug Enforcement Agency codes for hospitals, toxicology texts - resources, pharmacy texts, and etc.	**INTERVIEW & OBSERVATION** Verify that current references are available: • State Practice Act; • Toxicology, including the regional poison control phone number; • Pharmacy texts; • On-call, or readily available pharmacist for consultation	1 2 3 4 NA 1 = Full compliance 3 = Some references available, but not sufficient for complexity of service. 4 = Inadequate or nonexistent written resources, and/or pharmacist not available 24/7 for consultation.
25.01.11 Formulary System. *A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.* 482.25(b)(9)	The medical staff must establish a formulary system. **The formulary is reviewed at least annually to ensure the contents are current.** The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. a. Written criteria should be developed for determining what medications are available for dispensing or administration. At a minimum, the criteria include the indication for use, effectiveness, risks and costs. Drugs are listed by type, strength, route, brand and generic equivalent.	**DOCUMENT REVIEW, OBSERVATION, & INTERVIEW** Examine the hospital Formulary / Drug List. Determine the date of approval by the Medical Staff. Interview the pharmacy director to determine the process for periodic review of the formulary. Observe for availability of the formulary in the clinical areas. Interview clinical staff regarding the availability of the formulary. Verify: 1. The formulary is current and has been approved by the medical staff.	1 2 3 4 NA 1 = Current and comprehensive. 2 = Not current but comprehensive. 3 = Current but not comprehensive 4 = Neither current / comprehensive. OR 4 = Not available in all clinical areas OR 4 = Has not been approved by the medical staff.

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	b. The formulary / drug list can be by drug type, action, or an alpha listing. c. Addenda may be utilized to reflect pharmaceuticals not purchased and / or stored in the pharmacy such as radiopharmaceutical and other injectables, ingestible diagnostic testing agents. Processes and mechanisms should be established to: • Monitor patient responses to newly added medication before the medication is made available for dispensing or administration within the hospital. • Approve and procure medications that are not on the hospital's **formulary / drug list**. The hospital should have processes to address medication shortages and outages including the following: a. Communicating with appropriate prescribers and staff b. Developing approved substitution protocols c. Educating appropriate Licensed Independent Practitioners (LIPs), appropriate health care professionals, and staff about these protocols d. Obtaining medications in the event of a disaster.	2. The formulary / drug list is more than a pharmacy charge - master; it includes remotely purchased / stored drugs / biologicals / diagnostic testing agents. 3. The formulary is available in the clinical areas. Clinical staff are aware of the availability of the formulary.	

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25.01.12 Nonformulary Medications There is a mechanism for ordering drugs not available in the formulary.	Methods for changing the formulary are identified. Bona fide orders for immediate use of non-formulary drugs are processed to meet patient therapeutic needs.	**INTERVIEW** Determine the mechanisms for amending the formulary and for obtaining non-formulary drugs when bona fide orders exist.	1 2 3 4 NA 1 = Full compliance. 4 = Non compliance
25.01.13 Integrity of Medication. Drugs and biologicals are stored at proper temperatures to maintain strength / potency. Records are maintained of drug refrigerator and freezer temperatures.	Daily **temperature** records, from accurate thermometers, are **maintained** for each drug refrigerator / freezer. Thermometer accuracy is verified against a known standard on a semiannual basis. Recommended guidelines* for consideration are: • Refrigerator 2 - 6 C° 36 - 46 F° • Freezer -20 - 10 C° -4 - 14 F° *Reference National Safety Council.	**OBSERVATION** Verify: 1. Drugs are stored **at temperatures specified by** manufacturer guidelines. 2. Daily **temperature** logs are maintained. (Graphs are recommended but not required.)	1 2 3 4 NA 1 = Full compliance. 2 = Logs not noted on nursing area. 3 = Thermometers not calibrated. 4 = Non compliance.
25.01.14 Consultations/Resource Availability. Pharmaceutical consultation is made available to prescribers of drugs, to staff administering drugs, and as appropriate to patients and families.	There **must be** sufficient pharmacist time to provide for consultations, even if there is only a part time or consulting pharmacist. In all instances, a pharmacist serves on the Professional Medical Staff committee (s) which discuss drug therapy.	**INTERVIEW** Verify: 1. A pharmacist serves on appropriate Medical Staff committees. 2. There is sufficient staffing to provide such consultations and educational services for: • clinical staff; • nursing staff;	1 2 3 4 NA 1 = Full compliance. 2 = No in-services provided. 3 = R.Ph. not available to Infection Control Committee; or, to provide consultation to prescribers. 4 = Non compliance

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	A pharmacist provides in-service programs for nursing staff and serves as a resource to clinical staff.	• patients and families.	
25.01.15 Medication Protocols. "Standing", routine or protocol orders are reviewed and revised by the prescribing practitioner and the Professional Medical Staff at least annually. A master copy of such orders is maintained in the pharmacy.	**When protocol orders are used, the practitioner individualizes the orders for each patient. The order is dated, timed, and signed by the ordering practitioner.** **Annually, protocol orders are reviewed, updated as indicated, and approved by the Medical Staff. The sponsoring practitioner authenticates the "master" copy as evidenced by his / her signature.**	**DOCUMENT REVIEW & INTERVIEW** Interview the Director of Pharmacy. Ask if there are protocols, which have not been so reviewed. Verify: 1. All standing or routine orders have been subject to annual review and / or revision. 2. Standing orders / protocols have been reviewed by the Professional Medical Staff via its committee structure.	1 2 3 4 NA 1 = All protocols, routine / standing orders are annually approved by the Staff. 2 = ≥ 90 % are current. 3 = < 75 % are current. 4 = < 50 % are current.
25.01.16 Home Medications. The Professional Medical Staff, via Policy and / or Rules and Regulations, establishes standards regarding the use of medications brought into the facility by patients.	If such drugs are to be given to patients there shall be positive identification of the drug, including manufacturer's lot number, **when available**, by a pharmacist or physician. Administration of drugs not supplied by the facility requires a specific policy and procedure.	**INTERVIEW** Verify: 1. Pharmacy policies and procedures and/or the Professional Medical Staff Rules/Regulations address medications obtained from sources other than the facility pharmacy service.	1 2 3 4 NA 1 = All issues in policy / practice. 4 = Non compliance.
25.01.17 Labeling. Drugs and biologicals leaving the pharmacy service, for other than "par" level storage are labeled with the full name of the patient, the	State and federal requirements regarding labeling of repackaged drugs are to be enforced.	**OBSERVATION** Inspect unit dose drawers or patient medication cupboards for the labeling of repackaged drugs. If outpatient	1 2 3 4 NA 1 = All labeling is congruent. 3 = Lot number or expiration date not

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prescriber's name, the name - strength - quantity - expiration date of the drug, and appropriate accessory / cautionary statements.	Mechanisms exist to track the manufacturer's lot number; this may be on the label or via logs for in-facility use. Outpatient dispensing requires the lot number on the label.	dispensing exists, ask to see a drug prepared **to ensure the required label information is present.** Verify: 1. **The facility has an effective system for tracking lot numbers.** 2. **Medications are labeled with the required information including lot number and expiration date.**	tracked on at least one outpatient label. 4 = Multiple parameters lost from > 3 labels.
25.01.18 Standardization of Labeling. The methods for labeling, packaging and storing medication have been standardized throughout the facility to reduce adverse events resulting from improper labeling, packaging and or storage of medications.	**Patient Safety Initiative:** Improper labeling and packaging of medications are well-known causes of serious medication errors. The evidence shows that there are effective methods for simplifying pharmacy and non-pharmacy dispensing by standardizing the labeling of medication containers and drawn-up syringes and the packaging of medications.	**DOCUMENT REVIEW & OBSERVATION** Review medication administration policies. Observe medication preparation and storage areas as well as administration to validate compliance. Review method for ensuring compliance with policies and procedures on medication labeling, packaging and storage throughout the organization. Verify: 1. **The medication administration labeling policy addresses:** • Labeling of all medications until they are administered to the patient • Validation of compliance for all areas. • An institution-wide approach	**1 2 3 4 NA** 1 = Policies are written to address all requirements and compliance is evident throughout the organization 2 = Policies address requirements but compliance is not evident in one or two areas 3 = Policies address requirements but compliance is not evident in more than two areas 4 = Policies were not available for review or did not address all requirements OR 4 = Compliance was not evident throughout the organization OR 4 = Compliance was not monitored routinely or in all areas.

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		• Storage of look alike, sound alike and varied strengths of medications in physically separate locations. **2. Compliance with the medication labeling policy is evident throughout the facility.**	
25.01.19 <u>High-Alert Medications.</u> The safe use of "high-alert" drugs will be facilitated by implementation of the following: 1. Identification of "high-alert" drugs available to workers in the facility 2. Implementation of a process to identify new medications for addition to the "high-alert" list 3. Development of protocols, guidelines, dosing scales, and/or checklist for each "high-alert" drug; make these available to relevant caregivers 4. Implementation of a process to audit compliance with the protocols and guidelines 5. Utilization of a multidisciplinary team to identify and regularly review safeguards for all "high-alert" drugs.	**<u>Patient Safety Initiative:</u>** Certain classes of medications have been repeatedly shown to cause adverse drug events and should be viewed as particularly serious threats to patient safety. Examples of high alert drugs are: • Intravenous adrenergic agonists and antagonists • Chemotherapy agents • Anticoagulants and antithrombotics • Concentrated parenteral electrolytes • General anesthetics • Neuromuscular blockers • Insulin and oral hypoglycemics • Narcotics and opiates	**<u>DOCUMENT REVIEW</u>** Review policies and procedures to validate that all 5 requirements are being addressed in the organization. Review audit materials for ongoing compliance. **<u>OBSERVATION</u>** Observe storage and use of high alert medications on the units to validate compliance.	**1 2 3 4 NA** 1 = Required policies are in place including required elements 1-5 and compliance throughout the organization is evident. 2 = Required policies are in place but compliance is not evident in one or two areas 3 = Policies do not contain all required element 1-5, OR 3 = Compliance is not evident in more than two areas 4 = Policies are not available for review OR 4 = Compliance is not evident throughout the facility

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25.01.20 Dispensing Methods. Medications will be dispensed in unit-dose or unit-of-use form whenever possible to reduce adverse events resulting from bulk packaging of medications. This is evidenced by: 1. Unit-dose packaging for medications whenever possible 2. Dispensing in ready-to- administer form 3. Unit dose package labeling containing product name, strength, manufacturer, expiration date, and lot number produced in machine-readable code. 4. Preparation and supply of daily unit doses of medications for individual patients under the purview of pharmacists when prepackaged unit dose is not commercially available. 5. Limiting of available supply in patient areas to 24 hours or less at any one time 6. A defined system for monitoring and improving the performance of the drug distribution system.	**Patient Safety Initiative:** Hospitals purchase oral dosage medications in two forms - bulk or commercially prepared, prepackaged dosages referred to as unit-of-use or unit dose. When purchased in bulk, the medications must be repackaged into unit-dose aliquots. The evidence shows that unit-dose packaging reduces the number of medication errors and appears to be widely used in most general medical and surgical wards. However, it is not used as much as it could be in other locations such as intensive care units, operating rooms, and emergency departments.	**INTERVIEW** Interview the pharmacy director to validate that the process being utilized is compliant with the standard. **OBSERVATION** Observe medication dispensing areas to validate that the standard is being met in all locations.	1 2 3 4 NA 1 – Standard is being met in all locations where medication is dispensed. 3 – Policy addresses all standards requirements, but is not applied to all locations. 4 – Policy does not address all requirements OR are not available for review
25.01.21 Preparation of Intravenous Drugs & Fluids. Intravenous drugs and admixed fluids are prepared in accordance with standards of pharmacy practice, congruent with State and federal regulations, in a manner to reduce the potential for bacterial or drug / drug contamination.	The expiration date of reconstituted drugs or admixed fluids is prominently printed on the solution label. The use of horizontal and vertical flow hoods **are used consistent with State and local regulations.** Horizontal and vertical flow hoods are inspected and cleaned according to manufacturer instructions and State and local	**OBSERVATION** Verify: 1. Review the admixture procedure and quality controls for congruence with current practice. 2. **The Pharmacy procedure for cleaning chemical spills, spill kits, and PPE are immediately available where cytotoxics are prepared.**	1 2 3 4 NA 1 – All elements met 2 = Hood quality controls not current. 4 – Cytotoxics prepared in horizontal hood. Or, No PPE / kits. Or, expiration date of reconstituted / admixed solutions not labeled NA – No admixture program

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	regulations. Cytotoxics are not to be prepared under a horizontal hood. Some states require certification for **personnel who are responsible for** admixing cytotoxics and other dangerous admixtures. **Chemical / hazardous material "spill" kits are readily available to the IV preparation area. Staff is knowledgeable as to using spill kits.** Personal Protective Equipment (PPE) **are used consistently and appropriately used with the preparation of IV drugs and solutions.**	3. Horizontal and vertical hoods are used for their intended purposes. Horizontal hoods are inspected and changed every six months; the external or vertical hood should be cleaned or changed by maintenance personnel quarterly, consistent with State and local regulations and manufacturer's instructions.	
25.01.22 <u>**Sample Drugs.**</u> The use of "sample" drugs, if permitted, is controlled by the pharmacy director and is in conformance with federal and state laws.	The use of sample drugs is discouraged. The repackaging and / or resale of sample drugs is prohibited. If samples **are allowed, hospital policy describes the use, storage, and distribution of sample drugs. Sample drugs are labeled according to hospital policy including lot number, patient name, prescriber's name, dose, and expiration date.** If samples are allowed, the director of pharmacy has full accountability for storage, distribution, and use. The director of pharmacy is responsible	**<u>INTERVIEW</u>** **<u>&</u>** **<u>OBSERVATION</u>** Review the policy regarding samples. Verify the practice; samples are often located in employee lounges, obstetrics and the ER. If these are the physician's personal property, sample medications should be secured. Verify: 1. There is an effective, accurate recall process, consistent with the pharmacy recall process. 2. If used for patients, verify that the pharmacist has control of **sample**	1 2 3 4 NA 1 = R.Ph has control of samples. 2 = Samples noted not on accession log. 3 = Policy/practice not congruent. 4 = Practice is in violation of state laws. NA - 0 samples

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	for maintaining a log of all sample drugs in the event of a product recall. The log includes lot numbers and patient distribution information.	**drugs.**	
25.01.23 Patient Medication Profile. There is a medication profile created for each inpatient and serial outpatient receiving drugs and biologicals. This profile includes data designed to assure safe and accurate administration of drugs and biologicals.	The profile may be manual or electronic and may be utilized as a charge document. The patient and drug data entered into medication profiles includes, at least: 1. Height, weight, diagnoses and age; 2. Food and drug sensitivities; 3. Allergies; 4. Diet order(s); 5. History of prescribed / non-prescribed drug use **including** legend, over the counter, home remedy, and street drugs; 6. Drugs (administered from floor stock and / or) dispensed for administration based upon direct review of current orders. 7. Drug data indicate the route, schedule, start and stop dates including automatic stop dates, and form dispensed.	**CHART REVIEW** Review the **medication profiles for** five (5) active inpatient records and one (1) active serial outpatient record (such as chemo) to determine the database. Verify: 1. **The medication profiles consistently document each of the seven (7) required elements.**	1 2 3 4 NA 1 – All elements consistently present. 2 – 1 profile non-compliant. 3 – 2 profiles non-compliant. 4 – Data in 3 or > non-compliant.

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25.01.24 **Profile Review.** The profile is reviewed daily and with every order change by an R.Ph. The review will occur before medication is dispensed or made available for administration except in those instances when review would cause a medically unacceptable delay. The review includes cognitive focus for potential drug and food-drug interactions, interferences, or incompatibilities. The review of orders will be documented in the patient record. The pharmacists will maintain a log documenting interventions stemming from the profile review. Compliance with the medication profile review will be audited to determine compliance with the process so that ongoing improvement in medication safety will be achieved.	**Patient Safety Initiative:** Nearly half of preventable adverse drug events (ADEs) result from a problem in medication ordering. It has been demonstrated in inpatient settings that having a pharmacist review medication orders before administration is associated with a significant decrease in preventable ADEs. Similar findings have been found in ambulatory settings. Including pharmacists on clinical rounds also can reduce medication errors. Methods are established to assure the daily profile review **by a Pharmacist**. A log is maintained of pharmacist interventions resulting from the profile review. The pharmacist / prescriber interface, as appropriate, for notification of food service for potential food - drug interactions.	**DOCUMENT REVIEW, CHART REVIEW, & INTERVIEW** Review the policy that defines what would be considered a medically acceptable delay in pharmacist review of new orders. Review a minimum of 10 patient records. Interview the pharmacist and nursing staff to determine **staff knowledge of the daily profile review**. Verify: 1. A log is maintained for pharmacist interventions stemming from the review for potential interactions, interferences or incompatibilities 2. The profiles are reviewed daily and upon order changes with documentation in the medical record. 3. **The pharmacist and nursing staff are knowledgeable of the medication profile review process.** 4. **A process is in place to audit compliance with the daily profile review.**	1 2 3 4 NA 1 = Demonstrated daily review with documentation in the record and by log for variances. Staff is aware of process and audit being done. 3 = Profile not reviewed per standard OR chart documentation/log inconsistently completed. 4 = No mechanism exists for profile view OR, Staff unaware of the review process requirements OR no audit being done to determine compliance.
25.01.25 **Drug Administration.** Mechanisms exist so that drugs and biologicals are administered in a safe, accurate, and effective manner.	Self-explanatory.	**CHART REVIEW** Check charts on units. Compare physician orders against the Medication Administration Records for accuracy.	1 2 3 4 NA 1 = Full compliance. 3 = Inaccuracies identified and quickly corrected with rare medication errors, but errors continue to occur

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		Verify: 1. **Medications administered are consistent with the physician order. Medications are administered safely and accurately.**	at a regular rate. Appears to be a process problem. 4 – All charts checked were non-compliance
25.01.26 Label Medications & Solutions on the Sterile Field. The facility must develop and implement policies for safe labeling of medications and solutions used on and off the sterile field in the perioperative settings. The facility must have policies and processes in place including, but not limited to: 1. The required labeling of medications and solutions, regardless of container, used on and off the sterile field throughout the perioperative experience. 2. The methods used to differentiate and label look-alike products and solutions with similar names. 3. The process used to verify and confirm each medication / solution and the respective matching label.	**PATIENT SAFETY INITIATIVE** In recent years, there have been numerous reports of death or serious injury secondary to unlabeled medications and solutions on the sterile field. All surgery settings and procedure rooms are expected to handle chemicals, reagents, specimen preservation agents, and diluents with the same caution as medications. A process must be in place to label all solutions used in the surgical area including, but not limited to intravenous fluids, medications, body fluids, hydrogen peroxide, formalin, Lugol's solution, radiopaque dyes, sterile saline, sterile water, isopropyl alcohol, skin preparation solutions, chlorhexidine, glutaraldehyde, and the like. Many of the above "look alike" as they are clear / colorless solutions. Labels must be applied to solutions stored in all types of container used on and off the surgical field in the	**DOCUMENT REVIEW** Review policies and practices relative to medication preparation. Determine that systems are in place relating to: 1. Required labeling of solutions and medications on and off the sterile field. 2. Procedure for differentiating look-alike and sound-alike medications / solutions. 3. Procedure for individually verifying and labeling medications / solutions and respective labels. *** When scoring this standard, incorporate standard compliance issues as identified in standards: • 18.00.24 • 21.00.25 • 30.00.19 • 30.04.24	1 2 3 4 NA 1 – Policy in place; practice is consistent with policy. 3 – Policy in place; one observation in which practice was not consistent with policy. 4 = No policy in place, -OR- 4 = Practice is inconsistent with policy.

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	perioperative area including, but not limited to medicine cups, solution basins, syringes, and specimen cups. A label is required even if only one solution is involved with the procedure. It would be unacceptable to write onto plastic containers such as IV bags with marking pens, as there is evidence that the ink may penetrate into the solution. Sterile medications / solutions that are placed onto the sterile field in the original packaging with the manufacturer's original label on the container that indicates the name and strength of the medication do not require additional labeling. Use sterile markers and labels that can be opened onto the sterile field. Commercially prepared products are available for this purpose, but labels prepared by the facility are acceptable if sterilization is maintained. Labels are to clearly state the medication / solution and strength. When feasible, include these labels and markers in pre-made surgical packs. Many medications and solutions have similar names. A process must be identified and implemented when preparing labels to differentiate these.		

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	A process must be in place to verify each medication or solution and complete its preparation, labeling, and delivery to the sterile field before preparing the next solution. Label only one medication / solution at a time. Use two staff to verbally and visually confirm each medication / solution and respective label; one of these staff must be a licensed professional involved with the procedure. A process must be in place to discard any unlabeled solution or medication found in the perioperative area. Unlabeled solutions should be considered a hazardous condition and reported using the facility incident reporting protocol. At shift change or relief for breaks, required the entering and exiting staff to concurrently read container labels and verify all medications on the sterile field. Keep original medication / solution containers in the surgical room until completion of the procedure for follow-up reference, if indicated. References: Medication Safety Alert, December 2, 2004, *The Institute for Safe Medication Practices.*		

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	AORN Guidance Statement: Safe Medication Practices in Perioperative Practice Settings, 2004.		
25.01.27 Investigational Drugs. In order to protect the rights of patient and the Professional Medical Staff, the facility policies shall address the administration of drugs which are: • Used for other than their FDA approved use. • Experimental. • Investigational, when the primary investigator(s) is a member of the facility's Professional Medical Staff. • Investigational, when the facility patient brings in the drug as a prescription from a practitioner who is not a member of the facility's Professional Medical Staff.	The pharmacy director collaborates with the Professional Medical Staff in defining these circumstances. At a minimum, these policies address the following concepts: 1. Patient knowledge of the nonapproved use of an FDA approved drug; 2. Patient informed consent in experimental or on-site investigational drug studies; 3. Mechanisms for presenting study protocols and data to an Institutional Review Board or equivalent; 4. The roles of pharmacists, nursing and other nonpractitioner staff in study protocols and data management; 5. The acquisition and storage of investigational drugs; 6. The need for the RN administering investigational drugs and / or planning and supervising the care of a patient receiving investigational drugs to document knowledge of the drug(s); 7. Notification and input from any off-site investigators when their study population is admitted.	**DOCUMENT REVIEW & CHART REVIEW** Review policies related to investigational drugs. Review patient records if available. **Verify:** 1. The facility **policy** addresses non-approved, experimental and investigational uses of drugs. Each of the seven **required** concepts is addressed. 2. **The actual use of investigational drugs is consistent with the investigational drugs policy.**	1 2 3 4 NA 1 = Full compliance. 4 – Non compliance.

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25.01.28 Documentation The effects of therapy are noted in clinical records. The patient's clinical record accurately reflects all doses given as well as the effects of these agents as indicated by: 1. The prescribing practitioner, and any other medical consultants, via progress notations; 2. The nursing staff via the medication administration record in progress notation for the effects of "Pro Re Nata" (PRN) dosing and for clinical outcome dosing; 3. Clinical outcomes; or 4. The recording of testing (laboratory, imaging, cardiogram, other objective) to determine the therapeutic effect.	Self-explanatory.	**CHART REVIEW** Review five recently closed inpatient records for physician progress notes, diagnostic testing data, and other clinical notations. Verify: 1. **Medical records provide** evidence **that all doses have been administered;** appropriate observations **are documented.**	1 2 3 4 NA 1 = 5 records compliant. 2 = 4 records compliant. 3 = 3 records compliant. 4 = 2 or <records compliant.
25.01.29 Antithrombotic Therapy. The facility ensures that anti-thrombotic (anticoagulation) therapy is effective and safe. The organization utilizes dedicated anti-thrombotic services that facilitate coordinated care management. Explicit organizational policies and procedures are in place regarding anti-thrombotic services.	**Patient Safety Initiative:** Anti-thrombotic (anticoagulation) therapy is a complex and labor-intensive intervention for which success depends upon correct dosing decisions, close attention to many details, and good communication among all parties involved. **A process is in place to identify and train staff to coordinate the management of patients receiving anti-thrombotic therapy. The process addresses:** • **Staff training requirements** • **Dose scheduling**	**DOCUMENT REVIEW** **&** **CHART REVIEW** Review facility policies and procedures in regard to anti-thrombotic services. Review the medical records of patients receiving anti-thrombotic therapy. Verify: 1. The policy is explicit with regards staff training requirements, dose scheduling and tracking mechanisms, and patient education materials and mechanisms for training.	1 2 3 4 NA 1 = Policy includes all required elements. 4 = Policy does not include all the required elements

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	• **Patient tracking** • **Patient education** Optimal anticoagulation management occurs when a systematic and coordinated process is used. This process includes dedicated management by a qualified healthcare professional that ensures: • Reliable patient scheduling and tracking; • Accessible, accurate, and frequent Prothrombin Time (PT)/ International Normalized Ratio (INR) testing; • Patient-specific decision support and interaction; and • Ongoing patient education.	2. Patient records reflect that anti-thrombotic services are being coordinated per policy and standard.	
25.02.01 Preparation & Administration of Drugs. *Drugs and biologicals must be prepared and administered in accordance with federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under 482.12(c), and accepted standards of practice.* 482.23(c)	Professional Medical Staff Rules and Regulations or Policies and facility policies identify the categories of personnel who can administer various types of drugs, radioisotopes and biologicals. Facility policy may require competency testing for various knowledge and skills. Personnel do not administer drugs outside their sphere of practice.	**DOCUMENT REVIEW, CHART REVIEW, & OBSERVATION** Verify: 1. Medical Staff and facility documents identify the skill levels and scopes of practice involved in medication administration. a. Practice limits are identified. b. If competency testing is employed, the test is current in terms of drugs and methods tested.	1 2 3 4 NA 1 = All elements. 2 = Facility, but not Medical Staff, policy conforms. 3 = 1 or 2 cases noted of staff administering drugs who are not on the authorized list 4 = Policies / practices do not protect patient safety / welfare and/or do not comply with practice guidelines

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		2. Practice matches policy. Medication administration is in accordance with Federal and State law, accepted national standards of practice, manufacturer's directions and hospital policy.	
25.02.02 Preparation & Administration of Drugs. *All drugs and biologicals must be administered by, or under the supervision of nursing or other personnel in accordance with Federal and State Laws and Regulations, including applicable licensing requirements and in accordance with the approved Medical Staff policies and procedures.* 482.23(e)(1) Facility policies regarding medication preparation and administration are approved by the Professional Medical Staff and Pharmacy and Therapeutics Committee. Policies address at least the following: 1. Pharmacist review of medication orders/profiles including documentation of review; defined exceptions to pharmacist review 2. Role of the pharmacist in the medication use process 3. When a full-time pharmacist is not available onsite, a pharmacist is available by telephone or accessible at another location that has 24-hour pharmacy services.	**Patient Safety Initiative:** Medication administration policies are based upon principles of sound nursing and pharmacy practice **with a focus on patient safety.** Policies are collaboratively developed by the pharmacy and the disciplines, e.g. nursing, respiratory, imaging, etc., administering drug products. Collaboratively developed policies are then reviewed and approved by the Professional Medical Staff for review, comment, and approval. **All required** subject areas are to be addressed by the facility in policy.	INTERVIEW Interview the pharmacy director and the nurse executive. Observe the preparation of drugs and their administration to patients. Observe at least three staff administering a drug or biological product. Verify: 1. Their respective medication administration policies are congruent and have been collaboratively developed. Similarly, verify these issues with other disciplines such as, imaging, respiratory therapy, etc. 2. The collaboratively developed medication administration policies have been presented to the Professional Medical Staff for review, comment and approval. 3. Patient identification procedures are consistently followed. Patients are addressed by name and / or identification checked. The nurse remains with the patient until medication is taken. Drugs are administered within 30	1 2 3 4 NA 1 = Full compliance. 2 = All policies and processes in place but not consistently implemented. 3 = 2 - 4 element not addressed 4 = 4 > elements not addressed and no Medical Staff approval OR 4 = Implementation of policies not evident.

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4. Order verification by the dispensing pharmacist (if the item is not stock in the patient care area); 5. Order verification by the staff administering the product; 6. Mechanisms to assure that the patient is positively identified prior to administering products; 7. Mechanisms to assure that the drug, route, dose, time(s), are accurately recorded for the correct patient; 8. Mechanisms for bedside supply for patient self-administration and for patient controlled dosing; (NOTE: bedside medication storage must comply with storage requirements. See 25.00.03) 9. Mechanisms to teach the patient (or his/her family) about the medications; and 10. Mechanisms for identifying and responding to medication variances.		minutes of the scheduled time for administration. 4. If personnel other than nursing personnel administer drugs or biologicals, this is in accordance with Federal and State laws and regulations. 5. The drug is identifiable up to the point of administration. The patient was positively identified. 6. If bedside patient self-administration of medication is permitted, verify: * All storage and administration standards are in compliance (e.g. secure storage, documentation of administration) FILE REVIEW Verify: 1. Nursing or other personnel authorized by medial staff policy to administer drugs have completed appropriate training courses, or, are licensed or authorized to do so by State law and function under supervision as necessary.	
25.02.03 Drug Orders. ***With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications, orders for***	**PATIENT SAFETY INITIATIVE:** Drug / biological orders generated from a licensed physician, dentist, or podiatrist within the scope of their licensure, certification, and as a result of their delineated privileges as a member	**DOCUMENT REVIEW** Verify that policies / rules and regulations relative to verbal and telephoned orders address all required elements, including: 1. The infrequent use of verbal orders	1 2 3 4 NA 1 = Full compliance. 3 = 70-79% of the medical records were in compliance. 4 = Less than 70% of the medical records were in

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drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under 482.12(c). 482.23(c)(2) *I. If verbal orders are used, they are to be used infrequently. 482.23(c)(2)(i)* *II. When verbal orders are used, they must be accepted only by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law. 482.23(c)(2)(i)* *III. All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner. 482.24 (c)(1)(i)* *IV. For the 5 year period following January 26, 2007, all orders, including verbal orders, must be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under 482.12(c) and authorized to write orders by hospital policy in accordance with State law. 482.24*	of the Professional Medical Staff of the facility. Physician extenders (Physician Assistants or Advanced Nurse Practitioners) may write orders within the scope of their license and privilege delineation, as approved by the hospital. Safe and effective healthcare delivery depends to a large extent on accurate and timely communication among caregivers. The need for clear, unambiguous communication of orders cannot be overstated. Electronically transmitted orders (via FAX) may be treated as a legally reproduced form of the original document and considered to be an original order, if permitted by State and local regulations. Orders transcribed from voice tape are treated as telephone orders. The terms "verbal" orders and "telephoned" orders are not interchangeable. 1. Verbal order refers to those situations in which the ordering physician is physically present and provides a verbal communication for patient care. This practice is to be used infrequently. 2. Telephoned orders (a type of	2. Limitations to verbal orders 3. The "read-back" process 4. Identification of individuals eligible to accept verbal orders 5. The time frame for authentication of verbal orders is specified. 6. The protocol for flu and pneumonia vaccine administration has been approved by the medical staff. 7. The verification and validation of senders of electronically transmitted orders; authentication of the content of the order. 8. All orders must be written by licensed physicians or other practitioners approved under state law and authorized by the medical staff. 9. Outpatient medication therapy may not be ordered by practitioners who are not credentialed / privileged by the medical staff. The medical staff must define the process for validation of credentials of practitioners ordering medications but do not have or want admitting or consulting privileges in the	compliance. OR 4 – Policies on medication orders do not address all required criteria. OR 4 – Verbal orders are used excessively or there is a pattern to use OR 4 – There is no physician approved protocol for influenza and pneumonia vaccine administration, and the drugs are administered without an order. OR 4 = Electronically transmitted orders are not authenticated 4 – No process for validation of credentials of practitioners requesting services who are not on staff. 4 – Verbal/phone order read back has not been implemented OR compliance is not consistently evident

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(c)(1)(ii) V. *All verbal orders must be authenticated based upon Federal and State law. If there is no State law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours. 482.24 (c)(1)(iii)* VI. Read back the verbal order immediately to the **ordering practitioner** after transcription to verify the accuracy of what was heard. VII. Verbal orders are not permitted for chemotherapy orders. The organization defines in policy any additional "high-risk" orders that are not approved to be given verbally, as appropriate. VIII. Hospital policies and procedures must address: A. Limitations or prohibitions on use of verbal orders B. A mechanism to ensure validity/authenticity of the prescriber C. The elements required for inclusion in a complete verbal order D. Situations in which verbal	verbal order) refer to those situations in which the ordering practitioner is not physically present when providing patient care orders. With telephoned orders, the practitioner may be in another location within the facility or outside the facility. All requirements for verbal orders also apply to telephoned orders, that is, telephoned orders are to be used infrequently, dated, timed, signed and authenticated promptly. Verbal Orders a. Verbal orders are used infrequently. If a hospital allows frequent and routine use of verbal orders, the hospitals risks being out of compliance with this Medicare Condition of Participation (CoP.) b. The use of verbal orders should be limited to those situations in which it is impossible or impractical for the ordering practitioner to write a manual or electronic order. The facility discourages the use of verbal orders when the ordering practitioner is physically present, except in an emergency or during a bedside procedure situation. Verbal and Telephoned Orders	organization. **CHART REVIEW** Review several charts with telephone orders. Verify: 1. All orders for drugs and biologicals, including verbal orders are legible, timed, dated and signed. Verbal orders include the name of the ordering practitioner. Verbal orders are received only by authorized hospital personnel. The ordering practitioner authenticates verbal orders within 48 hours of order; the practitioner documents the date and time of order authentication. 2. Verbal orders are used infrequently. Verbal orders are not used for chemotherapy and other "high risk" drugs. (There is no pattern to the use of verbal orders, e.g., frequent use of verbal orders by certain practitioners.) 3. Patients are assessed for risk prior to administration of the flu / pneumococcal vaccine. 4. Electronically transmitted orders are validated via a defined mechanism for authentication of the sender and the content of the order.	

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orders may be used E. The list of individuals who may send and receive verbal orders F. Guidelines for clear and effective communication of verbal orders. All services must be given in accordance with orders of practitioners authorized by the medical staff to order the services and the order must be incorporated in the patient's record.	a. The use of verbal orders and telephoned orders is an error prone process that increases the risk of miscommunication. b. All requirements for verbal orders also apply to telephoned orders, that is, telephoned orders are to be used infrequently, dated, timed, signed and authenticated promptly. c. The hospital promotes a culture in which it is acceptable and strongly encouraged for staff to question prescribers when there are any questions or disagreements about verbal / telephoned orders. d. Hospital policy outlines precautions to take when the use of verbal and telephoned orders is absolutely necessary. e. Verbal / telephone orders may be accepted by a nurse or other professional only as permitted by State law and hospital policy. f. Pharmacists, RN's, and LPN's may receive all drug orders. Other licensed / certified staff receive drug orders only in relation to their scope of practice, e.g., Respiratory Therapists for inhalants.	**INTERVIEW** **&** **OBSERVATION** Interview staff who are permitted to receive verbal orders to determine the process has been communicated. Observe the process to verify implementation.	

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
orders may be used E. The list of individuals who may send and receive verbal orders F. Guidelines for clear and effective communication of verbal orders. All services must be given in accordance with orders of practitioners authorized by the medical staff to order the services and the order must be incorporated in the patient's record.	a. The use of verbal orders and telephoned orders is an error prone process that increases the risk of miscommunication. b. All requirements for verbal orders also apply to telephoned orders, that is, telephoned orders are to be used infrequently, dated, timed, signed and authenticated promptly. c. The hospital promotes a culture in which it is acceptable and strongly encouraged for staff to question prescribers when there are any questions or disagreements about verbal / telephoned orders. d. Hospital policy outlines precautions to take when the use of verbal and telephoned orders is absolutely necessary. e. Verbal / telephone orders may be accepted by a nurse or other professional only as permitted by State law and hospital policy. f. Pharmacists, RN's, and LPN's may receive all drug orders. Other licensed / certified staff receive drug orders only in relation to their scope of practice, e.g., Respiratory Therapists for inhalants.	**INTERVIEW** **&** **OBSERVATION** Interview staff who are permitted to receive verbal orders to determine the process has been communicated. Observe the process to verify implementation.	

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	g. The content of verbal orders must be clearly communicated. The entire verbal order should be repeated back to the prescriber. h. Verbal / telephone orders are immediately entered into the patient's medical record by the receiving person. The written verbal / telephoned order must be legible, dated, and timed; it must include the name of the ordering practitioner and the signature of the accepting individual. i. Questions about verbal / telephoned orders should be resolved prior to the preparation, dispensing, or administration of the medication. AUTHENTICATION OF VERBAL ORDERS: a. All orders, including verbal and telephoned orders, must be legible, complete, dated, timed, and authenticated. Therefore, is necessary for the practitioner to date and time the authentication of the verbal / telephoned order. b. If there is no State law that designates a specific timeframe for the authentication of verbal / telephoned orders, the verbal / telephoned orders are authenticated		

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	within 48 hours by the ordering physician. c. It is acceptable for a covering physician to co-sign a verbal /telephoned order in the extended absence of the ordering physician. However, the practice must be addressed in the hospital's policy. d. A non-physician practitioner MAY NOT co-sign a physician order. e. Use of signature facsimiles, e.g., rubber stamps for authentication of drug orders is prohibited.		
25.02.04 <u>Administration of Blood Products & IV Medications.</u> *Blood transfusions and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.* 482.23(c)(3)	Training should be by qualified personnel. **Training content** includes regulations from the (AABB) American Association of Blood Banks and FDA.	**<u>DOCUMENT REVIEW, CHART REVIEW</u>** **<u>&</u>** **<u>FILE REVIEW</u>** Review blood transfusion and IV medication policies. Review a select sample of medical records. Review a sample of five RN staff development files. Verify: 1. The hospital has a special training program for administering blood transfusions and intravenous medications. 2. Blood transfusions and IV medications are administered by personnel who are trained and	1 ☒ 3 4 NA 1 – Full compliance. 3 – Appropriate, trained staff perform the service, but training is not consistently documented. 4 – Non compliance.

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		working within their scope of practice in accordance with State law and hospital policy. 3. Blood administration policies have been approved by the medical staff. 4. There has been in-service on the administration of blood transfusions and intravenous medications. 5. **Medical records reflect** that only specially trained personnel or doctors of medicine or osteopathy perform these duties.	
25.02.05 <u>Medication Preparation Environment.</u> The facility provides a work environment that facilitates attention to detail and promotes the accurate filling and dispensing of medication orders. Organizational policies and procedures are in place for the pharmacy and nursing work environments that include specific implementation guidelines that address safety in medication preparation areas, including the mechanism for ongoing monitoring of compliance.	**<u>Patient Safety Initiative:</u>** Although many medication errors have no or minor consequences for patients, others may cause serious morbidity or even death. Errors related to dispensing medications are common, occurring at rates ranging up to 24% of medications dispensed. A number of environmental factors in the medication **preparation and** dispensing area are known to increase the occurrence of errors. These include: • heavy workload, • cluttered workspace, • noise, and • poor lighting. Having an organized and well-lit workspace has been shown to both decrease errors and increase efficiency.	**<u>DOCUMENT REVIEW</u>** **<u>&</u>** **<u>OBSERVATION</u>** Review organizational policies. **Inspect** medication preparation areas in all locations where medication is prepared. Verify: 1. Policy addresses the required **work environment safety** elements and **applies to** all medication preparation areas. 2. **Medication preparation work areas** are clean, orderly, well lit, and free of clutter, distraction, and noise	1 2 3 4 NA 1 – Policies and procedures address environmental safety issues in medication preparation areas and all areas visited met the defined standards 2 – Policies and procedures are in place that address safety, but one or two areas failed to meet the standards 3 – Policies and procedures are in place that address safety, but more than two areas failed to meet the standard. 4 – Policies addressing workplace safety in medication preparation areas were not available for review OR 4 – Policies were in place but compliance was not evidenced upon review of medication preparation areas OR

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			4 – Ongoing monitoring of medication preparation areas for safety compliance is not being done.
25.02.06 Monitoring of Appropriateness. The appropriate use of drugs and biologicals is an interdisciplinary function in providing quality patient care services. The facility employs multiple mechanisms to document the monitoring of patients receiving drug / biological / medication products.	Self-explanatory.	Deferred.	
25.02.07 Medication Reconciliation. The organization has a formal and systematic approach to the reconciliation of medications across the continuum of care. A process is in place to reconcile current medications at each key transitional point of healthcare, specifically: 1. Upon admission, prepare a complete list of pre-admission medications the patient takes at home. 2. The patient or family member validates the list, when possible. 3. Admission orders are compared against the pre-admission medication list; any variances are reconciled. 4. The complete list of current medications is readily available to prescribers as a reference when writing medication orders.	**PATIENT SAFETY INITIATIVE** Background Preventable adverse drug events are associated with as many as one out of five patient injuries or deaths. The inadvertent omission of a pre-admission medication or failure to order a drug upon discharge can have deleterious outcomes. Through the formal process of medication reconciliation, errors can be prevented and/ or reduced throughout the continuum of care. According to the Institute for Healthcare Improvement (IHI), numerous studies indicate that poor communication of medical information at key transition points is responsible for up 50% of all medication errors. A 30 – 70% disparity rate was found between medications taken at home and those listed in hospital admission orders, in one study*.	**DOCUMENT REVIEW** Verify: 1. A complete list of home medications is obtained upon admission. A process is in place to generate a list of medications in the ambulatory setting. 2. A medication reconciliation process is in place upon admission, transfer to the next level of care, and at discharge. 3. The patient / family participates with the reconciliation process, when possible. 4. The patient receives a copy of the complete medication list upon discharge. 5. A process is in place to measure the	1 2 3 4 NA 1 – Full compliance 3 The reconciliation process is in place; inconsistencies are found. 4 Noncompliance

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5. The complete list of medications is provided to the next unit, service, or care setting when the patient is transferred and discharged. 6. The complete list of medications is given to the patient upon discharge.	The key transition points where errors with writing medication orders tend to occur are: a) Upon admission, b) Upon transfer to a new unit / service / practitioner, and c) At time of discharge. The goal of medication reconciliation is to ensure that every hospitalized patient continues with the same medications taken prior to admission, unless there is a specified need for change. Admission orders should actually be considered a modification of the patient's medication regimen. The patient or family member is involved with the reconciliation process to validate the list of pre-admission medications. This list includes prescribed and regularly taken over-the-counter drugs, vitamins, herbals, homeopathic, and nutritional supplements. As the intent is to develop the most accurate list of medications possible, the dose and frequency for each drug should be included in the complete list of home medications. The list of preadmission medications is readily available for prescribers to review when writing / changing medication orders.	effectiveness of this initiative with reducing adverse drug events.	

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	is a reconciliation process to ensure all appropriate medications (including pre-admission medications) are continued following discharge. In anticipation of discharge, the list of pre-admission medications should be compared against the current Medication Administration Record. The patient / family is informed of medications that will be discontinued or changed upon discharge. At time of discharge, a copy of the final medication list is provided to: 1. The patient / family 2. The next level of care such as home health agency, skilled nursing facility, or transfer to a higher level of care. <u>Monitoring Effectiveness</u> A process is in place to evaluate the effectiveness of this patient safety initiative with reducing adverse drug events. For example, review a random sample of patient records <u>Emergency Department</u> A complete list of current medications is to be obtained for Emergency Department patients. <u>Ambulatory Care</u> A complete list of current medications is		

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
	to be obtained for ambulatory care patients. The list will be updated as medications are added or discontinued. Ambulatory Services 1. A complete list of medications must be in place for those outpatient services in which medications will be administered, such as: a. Ambulatory surgery b. Radiological procedures requiring IV contrast and etc. 2. For those outpatient services in which no medications will be administered, such as outpatient radiology, obtaining a current list of medications is preferred, but not required. *Cornis, PL, et al.: Unintended medication discrepancies at the time of hospital admission. *Arch Intern Med* 165: 424-429, Feb. 28, 2005. The National Quality Forum, *National Quality Forum Updates Endorsement of Safe Practices for Better Healthcare,* October 16, 2006.		
25.03.01 Performance Improvement. A facility-wide Quality Assessment - Performance Improvement program is in place, which incorporates Adverse Drug Response (ADR) findings and monitors the	The greatest benefit to the facility accrues when QAPI efforts give priority to reviews, which focus on high volume (cost or frequency), high risk, or problem prone areas.	**DOCUMENT REVIEW** Review the medication use review plan. Verify: 1. **The facility prepares an annual Medication Use Review or Drug**	1 2 3 4 NA 1 – Full compliance, 4 – Non compliance.

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STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
desired outcomes of medication use. This program shall be utilized to reduce risk in order to maintain and improve clinical outcome. **Annually, the facility prepares a Medication Use Review Plan.**	The medication use review plan, **or a Drug Utilization Effectiveness (DUE) plan,** should indicate the rationale for selection, and actions taken to achieve improvement should be documented.	**Utilization Effectiveness Plan.** 2. The findings from Adverse Responses and Medication Variances have been studied and included in QAPI. Monitors are in place. Actions have been taken to achieve improvement.	
25.03.02 Data Collection & Monitoring. The medication use monitoring is established to assess: • prescribing (appropriateness); • preparing / dispensing; • administering, and • outcomes.	Medication use is an interdisciplinary process in providing patient care. Although review indicators may focus more heavily on one, all four aspects of the process are to be reviewed.	**DOCUMENT REVIEW** Verify: 1. The medication use review plan is an interdisciplinary process. 2. Data is collected on all four (4) required functions: • **prescribing /appropriateness;** • **preparing / dispensing;** • **administering; and** • **outcomes.**	1 2 3 4 NA 1 – 4 elements of process noted. 2 – 3 of 4 elements noted. 3 – 2 of 4 elements noted. 4 – Non compliance.
25.03.03 Medication Use Review. Medication use review monitors drugs used in all principal populations served by the facility.	Over the course of a year, the populations should include the age span (pediatric - geriatric) and service location (inpatient, outpatient, and emergency care). Antibiogram studies should be published and distributed to appropriate professionals at least annually.	**DOCUMENT REVIEW** Determine that life span and service setting populations have been incorporated in medication usage review. 1. The outcome of the review has been communicated to the medical staff. 2. An annual antibiogram report been prepared and distributed.	1 2 3 4 NA 1 – Full compliance. 4 – Non compliance.
25.03.04 Data Reporting. Findings from medication use review are reported quarterly to appropriate Medical Staff committees and/or departments, and considered by the QAPI program, in impacting improvements in the facility	Because medication use is interdisciplinary, the findings of medication use review are shared with various disciplines.	**DOCUMENT REVIEW.** Review the documentation. Verify: 1. Medication use reviews are prepared quarterly. 2. The medication use review	1 2 3 4 NA 1 – Full compliance 2 – 2 of 3 elements compliant. 3 – 1 of 3 elements compliant. 4 – Data not

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
service areas. Such reports are shared, as appropriate, with other disciplines to utilize in their QAPI.		information has been reported to appropriate Medical Staff committees and the QAPI program.	appropriately reported
25.03.05 <u>Annual Report on Medication Use.</u> The facility documents improvement, as a result of medication use review as reported, in an annual summary.	Self-explanatory.	**<u>DOCUMENT REVIEW.</u>** Verify: 1. An annual summary of Medication Use Review is prepared and submitted to QAPI. The summary addresses actual improvements, as applicable. NOTE: Reviews may not always (and legitimately) result in improvements. The process of study should yield worthy results.	1 2 3 4 NA 1 = Annual summary identifies significant improvement(s). 2 = Improvements verbalized but not clearly identified 3 = Improvements not identified. 4 = No annual summary or no improvements. QAPI activity

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
25.03.06 Performance Improvement in Medication Use. The organization utilizes information obtained from review of medication processes and outcomes to continuously improve the safety of medication administration for patients. The organization will consider technological advances available to them in improving these processes. If technological advances are not an option, the organization will implement alternatives that will resolve identified issues and reduce medication events.	**Patient Safety Initiative:** Medication errors are common. The literature indicates that between 28-56% of adverse drug events are preventable. Illegible handwriting, unknown or undetected allergies, drug interactions, incorrect dose, and many other factors can cause adverse drug events. Studies have demonstrated that a significant decrease in medication errors and adverse drug events can be achieved by using computerized prescriber order entry technology. Additional technologies are continuously being developed, and it is the responsibility of the organization to examine the feasibility of implementation of these technologies to achieve a safer patient environment. It is clear that some organizations will be unable to afford these technologies. However, that does not negate their responsibility to resolve identified issues by alternative means.	**DOCUMENT REVIEW** **&** **INTERVIEW** Review medication event data. Review minutes where improvement of the medication system and processes are discussed. Verify: 1. The organization has considered implementation of new technologies to reduce medication events. 2. If technology is not feasible, alternative strategies to reduce medication events have been implemented.	**1 2 3 4 NA** 1 = The organization is continuously working to improve the medication systems to reduce events. Technology has been considered for implementation. 4 = There is no documented evidence that the organization is continuously improving the medication systems. Technology has not been considered as an option

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Policy / Procedure

American Osteopathic Association
Healthcare Facilities Accreditation Program (HFAP)

Title: "Administrator Surveyor Participation Guidelines"

Developed: May 2001	Revision(s): October 2004, March 2007, May 2007, May 2008, February 2009, August 2009, March 2011	Page 1 of 4

CRITERIA FOR RECRUITING (PRE-REQUISITES):

A candidate for the position of administrator surveyor shall meet the following eligibility criteria.

A. Education:

1. A bachelor's degree is required.

2. A graduate degree in hospital administration is preferred

B. Experience: (Normally exhibited by the following experience)

1. At least 5 years experience as the Chief Executive Officer or Chief Operating Officer of an HFAP accredited hospital; or

2. At least 5 years experience as an associate/assistant administrator with responsibilities for at least two or more of the following areas:

   a. Nursing services,

   b. Two other responsibilities among the following: pharmacy, dietary, physical rehabilitation therapy, respiratory therapy, housekeeping, physical plant,

   c. Responsibilities regarding the governing board and medical staff committees, and interact directly with board and medical staff committee.

   d. For associate/assistant administrators, or any position other than CEO, a recommendation from the CEO must be included.

3. Have experienced one or two HFAP surveys (two preferred).

APPLICATION PROCEDURE AND PROCESSING:

1. Submit the following to the Chief Operating Officer (COO), Healthcare Facilities Accreditation Program (HFAP):

a. Letter of intent to become an HFAP Surveyor
b. Resume / curriculum vitae
c. Two (2) letters of recommendation. It is preferred that one of these is a letter of support by a member of the governing body.

2. Agree to serve as a Federal witness, if requested.

3. The HFAP COO will submit candidate resumes, applications, and letters of recommendation to the Bureau Healthcare Facilities Accreditation (BHFA) for review and approval. If approved by the Bureau, an appointment of "surveyor-in-training" will be awarded.

4. Appointment decisions are recorded in the minutes of the Bureau Healthcare Facilities Accreditation (BHFA) meeting.

5. The COO will notify the candidate of Bureau decisions. The COO will forward copies of the HFAP Surveyor Confidentiality Agreement and Busiuess Agreement forms to the new appointee for signature. Upon receipt of the signed documents, surveyor-in-training assignments will be prepared.

TRAINING REQUIREMENTS:

1. Surveyors-in-Training are required to participate with at least two surveys as observer/surveyor-in-training.

2. As available, attend appropriate:
   a. Training program
   b. Workshop

3. Surveyors-in-training must receive satisfactory evaluations by two (2) surveyor trainers prior to being advanced as a full surveyor.

4. During year one, the new surveyor is expected to participate in:
   a. Two surveys as an observer/surveyor-in-training followed with
   b. Two surveys as a full surveyor.

5. Special education, training and experience is required for surveyors of the following freestanding services:
   a. Behavioral Health
   b. Ambulatory Care/Ambulatory Surgery
   c. Physical Rehabilitation
   d. Mental Health/Substance Abuse Centers

REAPPOINTMENT CRITERIA:

Annually, the Bureau Healthcare Facilities Accreditation (BHFA) reappoints surveyors using the criteria (below).

1. Participates in four surveys per year.

2. Professionally conducts surveys

3. Maintains confidentiality of survey program materials, accreditation findings and decisions.

4. Advises HFAP staff immediately of any existing or potential conflicts of interest (such as former places of employment) related to survey of facilities for which they are scheduled, and precludes self from participation in such surveys unless approved to do so by the COO of the Healthcare Facilities Accreditation Program.

5. When conducting surveys, represents the HFAP only. No other business is conducted nor is any other business represented either expressed or implied.

6. Attends HFAP surveyor workshops, as provided.

7. Represents the HFAP in a professional manner.

8. Satisfactory evaluations by surveyor trainer, surveyed facilities, and team members. (Effective November 2004)

9. Individuals may be reapproved if they continue to be actively involved in inspections and receive satisfactory evaluations regarding performance.

10. Reappointment decisions are recorded in the minutes of the Bureau of Healthcare Facilities Accreditation (BHFA) meeting.

TERMINATION:

a. If a surveyor no longer wishes to continue in this role, the surveyor is asked to have a debriefing with the HFAP COO or designee.

b. If the surveyor makes the decision to resign, it is desirable that a four-month notice be provided. It is also desirable that the surveyor complete or find an alternative to any scheduled surveys.

c. Surveyors that receive unsatisfactory peer or facility evaluations will be counseled by the HFAP COO.

d. Surveyors will be terminated for:
   a. Unprofessional or unethical behavior
   b. Confidentiality breaches
   c. Behaviors demonstrating conflicts of interest

PERSONNEL FILES:

1. The Director of Accreditation Services, Healthcare Facilities Accreditation Program maintains a personnel file for each surveyor.

2. For each surveyor, the following documents will be maintained:
   a. Curriculum vitae
   b. Letters of Reference
   c. Signed Surveyor Agreement
   d. Signed Business Associate Agreement
   e. Initial BHFA appointment letter
   f. Attendance at education sessions
   g. Post-training test scores and other competency validation documents;
   h. Evaluations, including letters of commendation, investigation of complaints and action taken, if required.
   i. Other correspondence, information and/or materials related to their individual services as HFAP surveyors or consultants.

SURVEYS:

1. Surveyors will not be scheduled to survey a facility which is located within an 80 mile radius of their current employer and/or a facility which is a direct competitor of their employer.

2. Surveyors will not be scheduled to survey a facility in which they have been affiliated with in the past.

3. If the surveyor also acts as an HFAP consultant, the surveyor must notify the HFAP office at the time consultation services have been agreed upon with the facility.

CRITERIA FOR RECRUITING (PRE-REQUISITES):

A candidate for the position of Registered Nurse surveyor shall meet the following eligibility criteria.

A. Education:

1. A bachelor's degree is required.

2. A Graduate degree in nursing or healthcare administration is preferred.

B. Experience:

1. Have 5-years minimum, 10 years preferred active hospital experience, with a focus in administration, healthcare education or quality monitoring (Quality Manager or the equivalent) and be currently active in a hospital accredited by the HFAP.
2. Have experienced one or two HFAP surveys (two preferred).

APPLICATION PROCEDURE AND PROCESSING:

1. Submit the following to the Chief Operating Officer (COO), Healthcare Facilities Accreditation Program (HFAP):
   a. Letter of intent to become an HFAP Surveyor
   b. Resume / curriculum vitae
   c. Two (2) letters of recommendation.

2. Agree to serve as a federal witness if requested.

3. The HFAP COO will submit candidate resumes and letters of recommendation to the Bureau of Healthcare Facilities Accreditation (BHFA) for review and approval. If approved by the Bureau, an appointment of "surveyor-in-training" will be awarded.

4. Appointment decisions are recorded in the minutes of the Bureau of Healthcare Facilities Accreditation (BHFA) meeting.

5. The COO will notify the candidate of Bureau's decision. The COO will forward copies of the HFAP Surveyor Confidentiality Agreement and the Business Associate Agreement (BAA) forms to the new appointee for signature. Upon receipt of the signed documents,

surveyor-in-training assignments will be prepared.

TRAINING REQUIREMENTS:

1. Surveyors-in-Training are required to participate with at least two surveys as an observer / surveyor-in-training.

2. As available, attend appropriate:
   a. training program
   b. workshop

3. Surveyors-in-training must receive satisfactory evaluations by two (2) surveyor trainers prior to being advanced as a full surveyor.

4. During year one, the new surveyor is expected to participate in:
   a. Two surveys as an observer/surveyor-in-training followed with
   b. Two surveys as a full surveyor.

5. Special education and experience for inspection of specific disciplines required for survey of freestanding services:
   a. Behavioral Health
   b. Ambulatory Care/Ambulatory Surgery
   c. Physical Rehabilitation
   d. Mental Health/Substance Abuse Centers

REAPPOINTMENT CRITERIA:

Annually, the Bureau Healthcare Facilities Accreditation (BHFA) reviews the list of surveyors for reappointment using the criteria listed below.

1. Participate in four (4) surveys per year.

2. Professionally conducts surveys

3. Maintains confidentiality of survey program materials, accreditation-finding decisions.

4. Advises HFAP staff immediately of any existing or potential conflicts of interest (such as former places of employment) related to survey of facilities for which they are scheduled, and precludes self from participation in such surveys unless approved to do so by the Chief Operating Officer (COO) of the Healthcare Facilities Accreditation Program.

5. When conducting surveys, represents the AOA Healthcare Facilities Accreditation Program only. No other business is conducted, nor is any other organization represented, either expressed or implied.

6. Attends HFAP surveyor workshops as provided.

7. Represents the HFAP in a professional manner.

8. Satisfactory evaluations by surveyor trainer, surveyed facilities, and team members. (Effective November 2004)

9. Individuals may be re-approved if they continue to be actively involved in inspections and receive satisfactory evaluations regarding performance.

10. Reappointment decisions are recorded in the minutes of the Bureau Healthcare Facilities Accreditation (BHFA) meeting.

TERMINATION:

1. If a surveyor no longer wishes to continue in this role, the surveyor is asked to have a debriefing with the HFAP COO or designee.

2. If the surveyor makes the decision to resign, it is desirable that a four-month notice be provided. It is also desirable that the surveyor complete or find an alternative to any scheduled surveys.

3. Surveyors that receive unsatisfactory peer or facility evaluations will be counseled by the HFAP COO.

4. Surveyors will be terminated for:
   a. Unprofessional or unethical behavior
   b. Confidentiality breaches
   c. Behaviors demonstrating conflicts of interest

PERSONNEL FILES:

1. The Director of Accreditation Services, Healthcare Facilities Accreditation Program maintains a personnel file for each surveyor.

2. For each surveyor, the following documents will be maintained:
   a. Curriculum vitae
   b. Signed Surveyor Agreement
   c. Letters of Reference
   d. Signed Business Associate Agreement
   e. Initial BHFA appointment letter
   f. Attendance at education sessions
   g. Post-training test scores and other competency validation documents
   h. Evaluations, including letters of commendation, investigation of complaints and action taken, if required.
   i. Other correspondence, information and/or materials related to their individual services as HFAP surveyors or consultants.

SURVEYS:

1. Surveyors will not be scheduled to survey a facility which is located within an 80 mile radius of their current employer and/or a facility which is a direct competitor of their employer.

2. Surveyors will not be scheduled to survey a facility in which they have been affiliated with in the past.

3. If the surveyor also acts as an HFAP consultant, the surveyor must notify the HFAP office at the time consultation services have been agreed upon with the facility.

CRITERIA FOR RECRUITING (PRE-REQUISITES):

A candidate for the position of team captain surveyor shall meet the following eligibility criteria.

A. Education

1. Licensed DO / MD in a HFAP accredited facility.

B. Experience:

1. Have 5 years active practice experience, be currently in active practice or recently retired (within the last 12 months) from active practice, or function as a Medical Director, Director of Medical Education or Administrator for the same time frame. Certification in a specialty desirable.

2. Experience in medical staff organizational activities and committees preferably peer review type (i.e., Quality Assessment Performance Improvement, Utilization Review.)

3. Have experienced one or two HFAP surveys (two preferred).

APPLICATION PROCEDURES AND PROCESSING:

1. Submit the following to the Chief Operating Officer (COO), Healthcare Facilities Accreditation Program (HFAP):
   a. Letter of intent to become an HFAP Surveyor
   b. Resume / curriculum vitae
   c. Two (2) letters of recommendation.

2. Agree to serve as a federal witness if requested.

3. The HFAP COO will submit candidate resumes and letters of recommendation to the Bureau of Healthcare Facilities Accreditation (BHFA) for review and approval. If approved by the Bureau, an appointment of "surveyor-in-training" will be awarded.

4. Appointment decisions are recorded in the minutes of the Bureau of Healthcare Facilities Accreditation (BHFA) meeting.

5. The COO will notify the candidate of the Bureau's decision. The COO will forward copies of the HFAP Surveyor Confidentiality Agreement and the Business Association Agreement (BAA) forms to the new appointee for signature. Upon receipt of the signed documents, surveyor-in-training assignments will be prepared.

TRAINING REQUIREMENTS:

1. Surveyors-in-training are required to participate with at least two surveys as an observer / surveyor-in-training.

2. As available, attend appropriate:
   a. training program
   b. workshop

3. Surveyors-in-training must receive satisfactory evaluations by two (2) surveyor trainers prior to being advanced as a full surveyor.

4. During year one, the new surveyor is expected to participate in:
   a. Two surveys as an observer / surveyor-in-training followed with
   b. Two surveys as a full surveyor

5. Special education and experience for inspection of specific disciplines required for survey of freestanding services:
   a. Behavioral Health
   b. Ambulatory Care/Ambulatory Surgery
   c. Physical Rehabilitation
   d. Mental Health/Substance Abuse Centers

REAPPOINTMENT CRITERIA:

Annually, the Bureau Healthcare Facilities Accreditation (BHFA) reviews the list of surveyors for re-appointment using the criteria listed below.

1. Participates in four (4) surveys per year.

2. Professionally conducts surveys.

3. Maintains confidentiality of survey program materials, accreditation findings and decisions.

4. Advises HFAP staff immediately of any existing or potential conflicts of interest (such as former places of employment) related to survey of facilities for which he / she is scheduled, and precludes self from participation in such surveys unless approved to do so by the Chief Operating Officer (COO) of the Healthcare Facilities Accreditation Program.

5. When conducting surveys, represents the AOA Healthcare Facilities Accreditation Program only. No other business is conducted, nor is any other organization represented, either

expressed or implied.

6. Attends HFAP surveyor workshops as provided.

7. Represents the HFAP in a professional manner.

8. Satisfactory evaluations by surveyor trainer, surveyed facilities, and team members. (Effective November 1, 2004)

9. Individuals may be re-approved if they continue to be actively involved in inspections and receive satisfactory evaluations regarding performance.

10. Reappointment decisions are recorded in the minutes of the Bureau Healthcare Facilities Accreditation (BHFA) meeting.

TERMINATION:

1. If a surveyor no longer wishes to continue in this role, the surveyor is asked to have a debriefing with the HFAP COO or designee.

2. If the surveyor makes the decision to resign, it is desirable that a four month notice be provided. It is also desirable that the surveyor complete or find an alternative to any scheduled surveys.

3. Surveyors that receive unsatisfactory peer or facility evaluations will be counseled by the HFAP COO.

4. Surveyors will be terminated for:
   a. Unprofessional or unethical behavior
   b. Confidentiality breaches
   c. Behaviors demonstrating conflicts of interest.

PERSONNEL FILES:

1. The Director of Accreditation Services, Healthcare Facilities Accreditation Program (HFAP) maintains a personnel file for each surveyor.

2. For each surveyor, the following documents will be maintained:
   a. Curriculum vitae
   b. Signed Surveyor Agreement
   c. Letters of Reference
   d. Signed Business Associate Agreement
   e. Initial BHFA appointment letter
   f. Attendance at education sessions
   g. Post-training test scores and other competency validation documents
   h. Evaluations, including letters of commendation, investigation of complaints and action taken, if required.

i. Other correspondence, information and/or materials related to their services as HFAP surveyors or consultants.

SURVEYS:

1. Surveyors will not be scheduled to survey a facility which is located within an 80 mile radius of their current employer and/or a facility which is a direct competitor of their employer.

2. Surveyors will not be scheduled to survey a facility in which they have been affiliated with in the past.

3. If the surveyor also acts as an HFAP consultant, the surveyor must notify the HFAP office at the time consultation services have been agreed upon with the facility.

August 30, 2011

Janice Dang, Pharm.D.
Supervising Inspector
California State Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834

Dear Dr. Dang,

The Pharmacy Compounding Accreditation Board (PCAB) is pleased to submit an application for recognition as a California accreditation organization for compounding pharmacies.

Included in this application you will find:

- PCAB's response to the California Board of Pharmacy's application questions
- PCAB's Standards Manual
- PCAB's Guidance to Pharmacies Regarding Hazardous and Potent Substances and Primary Engineering Controls
- List of PCAB accredited pharmacies in California

I will be representing PCAB at the Board meeting. Once you have had an opportunity to review these materials, can we set up a time to discuss them, so that I may be fully prepared to address any questions from the Board?

Please do not hesitate to contact me (joec@pcab.org or 866-377-5104 ex. 804) if you have any questions.

Sincerely,

Joe Cabaleiro

Joe Cabaleiro R.Ph.
Executive Director

Pharmacy Compounding Accreditation Board Application For Recognition As A California Accreditation Organization For Compounding Pharmacies

Introduction

The Pharmacy Compounding Accreditation Board (PCAB) began accrediting compounding pharmacies in 2006. The primary mission of PCAB is to promote, develop and maintain principles, policies and standards for the practice of pharmacy compounding and to apply these in the accreditation of pharmacies to improve the quality and safety of compounded pharmaceuticals provided to the general public.

PCAB's founding organizations and Board of Directors includes:

American College of Apothecaries
www.americancollegeofapothecaries.com

American Pharmacists Association
www.pharmacist.com

International Academy of Compounding Pharmacists
www.iacprx.org

National Association of Boards of Pharmacy
www.nabp.net

National Alliance of State Pharmacy Associations
www.naspa.us

National Community Pharmacists Association
www.ncpanet.org

National Home Infusion Association
www.nhia.org

United States Pharmacopeia
www.usp.org

There are currently 125 accredited compounding pharmacies throughout the United States. PCAB accredits pharmacies for sterile compounding, non-sterile compounding or both types of compounding services. The application, survey and accreditation process is described in more detail below.

Responses

1. Periodic inspections: The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.

   The PCAB accreditation process consists of a comprehensive application. This application includes detailed demographics about the applicant pharmacy. In addition the process involves uploading a series of Standard Operating Procedures for review by PCAB.

   As part of the application process PCAB performs license verification through an NABP. Certain active disciplinary actions by state boards of pharmacy, the FDA or other regulators may disqualify a pharmacy from PCAB accreditation.

   Once the application process is complete, PCAB performs an on-site survey. The on-site survey lasts a minimum of one day, but is based upon the prescription volume and services the pharmacy provides. A busier pharmacy may have an up to two-day survey with 2 surveyors.

   During the on-site survey the PCAB surveyor evaluates compliance with the PCAB standards. This evaluation includes personnel interviews, observation of sterile and non-sterile compounding, record review including logs and personnel records, review of SOP documents and evaluation of the facility against established USP and PCAB standards for compounding facilities.

   As a result of the on-site survey, the PCAB surveyor generates a written survey report that is submitted to the PCAB central office. At the central office, a registered pharmacist produces a report for the pharmacy detailing the findings. If the pharmacy is found to be noncompliant with any PCAB requirement, the pharmacy is provided with corrective actions to address the noncompliance. The pharmacy is given a time frame in which to perform the corrective actions. Documentation of the corrective actions must be submitted to the PCAB central office.

   Once the PCAB central office has received any corrective actions from the pharmacy, an accreditation committee reviews the initial survey report and subsequent corrective actions. The accreditation committee makes the final decision on whether to award accreditation to a pharmacy. PCAB's accreditation committee currently consists of 5 pharmacist members: A representative from the United States Pharmacopeia (USP), National Association Of Boards of Pharmacy (NABP) and 3 pharmacists who are owners of compounding pharmacies and who are highly qualified experts in compounding.

Accredited pharmacies are resurveyed every 3 years. Therefore, at three-year intervals the process described above is repeated for each accredited pharmacy.

2. Documented accreditation standards: The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California Law and sound professional practice as established by nationally recognized professional or standard setting organizations.

   PCAB standards were developed with the participation of various authorities in the field of pharmaceutical compounding. The PCAB Board of Directors includes the following 7 organizations:

   American College of Apothecaries
   www.americancollegeofapothecaries.com

   American Pharmacists Association
   www.pharmacist.com

   International Academy of Compounding Pharmacists
   www.iacprx.org

   National Association of Boards of Pharmacy
   www.nabp.net

   National Alliance of State Pharmacy Associations
   www.naspa.us

   National Community Pharmacists Association
   www.ncpanet.org

   National Home Infusion Association
   www.nhia.org

   United States Pharmacopeia
   www.usp.org

   This application includes a copy of the PCAB standards manual and a comparison of PCAB standards against California Board of pharmacy regulations. It is PCAB's opinion that California Board of pharmacy reviewers will find that PCAB Standards are consistent with California regulatory requirements.

3. Evaluation of surveyor's qualification: The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.

   PCAB surveyors are all registered pharmacists with extensive sterile and nonsterile compounding experience. All PCAB surveyors have received initial and ongoing training on conducting on-site surveys, standards interpretation and the use of PCAB survey tools.

   - Include how the surveyors are trained on California's compounding regulations and would they be able to determine if the pharmacy is compliant with California laws.

     Please review the attached comparison of California regulations against PCAB standards. PCAB standards and California regulations are very consistent in regards to requirements for compounding pharmacies. If PCAB is selected as an accreditation organization, PCAB will conduct training regarding those items where PCAB standards do not address California regulation. These very limited items generally relate to record retention requirements; however in meeting California standards, the three year retention requirement would be surveyed for.

   - Include whether the surveyors are pharmacists, nurses, or other. If other, please specify.

     As noted above all PCAB surveyors are registered pharmacists with compounding experience.

4. Acceptance by major California payors: Recognition of the accrediting agency by at least one California healthcare payors (e.g. HMO's, PPO's, PBGH, CalPERS).

   PCAB accredits compounding pharmacies only, and therefore, if a compounding pharmacy submits claims to insurance (and many don't), the only "acceptance as an accrediting agency" PCAB has or needs is the fact the pharmacy has a contract for prescription services with a payor. This is somewhat different than the other accreditation services approved by the California Board, who accredit healthcare services in addition to pharmacy services. PCAB accreditation relates purely to pharmacy services, and as such the relationships you mention above do not exist at the moment.

   On the other hand, the Californian Board should note that PCAB Standards very closely mirror California regulations. It should also be noted that Pharmacist's Mutual, an insurance company providing services to pharmacies has recognized PCAB's Standards [Note Pharmacist's Mutual does not sell into California however].

The American Medical Association in policy 120.945, "recognizes the accreditation program of the Pharmacy Compounding Accreditation Board (PCAB™) and the PCAB™ Seal of Accreditation as a means to identify compounding pharmacies that adhere to quality and practice standards, including those set forth in the USP-NF, for the preparation of individualized medications for specific patients." A full copy of the AMA policy is available at: http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.pdf.

5. Include whether PCAB will notify the board of any serious noncompliance requiring the board to follow up with an inspection.

   PCAB will inform the Board when the PCAB accreditation committee notes that noncompliance with PCAB standards or other practices documented by the surveyor place the public at harm. In addition, PCAB can notify the Board of those situations where PCAB denies or revokes a pharmacy's accreditation.

California Requirement	Equivalent PCAB Requirement
Definitions (CCR 1735 and 1735.1) (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription: (1) Altering the dosage form or delivery system of a drug(2) Altering the strength of a drug(3) Combining components or active ingredients(4) Preparing a drug product from chemicals or bulk drug substances (b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability. (c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace. (d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7(Section 1735 et seq.). 150 Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.	Compounding Traditional pharmacy practice which includes the preparation, mixing, assembling, packaging, or labeling of a completed compounded preparation (CCP) or administration device by compounding personnel (i) as the result of a practitioner's prescription order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis, and shall not be dispensed for resale by a third party, (iii) preparation of drugs or devices in anticipation of prescription orders to be received by the compounding pharmacist based on routine, regularly observed prescribing patterns, (iv) preparation of CCPs (completed compounded preparation) for practitioner administration, pursuant to state and federal regulations, (v) preparation of Non-Legend CCPs (completed compounded preparation), pursuant to state requirements, and (vii) preparing CCPs (completed compounded preparation) for both human and non-food producing animal patients. Compounding Scope of Practice **Nonsterile Basic** Nonsterile Basic – compounding which involves the preparation of a formulation containing two or more nonsterile commercially available products employing basic pharmacy training skill sets, as well as, defined policy, procedures and processes necessary to

	assure quality and consistency of the completed compounded preparation. **Nonsterile Complex** Nonsterile Complex - compounding which involves the art and science of preparing a formulation using bulk drug substances, drug products, and/or other excipients. These formulations require complex procedures or calculations in their preparation and include formulations that incorporate the use of potent or hazardous pharmaceutical ingredients. **Sterile, Low and Medium** Sterile, Low and Medium - compounding which involves the preparation of Compounded Sterile Preparations (CSPs) in closed-system steps or procedures using a few basic aseptic manipulations, as well as those Compounded Sterile Preparations (CSPs) prepared via complex or numerous aseptic manipulations for administration to one patient on multiple occasions or to multiple patients. **Sterile, High** Sterile, High – compounding which involves the preparation of sterile preparations from non-sterile ingredients or with a nonsterile device. Source: PCAB Standards - Definitions
The compounding pharmacist understands the definitions of integrity, potency, quality and strength as defined in CCR 1735.1.	***Standard 2.20 Pharmacist in Charge*** *There is a pharmacist in charge of the compounding activities who establishes the scope of compounding practice for relevant staff based on the education, training, and demonstrated competence. The pharmacist in charge supervises all compounding personnel, assures that compounded preparations meet SOPs, and maintains compliance with state and Federal regulations and PCAB standards.*

	Compliance Indicators • The pharmacy provides documentation that the pharmacist in charge has the education, training, and experience consistent with the responsibilities and the scope of compounding practice performed in the pharmacy. • The pharmacy demonstrates that the pharmacist in charge has sufficient authority to carry out these responsibilities. • The pharmacist in charge demonstrates an awareness of these responsibilities under applicable state and/or Federal law, compounding practice within the pharmacy, and current USP standards related to non-sterile and, if applicable, sterile compounding. • The pharmacist in charge demonstrates an adequate knowledge of all operations of the pharmacy relating to good compounding practices as identified in the SOPs. ***Standard 2.30 Staff Pharmacists*** *There are staff pharmacists to assure that compounded preparations are prepared, packaged, labeled, stored, and dispensed according to SOPs of the pharmacy. Staff pharmacists are responsible for patient counseling and/or patient care services required by applicable state law or practice standards.* **Compliance Indicators** The pharmacy provides documentation that staff pharmacists are competent, as defined in the SOPs, to assure the quality of preparations compounded, packaged, labeled, stored, and dispensed in the pharmacy. • Staff pharmacists demonstrate adequate knowledge of operations of the pharmacy related to the scope of compounding and dispensing in which they participate or supervise. • Staff pharmacists demonstrate their education and training in good compounding practices.

	• Staff pharmacists demonstrate that they are knowledgeable about current USP standards related to non-sterile compounding. • Staff pharmacists demonstrate that they are knowledgeable about current USP standards related to sterile compounding, if applicable. • Staff pharmacists demonstrate knowledge of dispensing requirements and procedures used in the pharmacy. • Staff pharmacists are responsible for verifying that SOPs are being followed for preparing compounded preparations. • Staff pharmacists are responsible for direct supervision of all compounding personnel. Source: PCAB Standards Manual
The pharmacy prepares and stores a limited quantity of a compounded drug product in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified patient population as defined.	Addressed in the definition of compounding above: (iii) preparation of drugs or devices in anticipation of prescription orders to be received by the compounding pharmacist based on routine, regularly observed prescribing patterns,
2.2. The pharmacy compounds a reasonable quantity of drug product that is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2 (c) that: 2.2.1. Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 72-hour supply. 2.2.2. Is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice, 2.2.3 Is an amount, which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength for any individual prescriber or for all prescribers taken as a whole.	This is a California requirement. PCAB would train its surveyors to survey against this requirement for pharmacies licensed in CA. PCAB standard 8.20, Patient Education, element D, addresses this issue: The pharmacy demonstrates that prospective drug reviews are conducted prior to dispensing compounded preparations.

	In addition, when reviewed as a whole, PCAB standards fully address the pharmacy's capabilities, and QA/QC systems in regards to 2.2.3.
2.3. The pharmacy does not compound medication until it has prepared a written master formula that includes the following elements (CCR 1735.2[d][1-6]): 2.3.1. Active ingredients used. 2.3.2. Inactive ingredients used. 2.3.3. Process and/or procedure used to prepare the drug. 2.3.4. Quality reviews required at each step in the preparation of the drug. 2.3.5. Post-compounding process or procedures if required. 2.3.6. Expiration dating requirements.	**Standard 5.00 Formulation Record and Compounding Record** *The pharmacy uses a Formulation Record (FR) that assures the strength quality, purity, integrity, and where applicable, sterility of the compounded preparation. The pharmacy uses a Compounding Record (CR) for assuring that the procedures employed to prepare compounded preparations are consistent and reproducible. Compounding activities and processes shall be subject to verification of preparations for strength, quality, purity, integrity, and where applicable, sterility that meet or exceed compendial standards.* **Compliance Indicators** A. The pharmacy demonstrates that the SOPs provide for verification of strength, quality, purity, integrity, and, where applicable sterility for all compounded preparations. B. The pharmacy documents that, when available, it incorporates into its FR those formulations and formulation procedures developed, tested, and verified by non-governmental standard setting organizations including, but not limited to the United States Pharmacopeial Convention: 1. The pharmacy documents that it maintains a FR for each compounded preparations. 2. The pharmacy identifies which compounding personnel may enter new FR and edit existing FR. C. The pharmacy provides documentation of a FR that maintains the following information on preparations that it compounds: 1. Name, strength, and dosage form of the compounded preparation; 2. Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients; 3. Description of all components and ingredients, and their quantities; 4. Compatibility and stability information, including

	references when available; 5. Equipment used to prepare the compounded preparation, when appropriate; 6. Mixing instructions that include, at a minimum: order of mixing, mixing temperatures or other environmental controls, duration of mixing, and other factors pertinent to the replication of the compounded preparation; 7. Assigned beyond-use date of the compounded preparation; 8. Container used in dispensing; 9. Packaging and storage requirements; 10. Quality control procedures; and 11. References used in the development of the FR, if applicable.
2.4. The master formula for a drug product that is not routinely compounded by the pharmacy is recorded on the prescription document itself. (CCR 1735.2 [e])	This situation does not apply to PCAB accredited compounding pharmacies, as it is a violation of the PCAB Standard 5.00 above requiring every compound to have both a formula record and a compounding record.
2.5. All chemicals, bulk drug substances, drug products and other components for compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2 [g])	**Standard 4.20 Handling, Storage, and Disposal** *The pharmacy safely handles, stores, and disposes of all chemicals, drug products and components according to compendial and other applicable requirements. Appropriate storage of chemicals, components, and completed compounded preparations shall be designed to maintain their strength, quality, purity, integrity, and where applicable, sterility.* **Compliance Indicators** A. The pharmacy has SOPs assuring that chemicals, components and completed compounded preparations are maintained within appropriate standards, as established by the current USP, including: 1. Acceptable storage temperature ranges and temperature monitoring and documentation procedures, 2. Contingency plans if conditions fall outside of acceptable ranges, 3. Guidelines to be followed to determine if a component has been compromised and when it should be destroyed,

	4. Procedure for handling and storing hazardous and potent chemicals, 5. Individuals responsible for making decisions regarding compromised components, 6. Quarantine specifications, including expired and recall storage, 7. Disposal or return of expired components and completed compounded preparations, 8. Storage and disposal of drug substances and drug products used as components in the compounding of preparations. B. Storage containers include labels that include all relevant information, including but not limited to drug name, strength, lot number, date received, etc. C. The pharmacy conducts periodic inspections to assure that expired components and completed compounded preparations do not remain in stock. D. Storage of chemicals to be utilized for high-risk sterile compounding are stored in a separate area according to current USP <797> standards.
2.6. Compounded drug products are given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. The "beyond use date" of the compounded drug product does not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[h])	PCAB requires compliance with USP standards in regards to the assignment of BUDs. Consistent with CA law, if the BUD will exceed USP standards, the pharmacy must document the rationale for the extended BUD. **Standard 6.10 Beyond-Use Date** *The pharmacy determines and assigns beyond-use dates to all its compounded preparations.* **Compliance Indicators** E. The pharmacy demonstrates that the SOPs provide for the determination and assignment of beyond-use dating for all of its compounded preparations. F. The pharmacy demonstrates by inspection the use of beyond-use dates on compounded preparations. G. The pharmacy documents the rationale and sources used to

	establish beyond-use dates which exceed current USP standards. H. The pharmacy documents how it communicates beyond-use dating information to compounding personnel and the patient and/or caregiver. I. The pharmacy provides rationale for beyond-use dating which exceeds current USP standards arrived at based on the pharmacist's professional judgment.
3.1. A record for each compounded drug product includes the following (CCR 1735.3[a][1-10]): 3.1.1. The master formula record. 3.1.2. The date the drug product was compounded. 3.1.3. The identity of the pharmacy personnel who compounded the drug product. 3.1.4. The identity of the pharmacist reviewing the final drug product. 3.1.5. The quantity of each component used in compounding the drug product. 3.1.6. The manufacturer or supplier and lot number of each component. Exempt from this requirement are sterile drug products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. 3.1.7. The equipment used in compounding the drug product. 3.1.8. The pharmacy assigned reference or lot number for the compounded drug product. 3.1.9. The expiration date of the final compounded drug product. 3.1.10. The quantity or amount of drug product compounded.	Element D of PCAB Standard 5.00 addresses this item: **Standard 5.00 Formulation Record and Compounding Record** *The pharmacy uses a Formulation Record (FR) that assures the strength, quality, purity, integrity, and where applicable, sterility of the compounded preparation. The pharmacy uses a Compounding Record (CR) for assuring that the procedures employed to prepare compounded preparations are consistent and reproducible. Compounding activities and processes shall be subject to verification of preparations for strength, quality, purity, integrity, and where applicable, sterility that meet or exceed compendial standards.* D. The pharmacy provides documentation of a Compounding Record (CR) that maintains the following information on components of preparations that it compounds to verify accurate compounding in accordance with the FR: a. Name and strength of the compounded preparation; b. FR reference for the preparation; c. Sources, lot numbers, quantities, and expiration dates of components and ingredients; d. Total quantity compounded and actual net measurements; e. Name of the personnel involved in the compounding process and the name of the pharmacist who approved the compounded preparation; f. Date of preparation; g. Assigned internal identification number or prescription number; h. Equipment used;

	i. Assigned beyond-use date of the compounded preparation; and j. Results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids, etc.).
3.2. The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products and components used in compounding. (CCR 1735.3 [b]) 3.3. Chemicals, bulk drug substances, drug products, and components used to compound drug products are obtained from reliable suppliers. (CCR 1735.3 [c]) 3.4. The pharmacy acquires and retains any available certificates of purity or analysis for chemicals, bulk drug substances, drug products and components used in compounding. (This is not a requirement for drug products approved by the FDA.) (CCR 1735.3 [c])	Standard 4.20 (See CA requirement 2.5 above) addresses this item. In addition, PCAB Standard 4.10 also addresses these items: **Standard 4.10 General** *The pharmacy maintains standard operating procedures related to the acquisition, storage, usage and proper destruction of drug substances and drug products, which are used as components in the compounding of preparations. Drug substances and products used to compound meet official compendial standards, if any, including current USP-NF standards, and are accompanied by certificate of analysis, which documents the strength, quality, purity and integrity of the drug substance.* **Compliance Indicators** A. The pharmacy has SOPs governing the acquisition of all chemicals, drug products, and components from reliable sources. B. The SOPs provide that certificates of analysis be retained electronically or in hard copy by the pharmacy for a period of not less than two years. C. The SOPs provide that certificates of analysis be reviewed by properly trained personnel prior to the release drug substances of chemicals for use in compounding. D. The pharmacy documents that it uses appropriate suppliers as the source of all bulk chemical ingredients, inactive ingredients or excipients, and other components used in compounding. The pharmacy obtains the following information from appropriate suppliers: 1. FDA registered and inspected, if applicable; 2. Documentation indicating compliance with FDA current Good Manufacturing Practices 3. Proof of licensure in good standing with applicable state and/or Federal regulatory bodies. 4. Ability to provide ready access to Certificates of Analysis (CofA) and Material Safety Data Sheets (MSDS) with all

	bulk chemicals. E. The pharmacy demonstrates that the SOPs address criteria for identifying and using suppliers for devices, containers, and closures used in compounding including complying with any applicable compendial standards, if applicable. F. The SOPs address contingency plans should an active pharmaceutical ingredient, inactive ingredient, excipient, or other component used in compounding become unavailable from any supplier meeting the above criteria. The SOPs set forth an adequate mechanism directing the pharmacist in charge to employ professional judgment in receiving, storing, and using such components from another quality source. G. The pharmacy documents that it uses high quality active pharmaceutical ingredients (APIs) for use in compounding that: 1. Meets current USP/NF grade substances. If not available, then the use of other high-quality sources, such as: i. Analytical reagent (AR), ii. Certified American Chemical Society (ACS), or iii. Food Chemicals Codex (FCC) grade, are permitted as sources of active ingredients when appropriate. iv. Dietary and nutritional supplements that are "Generally Recognized As Safe" 2. Meets other compendial standards, or 3. Are components of products that have been approved by FDA or grand-fathered under the Food, Drug & Cosmetic Act of 1938 (FDCA). H. The pharmacy complies with the FDA's "List of Drug Products That Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness," subject to the exceptions provided in such list. Written SOPs exist to safeguard against the use of such components in compounded preparations for human patients. I. The pharmacy demonstrates that it has a designated area for the receiving and inspection of chemicals, devices, containers,

	closures, and other components or supplies used in the compounding operation. J. The pharmacy has SOPs that assure Material Safety Data Sheets (MSDS) are properly maintained and readily retrievable. K. The pharmacy has SOPs that outline the criteria for acceptance or refusal of components. L. The pharmacy demonstrates that upon receipt of a chemical or drug substance, it is quarantined until the Certificate of Analysis (CofA) information is verified by properly trained compounding personnel and the MSDS information is assessed for review, as necessary.
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]).	Federal and State laws vary in regards to records retention. In addition, a pharmacy's legal counsel and the types of patients it serves (for example, pediatric patients vs. animals) may dictate the pharmacy's record retention policy. As such, PCAB does not have a specific standard addressing this item.
4.1. The label of the compounded drug product contains the generic name(s) of the principle active ingredient(s). (CCR 1735.4[a]) 4.2. The prescription label contains all the information required in B&PC 4076 and is formatted in accordance with CCR 1707.5. (CCR 1735.4[a])	**Standard 7.30 Labeling** *The pharmacy labels completed compounded preparations according to the PCAB Labeling Guidelines.* **Compliance Indicators** *PCAB Labeling Guidelines* A. The primary label of each compounded medication prepared in response to a prescription for a specific patient from a licensed prescriber includes a statement notifying the patient that the medication has been compounded. If space limitations or clinical reasons preclude inclusion on the primary label, the information may be affixed through auxiliary labeling.[1] For all

1 For example, when there is concern that a label applied directly to the primary container may affect the quality of the compounded medication. In such cases, the pharmacist may decide, in the pharmacist's professional judgment, that the label and statement be applied in another manner, such as to exterior packaging

	such prescriptions, the statement is prominently displayed in the medication labeling. *"This medicine was specially compounded in our pharmacy for you at the direction of your prescriber."*[2] B. The following items of information, or a reasonable alternative, is included on all compounded prescription labels:[3] *(1) Patient's name, and/or species, if applicable;* *(2) Prescriber's name;* *(3) Name, address, phone number of the pharmacy preparing the medicine;* *(4) Prescription number;* *(5) The medication's established or distinct common name;* *(6) Strength;* *(7) Statement of quantity;* *(8) Directions for use;* *(9) Date prescription filled;* *(10) Beyond-use date* *(11) Storage instructions; and* *(12) All state labeling* requirements.
4.3. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])	This item is not specifically addressed by PCAB standards.
4.4. The pharmacy is exempt from the prescription label requirements in CCR 1707.5. (B&PC 4076.5[d])Exemption approved by the board from: _____ to: _____	PCAB would respect Board rulings in regards to exemptions, provided that the exemption did not result in a violation of PCAB standards.
4.5. The container or receipt contains a statement that the drug has been	See Standard 7.30 Compliance Indicator A

2 Alternate language providing a clear designation that the medication has been compounded may be used, where, in the pharmacist's professional judgment, the welfare of the patient requires and the information is adequately and prominently communicated.

3 Label must be in conformity with applicable state, Federal, and compendial regulations and standards. Alternative placement may be acceptable if determined necessary because of space requirement or, in the pharmacist's professional judgment for the needs of the patient.

compounded by the pharmacy. (CCR 1735.4[b]) 4.6. Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of [a] and [b] 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 expiration date. (CCR 1735.4[c])	As a matter of survey process, PCAB adheres to the requirements of USP <681> Repackaging into Single-Unit Containers for Nonsterile Solid and Liquid Dosage Forms. PCAB generally requires adherence to the labeling requirements outlined in 4.6 and USP 681, except in those rare situations where the labeling may interfere with the safe use or administration of the medication. In those situations, PCAB still requires external labeling.
5.1. The pharmacy maintains a written policy and procedure manual for compounding that establishes the following (CCR 1735.5 [a]): 5.1.1. Procurement procedures. 5.1.2. Methodologies for the formulation and compounding of drugs.	PCAB has various standards that address SOPs. Standard 1.40 is a general requirement for an SOP manual: **Standard 1.40 Standard Operating Procedures** *The pharmacy develops, maintains, follows, and periodically updates written Standard Operating Procedures (SOPs) which address all aspects of the compounding operation.* In addition, various individual PCAB standards outline certain specific SOPs required by PCAB. Examples are noted below. Standard 4.10, Chemicals, Components, and Completed Compounded Preparations, General, various elements: A. The pharmacy has SOPs governing the acquisition of all chemicals, drug products, and components from reliable sources. B. The SOPs provide that certificates of analysis be retained electronically or in hard copy by the pharmacy for a period of not less than two years. C. The SOPs provide that certificates of analysis be reviewed by properly trained personnel prior to the release drug substances of chemicals for use in compounding. D. The pharmacy demonstrates that the SOPs address criteria for identifying and using suppliers for devices, containers, and closures used in compounding including complying with any applicable compendial standards, if applicable.

	Standard 5.0, Formulation Record and Compounding Record, Element A: A. The pharmacy demonstrates that the SOPs provide for verification of strength, quality, purity, integrity, and, where applicable sterility for all compounded preparations.
5.1.3. Facilities and equipment cleaning, maintenance and operations.	Various PCAB standards address this requirement. For example: Standard 3.10, Facilities and Equipment, General: A. The pharmacy has SOPs for each piece of equipment used in the compounding process that addresses cleaning, maintaining, calibrating and verification according to compendial standards or manufacturers' standards. At a minimum, the SOPs include documentation that equipment is regularly cleaned, maintained, calibrated and verified according to compendial standards or manufacturers' standards. Standard 3.20 Non-Sterile Compounding: A. The pharmacy has SOPs for cleaning and maintaining equipment and for the establishment of cleaning and maintenance schedules. Standard 3.20, Sterile Compounding: A. The pharmacy has SOPs for cleaning and maintaining equipment and for the establishment of cleaning and maintenance schedules.
5.1.4. Other standard operating procedures related to compounding.	As noted above, various PCAB standards establish requirements for specific SOPs.
5.3. The policy and procedure manual includes procedures for notifying staff assigned to compounding duties of any changes in process or to the policy and procedure manual. (CCR 1735.5[c][1])	This item is addressed by PCAB's Standard 2.10, Personnel, General: A. The pharmacy has SOPs for educating, training, and assessing the

	competencies of all compounding personnel on an ongoing basis, including documentation that compounding personnel is trained on SOPs.
5.4. The manual includes documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product. (CCR 1735.5[c][2]) 5.5. The manual includes procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding and for training on these procedures. (CCR 1735.5[c][3])	**Standard 7.20 Internal and External Recalls** *The pharmacy has procedures for the appropriate and timely recall of dispensed compounded preparations where subsequent testing or other information demonstrates that the compounded preparation does not meet its declared strength, quality, purity, and, where appropriate, sterility and bacterial endotoxin limit.* **Compliance Indicators:** A. The pharmacy demonstrates in the SOPs a recall procedure which consists of: 1. A procedure to determine the distribution of any compounded product, the date, quantity of distribution, quantity , dosage, and to identify patients receiving compounded preparations in a manner sufficient to allow the recall to be timely and effective based on severity, 2. A method of timely informing prescribers, patients and/or caregivers concerning recalls based on severity, 3. The necessary information to identify patients affected by a recall is readily retrievable. B. The pharmacy documents the implementation of a recall, including procedures concerning the disposition and reconciliation of the recalled preparation.
5.6. The manual includes documentation on the methodology used to test integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.5[c][4])	**Standard 6.20 Potency** *Compounded preparations meet established and/or compendial requirements of strength, quality, purity, potency and stability throughout the period for intended use when stored as labeled.* **Compliance Indicators** A. The pharmacy's SOPs satisfy current USP standards regarding potency and microbiological integrity of compounded preparations. B. The pharmacy provides documentation that it complies with all applicable state and Federal regulations regarding strength, quality, purity,

5.7. The manual includes documentation of the methodology used to determine appropriate expiration dates for compounded drug products. (CCR 1735.5[c][5])	potency and stability throughout the period for intended use of compounded preparations. **Standard 6.10 Beyond-Use Date** *The pharmacy determines and assigns beyond-use dates to all its compounded preparations.* **Compliance Indicators** A. The pharmacy demonstrates that the SOPs provide for the determination and assignment of beyond-use dating for all of its compounded preparations. B. The pharmacy demonstrates by inspection the use of beyond-use dates on compounded preparations. C. The pharmacy documents the rationale and sources used to establish beyond-use dates which exceed current USP standards. D. The pharmacy documents how it communicates beyond-use dating information to compounding personnel and the patient and/or caregiver. E. The pharmacy provides rationale for beyond-use dating which exceeds current USP standards arrived at based on the pharmacist's professional judgment.
6.1. The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products to include records of certification of facilities or equipment, if applicable. (CCR 1735.6[a]) 6.2. All equipment used to compound drug products is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b]) 6.3. All equipment used to compound drug products is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])	Various PCAB standards address these requirements: 2.10, Personnel: The pharmacy demonstrates that it continually assesses its staffing needs relevant to all elements of the compounding and dispensing process including environmental and equipment maintenance. Standard 3.10, Non-sterile compounding, address 6.1-6.4: **Standard 3.10 General** *The pharmacy has facilities and equipment sufficient for the safe and accurate compounding of preparations.* **Compliance Indicators** B. The pharmacy demonstrates that the size, type, and quality of facilities and equipment in the pharmacy is adequate to safely and

	accurately compound preparations in the amount and type relative to the nature of compounding that is performed in the pharmacy. This should include procedures for the control and containment of powders during compounding. C. The pharmacy has SOPs for each piece of equipment used in the compounding process that addresses cleaning, maintaining, calibrating and verification according to compendial standards or manufacturers' standards. At a minimum, the SOPs include documentation that equipment is regularly cleaned, maintained, calibrated and verified according to compendial standards or manufacturers' standards. D. If the pharmacy handles hazardous materials, it demonstrates that its SOPs are adequate to protect personnel based on volume and scope of compounding performed. Standard 3.20, Non-Sterile Compounding, also has elements addressing equipment: A. The pharmacy demonstrates that any equipment and surfaces involved in the compounding process is appropriately cleaned and/or sanitized before and after compounding activity as appropriate to prevent contamination. B. The pharmacy has SOPs for cleaning and maintaining equipment and for the establishment of cleaning and maintenance schedules. Standard 3.30, Sterile Compounding, also has addresses equipment: A. The pharmacy demonstrates that any equipment and surfaces involved in the compounding process is appropriately cleaned and/or sanitized before and after compounding activity as appropriate to prevent contamination. B. The pharmacy has SOPs for cleaning and maintaining equipment and for the establishment of cleaning and maintenance schedules. Standard 5.00, Formulation and Compounding Record, requires documentation of the equipment used: A. Equipment used to prepare the compounded preparation, when

6.4. Documentation of each calibration is recorded in writing and maintained and retained in the pharmacy. (CCR 1735.6[c])	appropriate; This item is addressed as part of the onsite survey processes. During the onsite survey, PCAB surveyors review evidence of compliance with PCAB standards by examining logs and other documentation. Initial applicants are required to have a 3 month track record of logs complying with PCAB requirements. Accredited pharmacies must maintain compliance throughout their accreditation period.
7.1. The pharmacy maintains written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform assigned responsibilities relating to compounding. (CCR 1735.7[a]) 7.2. The pharmacy develops and maintains an on-going competency evaluation process for pharmacy personnel involved in compounding. (CCR 1735.7[b]) 7.3. Documentation on any and all such training for pharmacy personnel is maintained. (CCR 1735.7[b]) 7.4. Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product. (CCR 1735.7[c])	PCAB has several standard related to orientation, competency, initial and on-going training: **Standard 2.10 General** *Supervision and level of personnel is sufficient to assure the safety and integrity of compounding. All personnel affiliated with compounding in the pharmacy are competent to perform their assigned duties.* **Compliance Indicators** B. The pharmacy provides a written description of the responsibilities and functions of all compounding personnel. C. The pharmacy has SOPs for orienting and training new compounding personnel, including temporary and contracted employees. D. The pharmacy has SOPs for educating, training, and assessing the competencies of all compounding personnel on an ongoing basis, including documentation that compounding personnel is trained on SOPs. E. The pharmacy demonstrates that it continually assesses its staffing needs relevant to all elements of the compounding and dispensing process including environmental and equipment maintenance. There are similar standards for the Pharmacist in Charge, and for staff pharmacists. (Standards 2.20 & 2.30)

	In addition, PCAB requires compliance with USP 797 sterile compounding competency assessment requirements, such as fingertip testing and process simulation testing. The competency of all staff should be continually evaluated and documented. Staff competency can be evaluated through a combination of various means, for example: By direct observation: A pharmacy may develop checklists to evaluate particular activities, such as operating a balance and/or capsule machines. By testing: A pharmacy may develop written tests to verify competency in pharmaceutical calculations and unit conversions. As a direct result of other pharmacy quality control activities: For example, a pharmacy may send products to outside laboratories for testing. In addition to confirming product quality, the results of these tests can be used to document the competency of the individual that made the product. Media fill testing and touch plate results may also be used to verify competency. PCAB requires documentation of the above, and the onsite survey includes a personnel record review.
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 products. (CCR 1735.8[a])	PCAB Standards 1-8 are in essence a quality assurance plan. In addition, the following three standards address QA/QC/QI. The entire language of each standard is not included here for brevity, only the standard statement: **Standard 9.10 Quality Assurance (QA) Activities** *The pharmacy has in place and adheres to a written quality assurance plan that, at a minimum on an annual basis, verifies, monitors, and reviews the adequacy of the compounding process. Quality assurance activities assure that compounded preparations meet criteria for identity, strength, quality, purity, and, where appropriate, sterility and bacterial endotoxin limit.* **Standard 9.20 Quality Control (QC) Activities** *The pharmacy has in place and adheres to a written quality control plan.* **Standard 9.30 Quality Related Events (QREs)**

	The pharmacy has in place and adheres to written SOPs for documenting and handling QREs. **Standard 9.40 Quality Improvement (QI) Activities** *The pharmacy has in place and adheres to a quality improvement plan that is designed to* • *objectively and systematically collect data about the operations of the compounding process;* • *evaluate this data and its effect on patient care;* • *propose and select resolutions to identified problems;* • *and collect data on whether the selected resolution(s) has/have the intended effect.* The following two standards specifically address quality and sterility of preparations: **Standard 6.20 Potency** *Compounded preparations meet established and/or compendial requirements of strength, quality, purity, potency and stability throughout the period for intended use when stored as labeled.* **Compliance Indicators** A. The pharmacy's SOPs satisfy current USP standards regarding potency and microbiological integrity of compounded preparations. B. The pharmacy provides documentation that it complies with all applicable state and Federal regulations regarding strength, quality, purity, potency and stability throughout the period for intended use of compounded preparations. ***Standard 6.30 Sterility*** *Compounded preparations adhere to established and/or compendial requirements of sterility and bacterial endotoxin limits, throughout the period for intended use when stored as labeled.* ***Compliance Indicators*** *A. The pharmacy's SOPs satisfy current USP standards regarding sterility*

	and bacterial endotoxicity of compounded sterile preparations. *B. The pharmacy provides documentation that it complies with all applicable current USP standards, state and/or Federal regulations regarding sterility and bacterial endotoxin limits of compounded sterile preparations.* ***Standard 6.30Sterility*** *Compounded preparations adhere to established and/or compendial requirements of sterility and bacterial endotoxin limits, throughout the period for intended use when stored as labeled.*
8.2. The pharmacy's quality assurance plan includes the written procedures and standards for 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])	See Standards 9.10-9 above.
8.2.2. Qualitative and quantitative integrity, potency, quality and labeled strength analysis of compounded drug products. (CCR 1735.8[c])	See Standards 6.20 & 6.30 above.
8.2.3. Such reports are retained by the pharmacy and collated with the compounding record and master formula. (CCR 1735.8[c])	As previously noted PCAB requires written evidence & a track record of compliance with all standards. Collating with the MFR and CR is not a specific PCAB requirement because PCAB gives pharmacy's the opportunity to collate and file the data in a manner that best suits the particular pharmacy's needs. However, PCAB can honor this CA requirement.
8.2.4. Scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength.(CCR 1735.8[d])	See Standard 9.30 above related to Quality Related Events.
The pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of	This item will be addressed by the approval of PCAB by the California Board of Pharmacy.

Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1[a] and 4127.1[d])	
10.1. The pharmacy contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy. 10.1.1. The contractual arrangement is reported to the board within 30 days of commencing that compounding.	There is no PCAB standard that specifically addresses this item, as PCAB standards generally focus on quality assurance/quality control and quality improvement. It appears these items are best addressed by a Board inspection.
11.1 If the pharmacy compounds sterile injectable drugs from a nonsterile source, the pharmacy has a designated area or clean room for the preparation of sterile products that has one the following: 11.1.1 An ISO class 5 laminar airflow hood within an ISO class 7 clean room. A positive air pressure differential in the clean room that is relative to adjacent areas; (B&PC 4127.7[a]) 11.1.2. An ISO class 5 clean room (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]) 11.2. The clean room walls, ceiling and floors are made of non-porous, cleanable surfaces and the room is well ventilated (CCR 1751) 11.2.1. The laminar airflow hoods and clean room are certified annually; (CCR 1751) 11.2.2. Supplies are stored in a manner, which maintains integrity of an aseptic environment; 11.2.3. A sink with hot and cold running water; (CCR 1751) 11.2.4. A refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration. (CCR 1751)	PCAB requires compliance with USP 797 Standards. California law is consistent with USP 797 Standards. PCAB validates compliance with these requirements during the onsite survey. **Standard 3.30 Sterile Compounding** *The pharmacy that compounds sterile preparations maintains facilities that provide for minimization of interruption, avoidance of contaminations, and an exclusive area for compounding of sterile preparations.* **Compliance Indicators** A. The pharmacy has an area for aseptic compounding of sterile preparations that meets current USP <797> standards. B. The pharmacy demonstrates that it organizes work flow to minimize interruption of compounding staff during the compounding process. Traffic from employees not involved with compounding is minimized. C. The pharmacy demonstrates that it maintains facilities and procedures adequate to avoid cross contamination and contamination by dust and other particulates in the compounding area. D. The pharmacy demonstrates that any equipment and surfaces involved in the compounding process is appropriately cleaned and/or sanitized before and after compounding activity as appropriate to prevent contamination. E. The pharmacy has SOPs for cleaning and maintaining equipment

	and for the establishment of cleaning and maintenance schedules. F. The pharmacy documents that it performs periodic environmental tests of the aseptic environment according to current USP <797> standards. G. The pharmacy documents that it monitors and tests sterile compounded preparations for sterility, bacterial endotoxins, pyrogenicity, and strength of ingredients potency according to current USP <797> standards.
12.1. Pharmacy records are made and kept for sterile injectable products produced for future use (pursuant to section 1735.2), in addition to record requirements of section 1735.3, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.1[a])	Addressed by the previously mentioned PCAB standards requiring a compounding record. In addition the following Standard would require compliance with 12.1: *The pharmacy adheres to state, Federal, and compendial requirements related to packaging, labeling, dispensing, and delivery for administration of compounded preparations.* Finally, previously mentioned Standard 7.20, would require keeping these records for the purposes of a recall.
12.2. Records for sterile products compounded from one or more non-sterile ingredients are made and kept and contain the following: (CCR 1751.1[b][1-6])	
12.2.1. The training and competency evaluation of employees in sterile product procedures;	Please see the responses to 7.1-7.4.
12.2.2. Refrigerator and freezer temperatures;	Please see the responses to 6.1-6.4.
12.2.3. Certification of the sterile compounding environment;	Please see the response to 11.1.
12.2.4. Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);	Please see the responses to 6.1-6.4.
12.2.5. Inspection for expired or recalled pharmaceutical products or raw ingredients; and	Standard 4.20, Handling, Storage and Disposal, Element C, addresses this item: The pharmacy conducts periodic inspections to assure that expired components and completed compounded preparations do not remain in stock.

12.2.6. Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.	Please see the responses for 2.3 & 8.1.
13.1. In addition to the labeling information required under Business and Professions Code section 4076 and CCR 1735.4, the pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2[a-d])	PCAB Standard 7.30 addresses labeling. This standard applies to both sterile and non-sterile compounds. See response at 4.1.
13.1.1. Telephone number of the pharmacy, unless dispensed for a hospital in-patient;	Required by 7.30, Compliance Indicator B (12): All state labeling requirements.
13.1.2. Name and concentrations of ingredients contained in the product;	See above. PCAB requires compliance with USP 797, which states: *Labels on CSPs (Compounded Sterile Preparations) list the names and amounts or concentrations of active ingredients, and the labels or labeling of injections (see Preservation, Packaging, Storage, and Labeling in the General Notices and Requirements) list the names and amounts or concentrations of all ingredients (see Injections).*
13.1.3. Instructions for storage and handling; and	Addressed by 7.30, Compliance Indicator B (11): Storage instructions. Disposal is addressed by Patient Education Standard 8.20: The pharmacy has suitable written materials to provide the patient or caregiver with information on the appropriate use of compounded preparations, if applicable. PCAB interprets the above standard as including instructing the patient on proper disposal of medications. The evaluation tool PCAB surveyors use to conduct an onsite survey contains the following compliance element for the above standard: The pharmacy's training program ensures that patients and caregivers understand the proper storage, handling, use, and disposal of CSPs.
13.1.4. A special label that states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.	PCAB interprets Standard 7.10, Packaging, Labeling, and Delivery for Administration and Dispensing, Element B (12) as addressing this item: Compounded preparations are packaged and labeled for the safety of the patient.
14.1 The pharmacy has a written manual documenting the policies and	Please see the response at 5.1.

procedures associated with the preparation and dispensing of sterile injectable products and, in addition to the elements required by section 1735.5, includes: (CCR 1751.2[a][1-7])	
14.1.1. Compounding, filling, and labeling of sterile injectable compounds;	Please see responses at 4.1, 11.1, 5.6, 2.3, & 8.1
14.1.2. Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;	See 4.1
14.1.3. Equipment and supplies;	See 5.1.3
14.1.4. Training of staff in preparation of sterile injectable products;	See 7.1
14.1.5. Training of patient and/or caregiver in the administration of compounded sterile injectable products;	**Standard 8.20 Patient Education** *A pharmacy complies with state and Federal patient education and counseling requirements.* **Compliance Indicators** A. The pharmacy's SOPs include a responsibility to provide education and counseling to patients and/or caregivers, B. The pharmacy demonstrates that it offers and provides to patients and/or caregivers education and consultation. C. The pharmacy has suitable written materials to provide the patient or caregiver with information on the appropriate use of compounded preparations, if applicable. D. The pharmacy demonstrates that prospective drug reviews are conducted prior to dispensing compounded preparations.
14.1.6. Procedures for the handling and disposal of cytotoxic agents;	Addressed by Standard 3.1Facilities and Equipment, General, Element C: If the pharmacy handles hazardous materials, it demonstrates that its SOPs are adequate to protect personnel based on volume and scope of compounding performed. Standard 4.20, Handling, Storage and Disposal, Element D: Procedure for handling and storing hazardous and potent chemicals.

14.1.7. Quality assurance program; and	Please see the response at 8.1.
14.1.8. Record keeping requirements.	Please see the response at 3.1 and 6.1. In addition, this item is covered in various other elements of this application.
14.2. Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. (CCR 1751.3[b])	Please see the response at 2.3.
14.3. Policies and procedures address the disposal of infectious materials and/or materials containing cytotoxic residues and include cleanup of spills in conformance with local health jurisdictions. (CCR 1751.3 [c])	Please see the response at 14.1.6 above.
14.4. If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following: (CCR 1751.3[d][1-3])	Please see the response at 5.3 above.
14.4.1. Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.3[d][1]); and	Please see the response at 5.3 above.
14.4.2. All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.3 [d][2])	Please see the response at 5.3 above.
14.5. Policies and procedures address the following: (CCR 1751.3 [d][3] [A-K])	
14.5.1. Competency evaluation;	Please see the response at 7.1.
14.5.2. Storage and handling of products and supplies;	Please see the response at 2.5.
14.5.3. Storage and delivery of final products;	Please see the response at 2.5, and Standard 7.10:
	Standard 7.10 Packaging, Labeling, and Delivery for Administration

	and Dispensing *The pharmacy adheres to state, Federal, and compendial requirements related to packaging, labeling, dispensing, and delivery for administration of compounded preparations.* **Compliance Indicators** A. The pharmacy demonstrates that it complies with applicable state, Federal, and compendial dispensing requirements related to the packaging, labeling, dispensing, and delivery for patient administration of the preparations that it compounds. B. The pharmacy demonstrates and documents that: 1. Compounded preparations comply with compendial standards regarding packaging, labeling and dispensing, when applicable, 2. Compounded preparations are packaged and labeled for the safety of the patient, 3. Compliance with HIPAA and state confidentiality laws and regulations, if applicable, 4. Procedures for packaging and shipping compounded preparations are verified periodically to assure the integrity of compounded preparations throughout the shipping process, 5. Packaging and shipment of hazardous substances protect shipping personnel and end users.
14.5.4. Process validation;	Please see the responses at 5.6, 7.1, & 8.1.
14.5.5. Personnel access and movement of materials into and near the controlled area;	Please see the response at 3.30.
14.5.6. Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 clean rooms, and barrier isolator workstations;	Please see the response at 3.30.

14.5.7. A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;	Please see the response at 3.30. Also note that the survey tool PCAB surveyors use to evaluate compliance with this standard includes the following evaluation element: *The pharmacy demonstrates that any equipment and surfaces involved in the compounding process has been appropriately cleaned and/or sanitized before and after compounding activity to prevent contamination*. PCAB evaluates compliance with this requirement against cleaning and disinfection parameters required by USP 797.
14.5.8. Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;	Please see the response at 2.5. PCAB surveyors also evaluate compliance with this requirement by direct observation of sterile compounding activities during the on-site survey.
14.5.9. For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;	Please see response at 2.3.
14.5.10. Sterilization; and	Please see the response at 8.1.
14.5.11. End-product evaluation and testing.	Please see the response at 8.1.
15.1. The compounding environment meets criteria specified in the pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.4[a])	Please see the response and 8.1
15.2. Only those who are properly attired pursuant to (CCR 1751.5) are allowed in the clean room during the preparation of sterile injectable products. (CCR 1751.4[b])	Please see the response at 8.1. In addition, The tool PCAB surveyors use to conduct the on-site survey includes the following evaluation element: Personnel demonstrate the proper procedures for garbing, gowning and gloving when performing sterile compounding.
15.3. All equipment used in the designated area or clean room is made of easily cleaned and disinfected material. (CCR 1751.4[c])	Please see the response at 8.1. This is consistent with the USP 797 requirements for which PCAB requires compliance.
15.4. Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (CCR 1751.4[d])	Please see the response at 8.1. This is consistent with the USP 797 requirements for which PCAB requires compliance.

15.5. The preparation of parenteral cytotoxic agents is done in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations and includes: (CCR 1751.4[e]) 15.5.1. A laminar airflow hood, which is certified annually.£ 15.5.2. Certification records are maintained for at least three years.	Please see the response at 8.1. This is consistent with USP 797 requirements for which PCAB requires compliance. In addition, the PCAB requirements for handling of hazardous materials have been addressed throughout this document. Attachment A is PCAB's guidance to pharmacy's regarding the handling of hazardous materials. It further outlines PCAB requirements.
16.1. When preparing cytotoxic agents, gowns and gloves are worn.(CCR 1751.5[a]) 16.2. When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used: (CCR 1751.5[b][1-5]) 16.2.1. Clean room garb is donned and removed outside the designated area; (CCR 1751.5[b][2]) 16.2.2. Individuals in the clean room wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.5[b][1]) 16.2.3. No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.5[b][3]) 16.2.4. Head and facial hair is kept out of critical area or covered (CCR 1751.5[b][4]); and 16.2.5. Gloves of low-shedding material are worn. (CCR 1751.5[b][5])	Please see the response at 15.5 above.
17.6. The pharmacy follows a written program of training and performance evaluation designed to ensure that 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 addresses the following: (CCR 1751.6[e][1][A-J]) 17.6.1. Aseptic technique; 17.6.2. Pharmaceutical calculations and terminology; 17.6.3. Sterile product compounding documentation; 17.6.4. Quality assurance procedures;	Please see the response at 7.1.

17.6.5. Aseptic preparation procedures; 17.6.6. Proper gowning and gloving technique; 17.6.7. General conduct in the controlled area; 17.6.8. Cleaning, sanitizing, and maintaining equipment used in the controlled area; 17.6.9. Sterilization techniques; 17.6.10. Container, equipment, and closure system selection.	
17.7. Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.6[e][2]) 17.7.1. checks involving adherence to aseptic area policies and procedures. (CCR 1751.6[e][2])	Please see the response at 7.1
17.7.2. Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751.6[e][2])	PCAB's requirements are consistent with USP. For high risk sterile compounding, this may include reassessments every six months.
17.7.3. Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])	This is a California specific requirement.
8.1. 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 that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])	Please see the response at 8.1.
18.2. The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-4])	PCAB Standards 1-8 are essentially a quality assurance/quality control program addressing these items. Comments regarding specific items are below.
18.2.1. Cleaning and sanitization of the parenteral medication preparation area; 18.2.2. The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature; 18.2.3. Actions to be taken in the event of a drug recall; and 18.2.4. Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1735.2[h]).	18.2.1-18.2.4 Have been previously addressed.

18.3. Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products.(CCR 1751.7[b]) 18.3.1. The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b]) 18.3.2. The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b]) 18.3.3. The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b]) 18.3.4. Completed medium samples are incubated. (CCR 1751.7[b]) 18.3.5. If microbial growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b]) 18.3.6. Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever aseptic techniques are observed. (CCR 1751.7[b])	PCAB requires compliance with USP 797 Standards in regards to validation testing. USP 797 is consistent with California requirements.
19. Current and appropriate reference materials regarding the compounding of sterile injectable products are maintained or immediately available to the pharmacy. (CCR 1751.8)	PCAB Standard 3.11 Addresses this item: **Standard 3.11 References** *The pharmacy maintains reference materials that are current and relevant to the compounding performed in the pharmacy and in accordance with state regulations.* *Reference materials are readily accessible to personnel responsible for compounding of preparations.* **Compliance Indicators**

	A. The pharmacy has access to references that meets state laws in which the pharmacy is licensed or registered and includes all current and applicable USP standards. B. The references are available and accessible to all compounding personnel. C. The pharmacy demonstrates that the reference materials are current and relevant to the type of compounding performed in the pharmacy. D. The pharmacy demonstrates that compounding personnel are trained in the use of reference material and that compounding personnel use reference material in compounding practice.

Attachment A: PCAB Standards

Attachment B: Powder Containment Guidance Document

Attachment C: List of California Accredited Pharmacies

Attachment A - PCAB Standards

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Standard 1.00 Regulatory Compliance

Standard 1.10 Facility

The pharmacy is licensed or registered with relevant state and Federal regulatory authorities to operate a pharmacy and if applicable, dispense controlled substances.

Compliance Indicators

A. " The pharmacy lists the state(s) in which it is licensed or registered to operate a pharmacy, including all licenses or registration numbers.

B. " If the pharmacy dispenses controlled substances, it provides documentation that it is registered with the Drug Enforcement Administration (DEA).

C. " If the pharmacy ships or intends to ship medications to residents of states that do not require non-resident pharmacy licensure during the period of accreditation, the names of those states are be listed.

D. " The pharmacy demonstrates that its employees have access to pharmacy rules and regulations of all states where pharmacy services are being provided.

E. " If the pharmacy has a pending regulatory action, it notifies PCAB within thirty (30) days.

Standard 1.20 Personnel

All personnel including pharmacists, technicians, students, temporary personnel, and those affiliated through contractual or other arrangements who are engaged in compounding and dispensing in the pharmacy are licensed, registered, certified, or otherwise credentialed, if applicable, by the states in which they practice, by an appropriate licensing agency, certifying agency, school of pharmacy, or other body.

Compliance Indicators

A. " The pharmacy provides documentation that all pharmacists, technicians, students, temporary personnel, and those affiliated through contractual or other arrangements who are engaged in compounding and dispensing in the pharmacy are licensed, registered, certified, or otherwise credentialed, if applicable, by the states in which they practice, by an appropriate licensing agency, certifying agency, school of pharmacy, or other body.

B. " The pharmacy provides evidence that its Standard Operating Procedures (SOPs) address the process for verifying the credentials of new independent contractors/employees.

Standard 1.30 External Standards

The pharmacy compounds according to standards of practice adopted by its state board of pharmacy and/or national practices and standards adopted by non-governmental standard setting organizations.

Compliance Indicators

A. " The pharmacy demonstrates that its SOPs provide that the compounding is performed in accordance with state and/or national practice standards.

B. " The pharmacy demonstrates that it has access to all current and applicable standards of the United States Pharmacopeial Convention (USP).

Standard 1.40 Standard Operating Procedures

The pharmacy develops, maintains, follows, and periodically updates written Standard Operating Procedures (SOPs) which addresses all aspects of the compounding operation.

Compliance Indicators

A. " The pharmacy provides a copy of its SOPs manual with a table of contents.

B. " The pharmacy demonstrates that the SOPs are readily available to and accessible by all relevant compounding personnel.

C. " The SOPs contain a "policy on policies" which may include:

1. " Identification of the individual(s) in the organization that have authority to approve SOPs and subsequent edits to SOPs;
2. " Outlining the process by which SOPs are approved;
3. " Recording the date new polices are implemented;
4. " Establishing and maintaining an indexing system to facilitate reference and retrieval of SOPs by staff;
5. " Document the review, revision, and archiving of existing SOPs.

Standard 2.00 Personnel

Standard 2.10 General

Supervision and level of personnel is sufficient to assure the safety and integrity of compounding. All personnel affiliated with compounding in the pharmacy are competent to perform their assigned duties.

Compliance Indicators

A. " The pharmacy provides a written description of the responsibilities and functions of all compounding personnel.

B. " The pharmacy has SOPs for orienting and training new compounding personnel, including temporary and contracted employees.

C. " The pharmacy has SOPs for educating, training, and assessing the competencies of all compounding personnel on an ongoing basis, including documentation that compounding personnel is trained on SOPs.

D. " The pharmacy demonstrates that it continually assesses its staffing needs relevant to all elements of the compounding and dispensing process including environmental and equipment maintenance.

Standard 2.20 Pharmacist in Charge

There is a pharmacist in charge of the compounding activities who establishes the scope of compounding practice for relevant staff based on the education, training, and demonstrated competence. The pharmacist in charge supervises all compounding personnel, assures that compounded preparations meet SOPs, and maintains compliance with state and Federal regulations and PCAB standards.

Compliance Indicators

A. " The pharmacy provides documentation that the pharmacist in charge has the education, training, and experience consistent with the responsibilities and the scope of compounding practice performed in the pharmacy.

B. " The pharmacy demonstrates that the pharmacist in charge has sufficient authority to carry out these responsibilities.

C. " The pharmacist in charge demonstrates an awareness of these responsibilities under applicable state and/or Federal law, compounding practice within the pharmacy, and current USP standards related to non-sterile and, if applicable, sterile compounding.

D. " The pharmacist in charge demonstrates an adequate knowledge of all operations of the pharmacy relating to good compounding practices as identified in the SOPs.

Standard 2.30 Staff Pharmacists

There are staff pharmacists to assure that compounded preparations are prepared, packaged, labeled, stored, and dispensed according to SOPs of the pharmacy. Staff pharmacists are responsible for patient counseling and/or patient care services required by applicable state law or practice standards.

Compliance Indicators

A. " The pharmacy provides documentation that staff pharmacists are competent, as defined in the SOPs, to assure the quality of preparations compounded, packaged, labeled, stored, and dispensed in the pharmacy.

B. " Staff pharmacists demonstrate adequate knowledge of operations of the pharmacy related to the scope of compounding and dispensing in which they participate or supervise.

C. " Staff pharmacists demonstrate their education and training in good compounding practices.

D. " Staff pharmacists demonstrate that they are knowledgeable about current USP standards related to non-sterile compounding.

E. " Staff pharmacists demonstrate that they are knowledgeable about current USP standards related to sterile compounding, if applicable.

F. " Staff pharmacists demonstrate knowledge of dispensing requirements and procedures used in the pharmacy.

G. " Staff pharmacists are responsible for verifying that SOPs are being followed for preparing compounded preparations.

H. " Staff pharmacists are responsible for direct supervision of all compounding personnel.

Standard 3.00 Facilities and Equipment

Standard 3.10 General

The pharmacy has facilities and equipment sufficient for the safe and accurate compounding of preparations.

Compliance Indicators

A. " The pharmacy demonstrates that the size, type, and quality of facilities and equipment in the pharmacy is adequate to safely and accurately compound preparations in the amount and type relative to the nature of compounding that is performed in the pharmacy. This should include procedures for the control and containment of powders during compounding.

B. " The pharmacy has SOPs for each piece of equipment used in the compounding process that addresses cleaning, maintaining, calibrating and verification according to compendial standards or manufacturers' standards. At a minimum, the SOPs include documentation that equipment is regularly cleaned, maintained, calibrated and verified according to compendial standards or manufacturers' standards.

C. " If the pharmacy handles hazardous materials, it demonstrates that its SOPs are adequate to protect personnel based on volume and scope of compounding performed.

Standard 3.11 References

The pharmacy maintains reference materials that are current and relevant to the compounding performed in the pharmacy and in accordance with state regulations. Reference materials are readily accessible to personnel responsible for compounding of preparations.

Compliance Indicators

A. " The pharmacy has access to references that meets state laws in which the pharmacy is licensed or registered and includes all current and applicable USP standards.

B. " The references are available and accessible to all compounding personnel.

C. " The pharmacy demonstrates that the reference materials are current and relevant to the type of compounding performed in the pharmacy.

D. " The pharmacy demonstrates that compounding personnel are trained in the use of reference material and that compounding personnel use reference material in compounding practice.

Standard 3.20 Non-Sterile Compounding

The pharmacy that compounds non-sterile preparations maintains facilities that provide for minimization of interruptions, avoidance of contamination, and reduction of the potential for contamination of the compounded preparation.

Compliance Indicators

A. " The pharmacy has a dedicated, exclusive area for general, non-sterile compounding that meets current USP <795> standards.

B. " The pharmacy demonstrates that it organizes work flow to minimize interruption of compounding staff during the compounding process. Traffic from employees not involved with compounding is minimized.

C. " The pharmacy demonstrates that it maintains facilities and procedures adequate to avoid cross contamination and contamination by dust and other particulates in the compounding area.

D. " The pharmacy demonstrates that any equipment and surfaces involved in the compounding process is appropriately cleaned and/or sanitized before and after compounding activity as appropriate to prevent contamination.

E. " The pharmacy has SOPs for cleaning and maintaining equipment and for the establishment of cleaning and maintenance schedules.

Standard 3.30 Sterile Compounding

The pharmacy that compounds sterile preparations maintains facilities that provide for minimization of interruption, avoidance of contaminations, and an exclusive area for compounding of sterile preparations.

Compliance Indicators

A. " The pharmacy has an area for aseptic compounding of sterile preparations that meets current USP <797> standards.

B. " The pharmacy demonstrates that it organizes work flow to minimize interruption of compounding staff during the compounding process. Traffic from employees not involved with compounding is minimized.

C. " The pharmacy demonstrates that it maintains facilities and procedures adequate to avoid cross contamination and contamination by dust and other particulates in the compounding area.

D. " The pharmacy demonstrates that any equipment and surfaces involved in the compounding process is appropriately cleaned and/or sanitized before and after compounding activity as appropriate to prevent contamination.

E. " The pharmacy has SOPs for cleaning and maintaining equipment and for the establishment of cleaning and maintenance schedules.

F. " The pharmacy documents that it performs periodic environmental tests of the aseptic environment according to current USP <797> standards.

G. " The pharmacy documents that it monitors and tests sterile compounded preparations for sterility, bacterial endotoxins, pyrogenicity, and strength of ingredients potency according to current USP <797> standards.

Standard 4.00 Chemicals, Components, and Completed Compounded Preparations

Standard 4.10 General

The pharmacy maintains standard operating procedures related to the acquisition, storage, usage and proper destruction of drug substances and drug products, which are used as components in the compounding of preparations. Drug substances and products used to compound meet official compendial standards, if any, including current USP-NF standards, and are accompanied by certificate of analysis, which documents the strength, quality, purity and integrity of the drug substance.

Compliance Indicators

A. " The pharmacy has SOPs governing the acquisition of all chemicals, drug products, and components from reliable sources.

B. " The SOPs provide that certificates of analysis be retained electronically or in hard copy by the pharmacy for a period of not less than two years.

C. " The SOPs provide that certificates of analysis be reviewed by properly trained personnel prior to the release drug substances of chemicals for use in compounding.

D. " The pharmacy documents that it uses appropriate suppliers as the source of all bulk chemical ingredients, inactive ingredients or excipients, and other components used in compounding. The pharmacy obtains the following information from appropriate suppliers:

1. " FDA registered and inspected, if applicable;
2. " Documentation indicating compliance with FDA current Good Manufacturing Practices
3. " Proof of licensure in good standing with applicable state and/or Federal regulatory bodies.
4. " Ability to provide ready access to Certificates of Analysis (CofA) and Material Safety Data Sheets (MSDS) with all bulk chemicals.

E. " The pharmacy demonstrates that the SOPs address criteria for identifying and using suppliers for devices, containers, and closures used in compounding including complying with any applicable compendial standards, if applicable.

F. " The SOPs address contingency plans should an active pharmaceutical ingredient, inactive ingredient, excipient, or other component used in compounding become unavailable from any supplier meeting the above criteria. The SOPs set forth an adequate mechanism directing the pharmacist in charge to employ professional judgment in receiving, storing, and using such components from another quality source.

G. " The pharmacy documents that it uses high quality active pharmaceutical ingredients (APIs) for use in compounding that:

1. " Meets current USP/NF grade substances. If not available, then the use of other high-quality sources, such as:
   i. " Analytical reagent (AR),
   ii. " Certified American Chemical Society (ACS), or

iii. " Food Chemicals Codex (FCC) grade, are permitted as sources of active ingredients when appropriate.
iv. " Dietary and nutritional supplements that are "Generally Recognized As Safe"

2. " Meets other compendial standards, or
3. " Are components of products that have been approved by FDA or grand-fathered under the Food, Drug & Cosmetic Act of 1938 (FDCA).

H. " The pharmacy complies with the FDA's "List of Drug Products That Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness," subject to the exceptions provided in such list. Written SOPs exist to safeguard against the use of such components in compounded preparations for human patients.

I. " The pharmacy demonstrates that it has a designated area for the receiving and inspection of chemicals, devices, containers, closures, and other components or supplies used in the compounding operation.

J. " The pharmacy has SOPs that assure Material Safety Data Sheets (MSDS) are properly maintained and readily retrievable.

K. " The pharmacy has SOPs that outline the criteria for acceptance or refusal of components.

L. " The pharmacy demonstrates that upon receipt of a chemical or drug substance, it is quarantined until the Certificate of Analysis (CofA) information is verified by properly trained compounding personnel and the MSDS information is assessed for review, as necessary.

Standard 4.20 Handling, Storage, and Disposal

The pharmacy safely handles, stores, and disposes of all chemicals, drug products and components according to compendial and other applicable requirements. Appropriate storage of chemicals, components, and completed compounded preparations shall be designed to maintain their strength, quality, purity, integrity, and where applicable, sterility.

Compliance Indicators

A. The pharmacy has SOPs assuring that chemicals, components and completed compounded preparations are maintained within appropriate standards, as established by the current USP, including:

1. " Acceptable storage temperature ranges and temperature monitoring and documentation procedures,
2. " Contingency plans if conditions fall outside of acceptable ranges,
3. " Guidelines to be followed to determine if a component has been compromised and when it should be destroyed,
4. " Procedure for handling and storing hazardous and potent chemicals,
5. " Individuals responsible for making decisions regarding compromised components,
6. " Quarantine specifications, including expired and recall storage,
7. " Disposal or return of expired components and completed compounded preparations,

8. " Storage and disposal of drug substances and drug products used as components in the compounding of preparations.

B. " Storage containers include labels that include all relevant information, including but not limited to drug name, strength, lot number, date received, etc.

C. " The pharmacy conducts periodic inspections to assure that expired components and completed compounded preparations do not remain in stock.

D. " Storage of chemicals to be utilized for high-risk sterile compounding are stored in a separate area according to current USP <797> standards.

Standard 5.00 Compounding Records

Standard 5.00 Formulation Record and Compounding Record

The pharmacy uses a Formulation Record (FR) that assures the strength, quality, purity, integrity, and where applicable, sterility of the compounded preparation. The pharmacy uses a Compounding Record (CR) for assuring that the procedures employed to prepare compounded preparations are consistent and reproducible. Compounding activities and processes shall be subject to verification of preparations for strength, quality, purity, integrity, and where applicable, sterility that meet or exceed compendial standards.

Compliance Indicators

A. " The pharmacy demonstrates that the SOPs provide for verification of strength, quality, purity, integrity, and, where applicable sterility for all compounded preparations.

B. " The pharmacy documents that, when available, it incorporates into its FR those formulations and formulation procedures developed, tested, and verified by non-governmental standard setting organizations including, but not limited to the United States Pharmacopeial Convention:
   1. " The pharmacy documents that it maintains a FR for each compounded preparations.
   2. " The pharmacy identifies which compounding personnel may enter new FR and edit existing FR.

C. The pharmacy provides documentation of a FR that maintains the following information on preparations that it compounds:
   1. " Name, strength, and dosage form of the compounded preparation;
   2. " Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;
   3. " Description of all components and ingredients, and their quantities;
   4. " Compatibility and stability information, including references when available;
   5. " Equipment used to prepare the compounded preparation, when appropriate;
   6. " Mixing instructions that include, at a minimum: order of mixing, mixing temperatures or other environmental controls, duration of mixing, and other factors pertinent to the replication of the compounded preparation;
   7. " Assigned beyond-use date of the compounded preparation;
   8. " Container used in dispensing;
   9. " Packaging and storage requirements;
   10. " Quality control procedures; and
   11. " References used in the development of the FR, if applicable.

D. The pharmacy provides documentation of a Compounding Record (CR) that maintains the following information on components of preparations that it compounds to verify accurate compounding in accordance with the FR:
   1. " Name and strength of the compounded preparation;
   2. " FR reference for the preparation;

3. " Sources, lot numbers, quantities, and expiration dates of components and ingredients;
4. " Total quantity compounded and actual net measurements;
5. " Name of the personnel involved in the compounding process and the name of the pharmacist who approved the compounded preparation;
6. " Date of preparation;
7. " Assigned internal identification number or prescription number;
8. " Equipment used;
9. " Assigned beyond-use date of the compounded preparation; and
10. " Results of quality control procedures (e.g. weight range of filled capsules, pH of aqueous liquids, etc.).

Standard 6.00 Beyond-Use Dating, Potency, and Sterility

Standard 6.10 Beyond-Use Date

The pharmacy determines and assigns beyond-use dates to all its compounded preparations.

Compliance Indicators

A. " The pharmacy demonstrates that the SOPs provide for the determination and assignment of beyond-use dating for all of its compounded preparations.

B. The pharmacy demonstrates by inspection the use of beyond-use dates on compounded preparations.

C. The pharmacy documents the rationale and sources used to establish beyond-use dates which exceed current USP standards.

D. " The pharmacy documents how it communicates beyond-use dating information to compounding personnel and the patient and/or caregiver.

E. " The pharmacy provides rationale for beyond-use dating which exceeds current USP standards arrived at based on the pharmacist's professional judgment.

Standard 6.20 Potency

Compounded preparations meet established and/or compendial requirements of strength, quality, purity, potency and stability throughout the period for intended use when stored as labeled.

Compliance Indicators

A. " The pharmacy's SOPs satisfy current USP standards regarding potency and microbiological integrity of compounded preparations.

B. The pharmacy provides documentation that it complies with all applicable state and Federal regulations regarding strength, quality, purity, potency and stability throughout the period for intended use of compounded preparations.

Standard 6.30 Sterility

Compounded preparations adhere to established and/or compendial requirements of sterility and bacterial endotoxin limits, throughout the period for intended use when stored as labeled.

Compliance Indicators

A. " The pharmacy's SOPs satisfy current USP standards regarding sterility and bacterial endotoxicity of compounded sterile preparations.

B. The pharmacy provides documentation that it complies with all applicable current USP standards, state and/or Federal regulations regarding sterility and bacterial endotoxin limits of compounded sterile preparations.

Standard 7.00 Completed Compounded Preparations

Standard 7.10 Packaging, Labeling, and Delivery for Administration and Dispensing

The pharmacy adheres to state, Federal, and compendial requirements related to packaging, labeling, dispensing, and delivery for administration of compounded preparations.

Compliance Indicators

A. " The pharmacy demonstrates that it complies with applicable state, Federal, and compendial dispensing requirements related to the packaging, labeling, dispensing, and delivery for patient administration of the preparations that it compounds.

B. " The pharmacy demonstrates and documents that:

1. " Compounded preparations comply with compendial standards regarding packaging, labeling and dispensing, when applicable,
2. " Compounded preparations are packaged and labeled for the safety of the patient,
3. " Compliance with HIPAA and state confidentiality laws and regulations, if applicable,
4. " Procedures for packaging and shipping compounded preparations are verified periodically to assure the integrity of compounded preparations throughout the shipping process,
5. " Packaging and shipment of hazardous substances protect shipping personnel and end users.

Standard 7.20 Internal and External Recalls

The pharmacy has procedures for the appropriate and timely recall of dispensed compounded preparations where subsequent testing or other information demonstrates that the compounded preparation does not meet its declared strength, quality, purity, and, where appropriate, sterility and bacterial endotoxin limit..

Compliance Indicators:

A. The pharmacy demonstrates in the SOPs a recall procedure which consists of:

1. " A procedure to determine the distribution of any compounded product, the date, quantity of distribution, quantity , dosage, and to identify patients receiving compounded preparations in a manner sufficient to allow the recall to be timely and effective based on severity,
2. " A method of timely informing prescribers, patients and/or caregivers concerning recalls based on severity,
3. " The necessary information to identify patients affected by a recall is readily retrievable.

B. The pharmacy documents the implementation of a recall, including procedures concerning the disposition and reconciliation of the recalled preparation.

Standard 7.30 Labeling

The pharmacy labels completed compounded preparations according to the PCAB Labeling Guidelines.

Compliance Indicators

PCAB Labeling Guidelines

A. " The primary label of each compounded medication prepared in response to a prescription for a specific patient from a licensed prescriber includes a statement notifying the patient that the medication has been compounded. If space limitations or clinical reasons preclude inclusion on the primary label, the information may be affixed through auxiliary labeling.[1] For all such prescriptions, the statement is prominently displayed in the medication labeling.

"This medicine was specially compounded in our pharmacy for you at the direction of your prescriber."[2]

B. " The following items of information, or a reasonable alternative, is included on all compounded prescription labels:[3]

(1) Patient's name, and/or species, if applicable;
(2) Prescriber's name;
(3) Name, address, phone number of the pharmacy preparing the medicine;
(4) Prescription number;
(5) The medication's established or distinct common name;
(6) Strength;
(7) Statement of quantity;
(8) Directions for use;
(9) Date prescription filled;
(10) Beyond-use date
(11) Storage instructions; and
(12) All state labeling requirements.

C. The following information, or a reasonable alternative, is included with all compounded medication:

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1 For example, when there is concern that a label applied directly to the primary container may affect the quality of the compounded medication. In such cases, the pharmacist may decide, in the pharmacist's professional judgment, that the label and statement be applied in another manner, such as to exterior packaging

2 Alternate language providing a clear designation that the medication has been compounded may be used, where, in the pharmacist's professional judgment, the welfare of the patient requires and the information is adequately and prominently communicated.

3 Label must be in conformity with applicable state, Federal, and compendial regulations and standards. Alternative placement may be acceptable if determined necessary because of space requirement or, in the pharmacist's professional judgment for the needs of the patient.

This medicine was compounded specifically for you in our pharmacy to fill the prescription your prescriber wrote for you. It was specially made to meet your individual needs. For this reason, no standardized information or literature is available with your prescription. If you have not done so, please discuss this medicine with your pharmacist or prescriber to assure that you understand (1) why you have been prescribed a compounded medicine, (2) how to properly take this medicine, and (3) the interactions, if any, this medicine may have with any other medicines you are taking.

Compounding is a long-standing pharmacy practice that allows prescribers to treat their patients' individual needs without being restricted only to off-the-shelf medicines or devices. This medicine was prepared in our compounding pharmacy to meet the specifications ordered by your prescriber.

1. Call your pharmacist or prescriber if:

- *You experience any side effects.*
- *You are taking additional medicines that may interact with this compounded medicine.*
- *You have allergies or other medical conditions that should be noted.*

2. Call our pharmacists if:

- *Information on the label is not clear to you.*
- *You have any concerns regarding precautions, ingredients, or proper storage.*

Our pharmacists are available to address any additional questions or concerns.

D. The following language is included on the primary label of each package compounded for use in the practitioner's office. If space limitations or clinical reasons[4] preclude inclusion on primary labeling, the information may be affixed through auxiliary labeling. In either case, the statement is prominently displayed in the medication labeling.

"This medicine was compounded in our pharmacy for use by a licensed practitioner only. This compounded preparation may not be resold."

4 For example, when there is concern that a label applied directly to the primary container may affect the quality of the compounded medication. In such cases, the label and statement should instead be applied to exterior packaging.

Standard 8.00 Prescriber Communication and Patient Education

Standard 8.10 Prescriber Communication

The pharmacy communicates with prescribers about preparations that are compounded for their patients.

Compliance Indicators:

A. " The pharmacy has SOPs which address:
   1. " A method to assure that, if it is not unmistakably evident or not indicated on the original prescription or order that the medication is to be compounded, it is confirmed with the prescriber that the preparation will be compounded,
   2. A method to disclose to prescribers all ingredients and methods of compounding as may be necessary in the event of an adverse event or possible untoward reaction.

B. " The pharmacy demonstrates that such communications with prescribers occur regularly.

Standard 8.20 Patient Education

A pharmacy complies with state and Federal patient education and counseling requirements.

Compliance Indicators

A. " The pharmacy's SOPs include a responsibility to provide education and counseling to patients and/or caregivers,

B. " The pharmacy demonstrates that it offers and provides to patients and/or caregivers education and consultation.

C. " The pharmacy has suitable written materials to provide the patient or caregiver with information on the appropriate use of compounded preparations, if applicable.

D. " The pharmacy demonstrates that prospective drug reviews are conducted prior to dispensing compounded preparations.

Standard 9.00 Total Quality Management

Standard 9.00 Total Quality Management

The pharmacy has in place and adheres to a plan for total quality management that is designed to assure, verify, and improve the quality of its compounded preparations and related services.

Standard 9.10 Quality Assurance (QA) Activities

The pharmacy has in place and adheres to a written quality assurance plan that, at a minimum on an annual basis, verifies, monitors, and reviews the adequacy of the compounding process. Quality assurance activities assure that compounded preparations meet criteria for identity, strength, quality, purity, and, where appropriate, sterility and bacterial endotoxin limit.

Compliance Indicators

(NOTE: Documentation of adherence to PCAB Standards 1 through 8 will provide evidence of a quality assurance plan)

A. The pharmacy provides evidence of investigation(s), if any, regarding the appearance of deviation or actual deviation for standardized compounding procedures, and how these deviations were investigated, evaluated, corrected, and documented, including deviations discovered prior to the dispensing of the compounded preparation.
B. The quality assurance plan provides that any compounded product that fails to meet quality standards, specifications, or other relevant quality control criteria will be rejected.

Standard 9.20 Quality Control (QC) Activities

The pharmacy has in place and adheres to a written quality control plan.

Compliance Indicators

A. The pharmacy maintains SOPs related to its QC activities and has designated personnel responsible for QC activities.
B. The pharmacy demonstrates that its QC plan references how compounded preparations meet current USP standards for strength, quality, purity, integrity, and where applicable, sterility and bacterial endotoxin limit.

Standard 9.30 Quality Related Events (QREs)

The pharmacy has in place and adheres to written SOPs for documenting and handling QREs.

Compliance Indicators

A. The pharmacy's SOPs address the investigation, documentation, and resolution of QREs, and steps to avoid similar QREs.
B. The pharmacy demonstrates that these SOPs are being followed.

C. When appropriate or required by law or regulation, QREs are reported to appropriate agencies.
D. Pharmacies are encouraged to report adverse drug events (ADE) to FDA's Medwatch system or a patient safety-organization (PSO) as defined by the Patient Safety and Quality Improvement Act of 2005.

Standard 9.40 Quality Improvement (QI) Activities

The pharmacy has in place and adheres to a quality improvement plan that is designed to

- *objectively and systematically collect data about the operations of the compounding process;*
- *evaluate this data and its effect on patient care;*
- *propose and select resolutions to identified problems;*
- *and collect data on whether the selected resolution(s) has/have the intended effect.*

Quality improvements are incorporated into SOPs, employees are trained in their use, and improvements are communicated to patients and prescribers, where appropriate.

The pharmacy uses data and findings from its QA, QC, and QRE monitoring and reporting to identify quality improvement priorities.

Compliance Indicators

A. The pharmacy maintains SOPs related to its QI activities.
B. The pharmacy demonstrates that its QI activities includes the collection of QA, QC, QRE and other data to identify priorities for improvement.
C. The pharmacy provides examples of communicating QI activities to patients and prescribers, when appropriate and applicable.

Appendix

Definitions

Balance, Analytical

An electronic Class A balance with a readability of 0.1mg or lower.

Balance, Electronic

An electronic instrument utilized for weighing components used in the compounding process.

Beyond-Use-Date

The date after which a compounded preparation is not to be used and is determined from the date the preparation is compounded.

CCP - Completed Compounded Preparation

A preparation made by the compounder pursuant to a valid prescription order, that is in its finished state, and which is ready to be dispensed to a patient or prescriber.

Compendial Standards

Standards contained in the *United States Pharmacopeia–National Formulary (USP–NF)* or other official compendium as defined in the Federal Food Drug and Cosmetic Act.

Compliance Indicator

A guide to the interpretation of a standard to be used by surveyors, pharmacy owners and staff to determine how a standard should be applied. Compliance indicators are not "laws" or strict rules, they are guidelines. The failure to adhere to one indicator does not mean the pharmacy failed the standard to which it is applied. Likewise, meeting all indicators may not necessarily mean the standard has been "passed".

Component

Any ingredient intended for use in the compounding of a completed compounded preparation (CCP).

Compounding Personnel

Any person involved with the compounding of a CCP (completed compounded preparation).

Compounding

Traditional pharmacy practice which includes the preparation, mixing, assembling, packaging, or labeling of a completed compounded preparation

(CCP) or administration device by compounding personnel

(i) " as the result of a practitioner's prescription order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice,

(ii) " for the purpose of, or as an incident to, research, teaching, or chemical analysis, and shall not be dispensed for resale by a third party,

(iii) preparation of drugs or devices in anticipation of prescription orders to be received by the compounding pharmacist based on routine, regularly observed prescribing patterns,

(iv) preparation of CCPs (completed compounded preparation) for practitioner administration, pursuant to state and federal regulations,

(v) " preparation of Non-Legend CCPs (completed compounded preparation), pursuant to state requirements, and (vii) preparing CCPs (completed compounded preparation) for both human and non-food producing animal patients.

Compounding Scope of Practice

Nonsterile Basic

Nonsterile Basic – compounding which involves the preparation of a formulation containing two or more nonsterile commercially available products employing basic pharmacy training skill sets, as well as, defined policy, procedures and processes necessary to assure quality and consistency of the completed compounded preparation.

Nonsterile Complex

Nonsterile Complex - compounding which involves the art and science of preparing a formulation using bulk drug substances, drug products, and/or other excipients. These formulations require complex procedures or calculations in their preparation and include formulations that incorporate the use of potent or hazardous pharmaceutical ingredients.

Sterile, Low and Medium

Sterile, Low and Medium - compounding which involves the preparation of Compounded Sterile Preparations (CSPs) in closed-system steps or procedures using a few basic aseptic manipulations, as well as those Compounded Sterile Preparations (CSPs) prepared via complex or numerous aseptic manipulations for administration to one patient on multiple occasions or to multiple patients.

Sterile, High

Sterile, High – compounding which involves the preparation of sterile preparations from non-sterile ingredients or with a nonsterile device.

Compounding Pharmacy

A pharmacy with staff skilled in the art and preparation of customized medications to meet specific patient and/or practitioner needs.

Critical Process

A process that is essential to assurehe quality of the compounded preparation. (Examples would include properly weighing or measuring the components, etc.)

Discussion

A narrative guide to the standard. It may be a window on the intent of the standard and/or a suggestion to the pharmacy of ways to go beyond the standard itself to serve its patients in additional ways. Often it is just a discussion of the general area covered by the standard. They are designed as an aid to the pharmacy in understanding the area covered by the standard.

Equipment

Any tool, device, container, structure or machine, movable or immovable, used in the preparation, measurement, storage or dispensing of a CCP (completed compounded preparation).

Error (or Err)

A quality related event (QRE) that reaches the patient and is no longer in the pharmacy's control. It is a failure of quality.

Near-Miss

A quality related event (QRE) that does not reach the patient. It represents a success story for the QI activities (See PCAB Standard 9.50) in that even though a mistake may have occurred, the mistake was caught before it reached the patient. The system worked.

Non-Legend CCP (completed compounded preparation)

A CCP (completed compounded preparation), labeled, handled and prepared in accordance with all applicable state and federal laws, that does not require a prescription order to sell to the consumer, and which is not for resale.

Orientation Program

Program, described in the pharmacy's written policy and procedure manual, designed to familiarize compounding laboratory staff with the operations of the pharmacy compounding lab.

Pharmacist in Charge

A pharmacist currently licensed by the board who accepts responsibility for the operation of the pharmacy in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs, and who is personally in full and actual charge of such pharmacy and personnel. The term "pharmacist-in-charge" will also be defined by individual state pharmacy practice acts and regulations pursuant to these acts.

Pharmacy

Premises, laboratory, area or other place:

1. "Where drugs are offered for sale and the profession of pharmacy is practiced and where prescriptions are compounded and dispensed; or
2. "Which has displayed upon it or within it the words "pharmacist," "pharmaceutical chemist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "drug sundries" or any of these words or combinations of these words or words of similar import either in English or any sign containing any of these words; or
3. "Where the characteristic symbols of pharmacy or the characteristic prescription sign "Rx" may be exhibited.

Purified Water

Water purified by distillation, reverse osmosis, deionization, ion exchange, filtration, or other suitable purification procedure.

Practitioner Administered Compounds (PAC)

A CCP (completed compounded preparation) prepared as the result of a prescription order, or initiative based on the triad relationship in the course of professional practice, by a licensed practitioner for administration by a practitioner for diagnostic or therapeutic purposes.

Prescription Order or Initiative

An order to be filled by a pharmacist for prescription medication issued and signed by a practitioner in the authorized course of professional practice

An order transmitted to a pharmacist through word of mouth, note, telephone or other means of communication directed by such practitioner.

Quality Assurance*

The planned and systematic activities implemented in a quality system so that quality requirements for the pharmacy's compounded preparations services are fulfilled.
Examples of quality assurance activities processes in the pharmacy setting include training staff to assure proper operation of equipment, developing master formulation records to assure standardized compounds, and using and verifying compounding process records prior to dispensing to assure that each batch is made correctly and consistently.

Quality Control*

The observation techniques and activities used to fulfill requirements of quality. Examples of quality control in the pharmacy include the sampling of sterile preparations for sterility and bacterial endotoxin limits, and the outside laboratory testing of compounded preparations to verify strength, purity, and other parameters.

Quality Improvement*

An ongoing effort to improve compounded preparations, services, or processes.

These efforts can seek incremental improvement over time or breakthrough improvement all at once. "
Examples of quality improvement activities in the pharmacy include identifying the cause of failure when a compounded preparation fails a quality control test, developing and implementing methods to prevent the failure, and continued testing to verify whether the improvements eliminate the problem.

* NOTE: The definitions for Quality Assurance, Quality Control, and Quality Improvement were developed based on information from the American Society for Quality – www.asq.org

Quality Related Event (QRE)

Any event occurring in at any point in the prescription process over which the pharmacy could exercise some level of control. A quality related event may be an error or a near-miss. A QRE may be made at any level, including the prescriber, nurse or a member of the pharmacy staff. They are generally preventable adverse medical events.

Reconstitution

For purposes of these guidelines, the term compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by a product's manufacturer.

Triad Relationship

Practitioner, patient, and pharmacist relationship in the delivery of *healthcare.*

Training Program

Process that assures that a staff member has demonstrated competency before being assigned to that task.

USP <795>

Chapter <795> Pharmaceutical Compounding-Nonsterile of the United States Pharmacopeia. It is the general non –sterile compounding standards chapter of the USP and can be found in the USP Pharmacists' Pharmacopeia.

USP <797>

Chapter <797> Pharmaceutical Compounding-Sterile of the United States Pharmacopeia. It is the general sterile compounding standards chapter of the USP and can be found in the USP Pharmacists' Pharmacopeia.

Utensils

Simple instruments utilized in the compounding process.

Attachment B: PCAB Guidance to Pharmacies Regarding Hazardous and Potent Substances and Primary Engineering Controls

PCAB Guidance to Pharmacies Regarding Hazardous and Potent Substances and Primary Engineering Controls

This document is designed to provide guidance to pharmacies regarding PCAB requirements for powder and fume containment devices in pharmacies that handle hazardous or potent drugs. Every pharmacy practice is unique and site-specific considerations should be addressed when implementing the suggestions outlined in this guidance document. Please email CONTACT@PCAB.ORG with any questions and recommended improvements to this guidance document.

Introduction

PCAB requirements for protective equipment and procedures for non-sterile compounding are primarily addressed in standard 3.00, Facilities and Equipment.

Standard 3.10 states, "A. The pharmacy demonstrates that the size, type, and quality of facilities and equipment in the pharmacy is adequate to safely and accurately compound preparations in the amount and type relative to the nature of compounding that is performed in the pharmacy. This should include procedures for the control and containment of powders during compounding."

"C. If the pharmacy handles hazardous materials, it demonstrates that its SOPs are adequate to protect personnel based on volume and scope of compounding performed."

Standard 3.30 states,

"A. The pharmacy has an area for aseptic compounding of sterile preparations that meets current USP <797> standards."

"C. The pharmacy demonstrates that it maintains facilities and procedures adequate to avoid cross contamination and contamination by dust and other particulates in the compounding area."

For sterile compounding, PCAB requires compliance with USP <797> standards that address compounding with hazardous materials. Compliance Indicator F states "If the pharmacy practices aseptic sterile compounding, it has an appropriate area for compounding of aseptic preparations that meets or exceeds USP <797>."

In order to meet the requirements of the above standards, PCAB requires pharmacies that handle hazardous substances to have appropriate primary engineering controls (Biological Safety Cabinets-BSCs) designed to protect the

operator from exposure to the hazardous substance. This requirement is consistent with NIOSH and OSHA standards and recommendations.

Non-Sterile Compounding

For non-sterile compounding, a Class I BSC, a device designed to protect personnel and the environment from hazardous and potent drugs is required. Class I BSCs are available in various sizes and configurations from a variety of vendors. These devices are sometimes called vented balance safety enclosures or powder hoods.

In order to meet PCAB, NIOSH, and OSHA requirements weighing and compounding of hazardous and potent drugs must occur in a type I BSC. Optimally, Class I BSCs should be vented to the outside. However, devices that are designed to recirculate room air are acceptable.

Regardless of whether a pharmacy purchases a class I BSC or designs and constructs a device in-house, PCAB surveyors will ask for documentation that device meets standards for operator protection.

In addition, there are testing protocols for Class I BSCs that include air flow and filter leakage tests. Devices should be tested upon installation and annually to assure they are working correctly.

Sterile Compounding

Sterile portions of the sterile compounding process such as weighing must, at a minimum, be performed in equipment meeting the requirements above for non-sterile compounding. The equipment must be situated in an environment meeting USP 797 standards.

Sterile compounding with hazardous or potent drugs must occur in a Class II BSC or compounding aseptic containment isolator (CACI), devices designed to protect personnel and the environment from the hazardous material, and the product from bacterial or particulate contamination.

For pharmacies that compound a significant amount of hazardous substances, the class II BSC must be located in a minimum ISO Class 7 environment that is physically separate from other preparation areas. This environment should have negative pressure relative to the outside environment of not less than 0.01 inches of water.

A CACI must be located in an ISO Class 7 or 8 environment that is physically separate from other preparation areas. This environment should have negative pressure relative to the outside environment of not less than 0.01 inches

In cases where the pharmacy only prepares a small volume of hazardous drugs, the use of two tiers of containment, for example, a Class II BSC or CACI and the use of closed system transfer devices is acceptable.

ISO environments must be tested every 6 months as required by USP <797>. Protective equipment such as Class I BSCs must be tested upon installation and annually to assure they protect operators as intended.

Storage

Hazardous drugs should be stored separately from other inventory, preferably within a negative pressure room.

Frequently Asked Questions

Our pharmacy rarely works with hazardous substances; do we need primary engineering controls?

Yes.

Our pharmacy provides our staff with masks, respirators and other personal protective equipment to work with hazardous drugs, is this Ok?

Yes…but PCAB, NIOSH and OSHA all recognize that personal protective equipment is not a substitute for primary engineering controls. PPE is an adjunct to primary engineering controls, and should be available in case of spills or accidents. PCAB will not accept personal protective equipment as a substitute for primary engineering controls.

Our pharmacy designed its own primary engineering control, is this acceptable?

Yes, provided that the device has passed appropriate testing by a qualified outside testing service.

Our pharmacy performs serum/saliva/air or other types of testing for hazardous substances and has never had a problem. Are we exempt from the requirements for primary engineering controls?

No. PCAB, OSHA and NIOSH require primary engineering controls regardless of any other precautions.

Additional Information/Resources

IACP Hazard Alert: Compounding with Hazardous or Potent Pharmaceuticals. www.iacprx.org.

NIOSH: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings. www.cdc.gov/niosh/docs/2004-165/

OSHA: Controlling Occupational Exposure to Hazardous Drugs. www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html

Koshland Pharm: Custom Compounding Pharmacy
301 Folsom Steet, Suite B
San Francisco, CA 94105
(415) 344-0600
Fax (415) 344-0607
www.koshlandpharm.com

Leiter's Pharmacy
1700 Park Ave. Suite 30
San Jose, California 95126
(800) 292-6773
www.LeiterRx.com

McGuff Compounding Pharmacy Services, Inc.
2921 W. MacArthur Blvd., Ste. 142
Santa Ana, CA 92704
(877) 444-1133
www.mcguffpharmacy.com

Pacifica Pharmacy
23560 S. Madison #112
Torrance, CA 90505
(310) 530-0831
www.pacificapharmacy.com

Attachment C: PCAB Accredited Pharmacies in California

Anchor Drugs Pharmacy
161 South Spruce Ave
South San Francisco, CA 94080
(650) 360-5300
Fax (650) 360-5301
www.anchorpharmacy.com

Central Drugs Compounding Pharmacy
520 W. La Habra Blvd.
La Habra, CA 90631
(562) 691-6754
Fax (562) 694-3869
www.anypharmacy.com

Corona Specialty Pharmacy
1280 Corona Pointe Court, Suite #114
Corona, CA 92879
(951) 278-1008
Fax (951) 278-1009
www.CoronaSpecialtyPharmacy.com

Golden Gate Pharmacy
1525 East Francisco Blvd, Suite #2
San Rafael, CA 94901
(415) 455-5590
Fax (415) 455-9039
www.ggvetrx.com

Hartley Medical Center Pharmacy
113 W Victoria St
Long Beach, CA 90805
(562) 595-7548
Fax (562) 595-9855
www.hartleymedical.com

Parkview Pharmacy
8283 Grove Avenue, Suite 105/107
Rancho Cucamonga, CA91730
(909) 981-0956
Fax (909) 981-8409
www.parkviewrx.com

The Remedy Pharm
23811 Hawthorne Blvd
Torrance, CA 90505-5907
(310) 375-06551
www.theremedypharm.com

San Ysidro Pharmacy
1498 East Valley Road
Santa Barbara, CA 93108
(805) 969-2284
Fax (805) 565-3174
www.sanysidropharmacy.com

Attachment 2

Continuing Professional Development

Step One: Meaningful Assessment

Proceedings from a Citizen Advocacy Center Conference

June 22, 2011

Note: These proceedings are not a verbatim transcript, but they are faithful to the speakers' presentations and the subsequent questions and comments. For the complete content of the conference, you can find the speakers' PowerPoint presentations at http://www.cacenter.org/files/powerpoint/ContinuingCompetence2011/index.html.

Introduction

The Citizen Advocacy Center (CAC) convened this conference in light of the growing consensus that any meaningful continuing professional development scheme must begin with an assessment of the knowledge and skills an individual needs to reinforce to maintain his or hear current competence.

CAC's *Roadmap to Continuing Competence* recommends routine periodic assessment. It reads in part:

> Periodic assessment is the key to tailoring lifelong learning programs to the needs of individual healthcare professionals and to demonstrating continuing competence over the course of one's career. Assessment pinpoints the knowledge gaps that can be filled by continuing education or other professional development mechanisms. Assessment also is used to determine whether a practitioner competently applies his or her knowledge and skills in clinical situations….
>
> There are two key questions that have to be answered about assessment: who should be assessed and who should do the assessing…. The question of who should do the assessing is more difficult to answer. Self- assessment is the option many voluntary credentialing organizations and some regulatory agencies have written into their emerging competency or professional development programs. This approach is likely to be more acceptable to many professionals than third-party assessment. It appears to be, therefore, a comparatively painless way to introduce periodic assessment into the routines of professional careers.
>
> But, critics of self-assessment point out that it does not provide the same degree of public accountability afforded by third-party assessment. They also wonder about relying on a professional's judgments about their own strengths and weaknesses.

Third-party assessment is by definition more objective and more accountable. It is also more expensive than self-assessment and potentially more disruptive to practice. Moreover, there are not a sufficient number of third-party assessment programs available right now to perform the task. So, hybrid approaches have potential appeal, such as methodologies combining self-assessment or professional portfolios with independent evaluation and consultation at the workplace and random review by certification and regulatory agencies.

CAC's Roadmap foresees that self-assessment is likely to predominate in nascent programs, but the goal is to move to independent third-party assessment over a period of time. Self- assessment tools need to be developed by third parties according to publicly developed standards. The pilot projects called for in the roadmap offer an opportunity to evaluate and compare various assessment methodologies: self-assessment, third-party assessment and a hybrid combination of the two.

Regardless of the chosen methodology, profession-wide periodic assessment must be mandated and performance assessment should have a high degree of correlation with real situations in practice settings. Advancements in information technology offer the possibility of evaluating electronic medical records and practitioner-specific practice profiles against practice guidelines and peer performance in order to assess individual clinical competence and, significantly, to determine the impact over time of continuing competency assurance on patient outcomes.

Is Self-Assessment Reliable? What Does the Literature Conclude? Research Conducted by the Association of State and Provincial Psychology Boards

Robert Brown, Chair, Maryland State Board of Examiners of Psychologists

There are many ways to think about competence. It is clear that professionals have to retain what they learn in graduate training and to acquire new skills during their careers appropriate to their current practice. They must learn new knowledge based on research findings and new practice methods, new theories, new assessment tools and treatment approaches and new technologies.

Looking back, graduate school was reassuring in lots of ways. While academicians do try to teach clinical skills and judgment, by and large, students are taught what they need to know in a series of core courses prescribed by the faculty. Students are lectured to, coached, tested, observed, and given feedback.

After students graduate, many practice in isolation or behind closed doors. Some are supervised, particularly early in practice, but that supervision is typically cursory and not

hands-on. Professionals take courses in subjects they feel they need to know, rather than subjects selected by others based on what each professional needs to know.

Consumers expect that healthcare providers are competent throughout their professional careers and most are surprised when they learn that regulatory bodies are not acting to ensure continuing competence. Professional societies assume that professionals can determine what kind of skills, knowledge, techniques, approaches, and theories they should be familiar with, and that they can select from the options available to acquire new learning, to stay updated, or to acquire new skills. The assumption that individuals engage in reflection and can accurately self-assess has been the cornerstone of adult education and continuing professional education.

Continuing education is one of several approaches to continuing professional development. One of the things that the psychology boards are trying to do is to broaden the definition, so that in addition to mandatory seminars, credit can be given for peer contacts, portfolios, publications, etc.

What are some of the challenges associated with continuing competence? One is the definition. What competencies are the relevant for individual practitioners? For most professions, declarative knowledge is what the licensing exam assesses. By and large, exams don't get at the delivery of services. They don't get at judgment and the ability to discriminate one situation from another. They don't get at applying knowledge to a set of facts, nor do they assess attitude.

How can we measure competence in ways that are true to consumer expectations, are acceptable to professionals, and are economically and practically feasible? Self-assessment is one of the reasonably economical ways to do this.

Other methods include objective tests and observation by experts. HIPPA regulations make it difficult to observe live patients, but simulations are an alternative. Practice audits, professional profiles are other methods. Patient outcomes are complicated because they are affected by the skill of the practitioner and many other variables, such as the type of illness involved, the resources available to the patient, and institutional constraints.

What can we do about maintaining and enhancing the competence of professionals, knowing that outcomes are not always going to be the most reliable measure of competence?

How accurately can people self-assess their own professional development needs? By this, I mean self-assessment in terms of what is my practice like. What do I do? What kind of skills do my colleagues and peers have? What demands are there on my professional time? What kind of treatment is indicated in particular cases? What is my patient population? It is difficult to mandate something that applies to everybody because professionals specialize in different areas.

Even if a professional can decide accurately what they need, how do they know that a particular educational experience is going to meet that need? How accurately do professionals evaluate what they have learned? There has been a movement to use test questions to determine what people have learned.

The research suggests that people aren't very good at assessing our needs, determining whether the experience meets the needs, and evaluating how much we have learned from the experience. In other words, self-assessment is not useless, but it is not very promising.

What about the accuracy of self-assessment? Poor Richard's Almanac said, "There are three things extremely hard: steel, diamonds, and to know one's self." Charles Darwin said, "Ignorance more frequently begets confidence than does knowledge."

Both of these statements impart some wisdom, and while they do not rule out the potential usefulness of self-assessment, they do temper any excitement that self-assessment is going to be the answer.

Some of the more prominent findings in the literature include these. Learners are not necessarily accurate in assessing their own knowledge as compared with when they are actually tested. Students and practitioners tend to avoid areas that are difficult for them and stay with what they are already good at. At least in Western societies, even people with the lowest objective ratings of competence rate themselves above average. Recent studies found that physicians have a limited ability to accurately self-assess, when self-assessments are compared to measured competencies. People who are less competent tend to exaggerate the quality of their knowledge and their performance more than do more competent people.

What are the sources of bias in self-assessment? Self-assessment of knowledge learned in continuing education (CE) is more related to satisfaction with the course than it is to actual learning. So, self-assessment is generally a more useful indicator of how learners feel about a course than it is an indicator of how much they learned from the course.

Other sources of bias include differences in self-esteem. People with high self-esteem are often more willing to accept that they have deficits than people with low self-esteem. People who fear negative evaluation will rate themselves more highly. People can become defensive if others challenge what they have learned or know. People who are not competent often are not able to recognize competence in others.

People who are more competent are more likely to recognize knowledge and skills they should acquire. People who need continuing professional development the most are the ones most likely to fail to recognize the need.

Should we give up on self-assessment? The evidence is mixed. People can be trained to increase the accuracy of their self-assessment.

The better question is: When and how and can self-assessments be useful? I said earlier that self-assessment indicates how satisfied a learner is with the learning experience. This satisfaction may serve as a motivating factor to do more.

Providing objective feedback, in the form of tests or other measures, can improve the accuracy of self-assessment. This feedback is most useful during the learning process, rather than at the conclusion. The feedback about learners' self-assessments helps students learn how to more accurately evaluate their own performance in the future.

Feedback is complicated. If it is too complimentary, it could interfere with motivation to learn more. If it is critical, it could motivate someone to learn more. On the other hand, critical feedback may prompt another learner to conclude that the evaluation was biased and discourage further learning.

How can self-assessment be used productively? Self-assessment should play a role in continuing professional development, but it should not be relied on solely as a measure of competence or new learning. Self-assessment may be a competency that can be developed among professionals. Self-assessment should be facilitated / supported by providing training and objective measures of feedback and peer feedback at multiple points longitudinally in the learning process. Learners should be given the opportunity to compare their actual knowledge and performance to motivate poor performers to learn more.

Question: My professional association has had conversations about continuing competence for many years. What is your perspective on how regulated professions should tackle this? We have a political challenge to get our constituents to accept the idea that they need to do more than just attend continuing education courses.

Brown: This is a critical point. People become anxious and sometimes huffy about being evaluated. I don't know the answer.

Comment: It depends on how it is done. I have a grandchild who wasn't doing well in math. The teacher could send a letter home threatening that the child will be held back if he doesn't improve. Or, the teacher can send a note saying the child isn't performing up to grade level and the school would like to help him by keeping him after school a few minutes for personalized tutoring.

Brown: There is a body of literature about steps that can be taken to encourage peoples' motivation. I'm not sure professional societies are doing much in that regard.

Comment: I would argue that this is a cultural issue. We have to start teaching in our undergraduate training programs that assessment and evaluation and continuing professional development are a part of being a professional.

Comment: The Federation of State Medical Boards is undertaking an initiative on maintenance of licensure. We believe committed leadership is necessary to make it

happen. State boards should do it because they have a mandate to protect the public. The public wants it because they deserve the highest quality care by the most competent professionals. Physicians should do it because they really care about their patients and care about giving them the best care. If professionals want to perpetuate the system of self-regulation, they need to incorporate procedures for periodically evaluating licensees.

Brown: I believe most professionals want to provide the best services they can. The problem is, how do they know when they are not providing the best possible services? This requires some sort of objective assessment in addition to self-assessment.

The Assessment Program Developed by the National Association of Boards of Pharmacy (NABP)

Carmen Catizone, Executive Director, National Association of Boards of Pharmacy

Our road to continuing professional development has been straight and narrow at times and a very crooked route at times, and we wound up in a completely different place than we ever imagined.

One barrier we faced is economic. Professionals say they are too busy to engage in continuing professional development activities. They are concerned about the impact on their licensure if they don't perform well. They are also concerned about the cost.

We also encountered questions about whether our continuing professional development program would inhibit a professional's ability to practice and to exercise the privilege they earned through licensure. Another twist is the involvement of other agencies, such as the Federal Trade Commission, which alleges that the dental board in North Carolina engaged in anti-competitive activity when defining the scope of practice. Where does the state board's authority end and the FTC's authority begin?

Our journey started almost thirty-five years ago. In 1967, the Department of Health and Human Services recommended mandating continuing competence requirements. In 1970, the Public Health Service questioned the relevance of continuing education to continuing competence and recommended a multi-faceted approach, including peer reviews, professional standard review, re-examination, and self-assessment techniques.

The pharmacy profession decided to establish continuing education requirements, just as other professions did. We believed that if professionals engaged in continuing education, they wouldn't need the mandate that HHS and others were calling for. The accrediting bodies began to approve providers of continuing education to make sure certain standards were met. Eventually, all the states mandated continuing education.

From the regulatory perspective, the boards of pharmacy and the educational accrediting bodies did all they could to ensure that continuing education would be valuable. But, there was no way to control practitioners who waited until their CE was due for

relicensure and hastily read journals and submitted their CE credits. There was no way to monitor that process, no way to say to the practitioner that we don't believe you have actually learned anything or benefitted from that CE. One of the lessons we learned at NABP is that voluntary works best when it is mandatory.

We got a wakeup call in 1997 when it was again recommended that states should require each board to develop, implement, and evaluate continuing competence requirements. We interpreted this to mean that the public no longer believed the "Trust me" philosophy that the healthcare professions had adopted. To say that, "We are learning; we are self-policing; we are competent; we have continuing education requirements" was no longer good enough. The public wanted more. They wanted a "Show me" approach that validated continuing competence.

NABP heeded that call and adopted the recommendation of the Pew Health Professions Commission that "states consider requiring the demonstration of continued competence through some sort of testing mechanism." The message was clear to us that continued competence needs to be assessed, so there needs to be a testing mechanism. They didn't say portfolios. They didn't say reflection. They didn't say let the profession develop it. They said state boards, continued competence, an assessment mechanism.

We looked at the literature to learn how we might measure competence across all practice settings and all levels of specialization. One study from Minnesota showed that fifty-three percent of the medications prescribed to patients were to treat twelve indications, not the ones you would expect: asthma, diabetes, and high cholesterol. In contrast, a study of Medicaid patients and emergency room visits in Mississippi found that those three disease states represented seventy percent of the medications being reimbursed by the state Medicaid program.

So, we realized that pharmacy practice varies by state, by sub-population, and by other factors. We decided we needed to develop a continuing competence mechanism that takes the same approach as the initial licensure examination. Why not use the initial licensure exam to assess continuing competence? Because we found that practitioners in practice for two years or more behave differently than new graduates, so we had to modify the continuing competence exam to measure that subtle difference.

We introduced a continued competence assessment mechanism in 1998 and offered it to boards on an optional basis initially, with the expectation that it would eventually become mandatory for relicensure. It was a computer adaptive multiple-choice tool, which pharmacists could use to assess their knowledge. We intended that completion of the tool would be followed by CE, portfolios, and other methods to address any weaknesses discovered in the assessment.

When we rolled this out to the profession, it generated accusations, controversy and conflict. We were accused of creating the program to generate revenue by selling the assessment tool. The professional associations asked why the regulatory boards should be earning this revenue, even though we planned to run the program at close to cost.

During the debate, these questions came up:

Who defines competence? The professional association said they define it and when the boards become involved, things become punitive. We said the public and regulatory groups define competence and are responsible for it, working with the profession.

Who is responsible for competence? Employer groups wanted to address competence internally, saying they fire incompetent people and don't want regulators involved.

What is the evidence to show competence? Some argued that specialty certification is an indication of competence. Others said that holding a license in good standing should be evidence of competence.

There is truth in all these arguments, but the bottom line for regulators is to demonstrate to the public that every practitioner is competent. A license in good standing sends an important message, but members of regulatory boards know that the resources available to state boards prevent them from becoming involved in a lot of activities to the level necessary.

Hearing all these critiques, we put together a pharmacist self-assessment mechanism. We used the same blueprint, but made it less high stakes. We made it available online instead of secure testing centers. We said to pharmacists: self assess and based upon the results, decide on a CE program for yourself appropriate to your practice and your needs.

The license to practice allows a pharmacist to practice in any setting, from hospital to retail, and in any specialty from pediatric to geriatric. That is why we put together a general assessment that cuts across all practice settings and allows an objective assessment of the pharmacist's competence across multiple areas.

We tried everything to make this a tool that pharmacists would use. The fee was reasonable. Some states recognized the tool for some portion of the CE requirement, providing a mandatory incentive to use the tool. Accommodating requests from the profession, NABP agreed to waive the fee in some states in an effort to persuade pharmacists to participate.

Participation was so disappointing that the program was disbanded and the continuing competence assessment mechanism was never launched. Practitioners are not ready or willing to participate.

So, the recommendations dating back some thirty-five years are now off our table. Some pharmacists are asking why pharmacy can't take the approach being taken by the Federation of State Medical Boards. We say fine, you take the lead. We tried and got no positive response.

So, we scrapped a mandatory continuing competence for state boards. We scrapped the pharmacist self-assessment mechanism. We went back to our member boards and asked what they need to fulfill their daily responsibilities. They replied that they are having trouble assessing practitioners who come back into practice after a lapse.

We have decided to develop an examination to give boards of pharmacy a pharmacist assessment remedial education tool. It will be a computer adaptive exam that pharmacists can take in a secure environment, such as the pharmacy board office. It will consist of 210 operational items in three distinct domains. Based upon a survey of pharmacy practice, we found that fifty percent of the remedial examination will cover the practice of pharmacy and the rest will cover prevention of medication errors and ethics.

We are also launching a program to accredit community pharmacies. It will focus on continuous quality improvement and advancing the practice of pharmacy to the next level so that pharmacists provide patient-centered care. We are giving the boards the tools to look at quality of care and clinical outcomes and to assess practitioners.

We are waiting to see if there is public demand for more continuing competence initiatives. Unfortunately, it is usually a horror story involving a medication error that garners public attention and leads to legislative changes.

Comment: You say you don't hear public demand for continuing competence. AARP Virginia did a survey a few years ago that found that the public assumes that licensing boards are monitoring ongoing competence and believes that healthcare providers should be assessed at least every five years. CAC once hosted a debate between officials from the Federation of State Medical Boards and the National Council of State Boards of Nursing about who needs to demonstrate current competence. The Federation representative said doctors should be assessed when there is a reason to believe they aren't competent. The spokesperson for the National Council said this is not a disciplinary matter, but a question of raising all ships, so every licensee should be assessed. So, it is disappointing to learn that NABP ended up where you have.

Catizone: We readily admit making mistakes along the way. When we introduced the continued competence assessment, we thought we were doing the right thing, but we came on too strong, and the profession viewed it as a disciplinary mechanism rather than something that would help practitioners. If we try again, we will be sure that the profession views our initiative as non-punitive. But any mechanism has to have teeth and be objective. If it is no more than a self-assessment by practitioners, it won't be valuable to our member boards.

Comment: It is very important to be clear that this is not about discipline, but about encouraging and supporting lifelong learning and continuing practice development. The public may be relatively quiet about this, but as regulators, our job is to engage the public because they are our biggest ally.

Catizone: One of the consequences of reduced resources is that boards don't have the time to engage in public outreach activities.

The Assessment Program of the Commission on Dietetic Registration

Grady Barnhill, Director of Recertification and Professional Assessment, Commission on Dietetic Registration

We have self-assessment in four different areas, one of which is a portfolio process. The self-assessment simulations are products used to prepare for specialty certification exams to obtain a credential. Our self-assessment series and assess and learn series are more closely related to continuing professional development.

We developed these products because we wanted a new way of looking at recertification. The first step in the process is self-reflection, which includes questions such as: What am I good at? What do I enjoy? What practice areas do I prefer? What knowledge or skills do I want to add?

Step two is a subjective self-assessment component. It is a checklist based on more than 150 learning need codes. Users assess what they know in each area, what they would like to learn, and at what level. It is easy to use, easy to develop, inexpensive, non-threatening, and it encourages reflective practice. It is voluntary because we do not require users to submit documentation of this step. So, we don't have any participation data to show whether it is being used.

Because self-assessment may not be accurate, we developed an objective self-assessment series. Objective self-assessment is less biased and it can be used in a normative way. And, it is based on a common metric rather than individual standards.

We started using an objective self-assessment tool in 1991. It was developed by the Penn State University Division of Continuing Professional Education and the W.K. Kellogg Foundation. It included performance objectives: what should a practitioner know and be able to do? It focused on the application of knowledge in practice. The original plan was to develop 42 modules covering 21 practice areas.

We used subject matter experts and conducted pilot tests. The modules were scenario based with realistic support materials. Some included video taped interviews, lab test results, and so on. Certificants would look at each scenario and then answer multiple-choice questions based on the materials and submit the sheets for scoring. We provided rationales for why answers were right or wrong. The users loved the normative feedback showing how they compared to their peers.

Follow up evaluation reveals how well the individual performed on a particular task, how important any particular task is to their current work, and how interested the person is in developing the necessary skill. From this, flows a learning plan.

How did it work? The cost was $65.00. People received 7 CPE units.

By 2004, sales had dropped to about 100 per year, out of 75,000 practitioners. The feedback from those who completed the series was outstanding. There were administrative challenges, storage issues, and currency concerns.

We concluded that making a program like this voluntary isn't effective. The product ends up being used most by those who need it least.

The second-generation objective self-assessment program is called Assess & Learn. These are online case-based scenarios using realistic clinical information, documents, case notes, lab tests, descriptive information, interview transcripts, evidence-based sources, and referrals to additional learning opportunities. Because it is online, there are no production or storage costs.

How is this working? It was an effort to streamline the self-assessment process and it is much less expensive than the earlier version. The modules provide realistic and sufficient clinical information and context. The feedback is simple and directly related to the performance of tasks. Feedback is not normative, but indirect links are provided for learning planning. It is self-scoring, which saves staff time. The online format enables candidates to sign on at their convenience.

We sold 350 units in 2010 – already three times better than the older version. This is still a small number, given that there are now 81,000 practitioners.

What we learned from all this is

- Control costs
- Leverage technology
- Keep it simple
- Provide incentives to participate (avoid voluntary)
- Provide utility and normative feedback to participants

Where should we go from here?

We will be using the same instrument for the initial assessment and the demonstration of competence at the end. If you do well in the initial self-assessment, you will be exempt from some or all of the continuing professional development hours for the recertification period. We think that this "carrot" or value-added incentive will be a good way to get better buy-in to the program.

Question: How much does the new product cost? How long does it take to complete?

Barnhill: It costs about $50.00 per person, so it is more economical. The startup costs were about $20,000.00 to get into the computer platform. It can be completed in five hours or less. The older module took closer to seven hours.

Question: Have you considered making this mandatory for recertification?

Barnhill: We are looking at possibly restructuring our credential. One of the things we are looking at is the vexing issue of focus areas. If we redo our initial certification exam to accommodate five different focus areas so candidates will take the basic core exam and then choose additional questions in a focus area, that sets the stage for us to develop self-assessment in focus areas.

I think one of the best models is mandatory self-assessment that practitioners are not required to pass. It is easier to sell a mandatory self-assessment that gives practitioners information, but they don't necessarily have to pass. At worst, they would have to do targeted CE in the areas where they are weakest. Many people really like getting feedback.

Question: Are employers interested in using this to assess their workforce?

Barnhill: One large employer has incorporated our portfolio process into their management scheme. We have not seen an employer requiring completion of the Assess and Learn series.

Question: Have you analyzed the user population?

Barnhill: We do not have good data on the participants, but it is a great idea to obtain demographic data.

The Assessment Program of the National Board for Certification in Occupational Therapy

Margaret Bent, Managing Director, Competency Assessment, National Board for Certification in Occupational Therapy

NBCOT has developed tools for assessment and self-directed learning for initial certification and renewal. The primary competency assessment for initial certification is an examination at either the occupational therapist registered (OTR) level or the certified occupational therapist assistant (COTA) level. The content is driven by periodic in-depth practice analysis studies based on large-scale surveys of practicing OTs about skills and attributes they need in their daily practice. Nothing that appears on the examinations should be outside the content of the practice analysis.

The examinations provide evidence of entry-level competence. They are computer-delivered on demand. There are multiple-choice sections in both exams and a clinical simulation section for the OTR exam.

We began using the clinical simulations in 2009. They are very popular with the students because they help them to think and make decisions as they would in practice. They are

designed to simulate actual situations a therapist is likely to encounter in every day practice.

They typically start with a description of a fictional client. The applicant is then asked what type of assessment is appropriate and what kind of treatment plan would be recommended based on the results of the assessment. The various sections complete the full picture of that client or patient. The simulations are dynamic in that there are lists of decisions and actions a candidate can choose. When they choose an option, a feedback box appears on the screen giving information about the consequences of that decision or action.

The simulation questions are designed to measure a candidate's knowledge and critical reasoning ability sequentially across the continuum of care, beginning with screening and continuing to formulating conclusions, providing and adjusting interventions and assessing outcomes. These questions take about ten minutes to answer. The majority of candidates agree that the simulation portion of the test covers situations that practitioners typically experience in the clinical practice.

We see self-assessment as the key to our certification renewal program. We promote lifelong self-reflection and encourage certificants to identify their learning needs and develop a plan that will benefit their practice. During the three-year recertification cycle, certificants are encouraged to complete some level of self-reflection and 36 professional development units. There are 28 different ways to accrue these units.

Last year, we introduced an option to renew with a practice area of emphasis. This is optional because some practitioners want to be viewed as generalists, able to move from one practice area to another. Others want to be viewed as specialists.

Our annual audit of a sample of the renewal group finds a compliance level of about 92 - 96 percent over six years. Reclassification of Certification Status is the renewal process for people who have been noncompliant or inactive. Part of the process is completion of one of the general practice self-assessment tools.

We have designed several study tools, including online practice tests, an Occupational Therapy Knowledge Exam, and entry-level self-assessment tools. Applicants use these tools to prepare for the entry-level exam. The objective is to identify candidate strengths and weaknesses. We encourage students to complete a self-assessment before going out on clinical rotations. We encourage a 360-feedback loop where students, supervisors and other colleagues independently complete the self-assessment tool.

Tools developed for certification renewal include self-assessment tools, a professional development tracking log, a professional development provider registry, an "Essentials Credentials" toolkit, and NBCOT's Connect E-zine.

Since April 2010, 59,274 certificants have used the self-assessment tools. They are designed to empower certificants to engage in critical self-reflection with the ultimate

goal of assessing current levels of proficiency within the domains of occupational therapy practice. The self-assessment tools cover these areas of practice: general practice, older adult, physical disabilities, mental health, pediatrics, orthopedics, and community mobility. Certificants can choose to complete the general practice tool and another one related to their current or anticipated practice area. The score report reveals areas of strength and weakness. It also provides links to professional development resources from the provider registry.

The uses of these tools include: documenting strengths in specific practice areas, identifying gaps in knowledge and skills, identifying professional growth opportunities, linking current abilities to critical job skills and performance plans, assessing learning needs prior to re-entry or transitioning between practice settings, assessing staff competence for planning in-service education.

NBCOT'S future plans for its recertification program include a review and a practice analysis study to be completed in 2012 which will identify the knowledge and skills necessary for ongoing competence. The practice analysis will reveal the knowledge required to transcend all practice areas, such as communication skills, ability to use evidence-based practice, ability to demonstrate effective service, and so on.

The results of the practice analysis will be used to develop tools to enable us to measure ongoing competence. Renewal requirements will be enhanced to embrace self-reflection, knowledge assessment and traditional continuing education.

Question: How are you linking the continuing competence requirements of voluntary certification with mandatory licensure?

Bent: We have worked with the state licensure boards to make our requirements consistent with theirs. We don't want to introduce a different set of requirements.

Question: What can be done with the information from the self-assessments? Could a state regulatory board request the results if, for example, they have a re-entry candidate for licensure who has completed a self-assessment, or if there were a disciplinary case before them?

Bent: The results of a self-assessment are not shared with any third parties. In a disciplinary situation, I could see the results of a self-assessment being used in evidence, but that has not happened so far.

Question: The first speaker addressed the limits of self-assessment. What do you do to overcome some of these limitations?

Bent: Remember that NBCOT certification is voluntary so we don't want to be burdensome. We want to support the professional development and clinical practice of certificants. The tools we have developed help the individual focus on where he or she

needs to go in terms of their own development, rather than having something imposed by an external body.

Comment: I am impressed with your provider registry and it occurs to me that it would be useful to identify courses that correspond to any weaknesses identified in an assessment.

Question: Do re-entry candidates have to take a test in addition to completing the self-assessment?

Bent: No, they do not have to take a test and they do not have to re-take the initial certification exam. But, they have to complete the self-assessment tool and the professional development unit requirements and submit all the documentation to verify completion.

Question: What kinds of questions are used in the self-assessment tool? Is this available online?

Bent: It is available online. The first section of the self-assessment asks about specific knowledge and skills an occupational therapist uses in a practice setting. The second section looks at ability to interpret the results of a client assessment. The third domain relates to detailed intervention strategies. The fourth relates to professional practice, including such things as documentation, working within clinical systems, and so on.

The Assessment Program of the North Carolina Board of Nursing

Linda Burhans, Associate Executive Director, North Carolina Board of Nursing

The North Carolina Board of Nursing uses a reflective practice model for continuing competence and encourages a commitment to lifelong learning. We determined that continuing competence is important for public protection. It serves an important regulatory function and contributes to patient safety and quality care.

Our board began working seriously on continuing competence after the Pew Health Commission report in the mid-1980ies. In 1998, we began developing a strategic plan for creating a continuing competence program in the state. At that time, the Board of Nursing had no requirements for even continuing education. In 1999, we began working with stakeholders, including public members, practicing nurses, employers and educators.

That group determined that it was important to look at more than just continuing education. By 2001, the board staff recommended a reflective practice model to the board. That model was based primarily on work done in Canada and Kentucky.

By 2002, we had developed tools and in 2003, focus groups were held across the state to evaluate the tools, seek recommendations for modifications, and explore options for

implementation. In 2004, we implemented a Web-based pilot, giving nurses an opportunity to fill out some of the self-assessment forms and give the board feedback.

In 2005, legislation was passed requiring continuing competence as a condition of renewal or reinstatement of a license. The board promulgated rules applying to RNs, LPNs, and APRNs.

Our reflective practice approach is based on individual responsibility. It requires routine biannual self-assessment at the time of license renewal. Nurses identify their strengths and opportunities for growth and improvement in their practice. Then they implement a learning plan, focusing on the areas they have identified for development.

We ask that when conducting their self-assessment, nurses compare themselves to existing standards of practice. We want them to collect feedback from peers, colleagues, supervisors, and/or patients. Licensees can choose from any one of eight learning options ranging from national certification to 30 contact hours of continuing education, to refresher or academic courses, to publications and presentations, and a combination of CE and active practice. Licensees are randomly selected for audit of the documentation showing that they completed the requirements. We do not require that the self-assessment or learning plan be submitted to us. Nurses told us they were uneasy about sharing a self-assessment with a regulatory agency.

Our challenges in implementation included resistance from licensees, employers, educators, and a little bit from the public. There was a fear of change and uncertainty about the time commitment and the cost. Nurses wondered where they would find educational opportunities. The biggest worry employers expressed was that the board would interfere with the supply of nurses by prohibiting non-compliant nurses from working.

We tried to overcome that resistance by focusing on public safety and nurses' responsibility for professional accountability and lifelong learning. We also tried to balance stakeholder viewpoints and concerns. We tried to stay realistic and to compromise.

We also tried to communicate as much as possible. Every nursing bulletin and our board Web site contained information about the program as it evolved. Board members and staff explained the program in every speech and public presentation.

Among the lessons learned is that it is impossible to communicate enough. Regardless of our efforts, a small number of licensees will fail to comply and will require disciplinary action. Their reasons for non-compliance remain a mystery to me. Most of the fewer than 30 nurses who have been disciplined for not meeting the requirements have also not come to the administrative hearing when their license was revoked.

We know we are dependent on self-assessment and we know that that is far from ideal. Our nurses are still getting used to the process of self-assessment. It is easiest for nurses

who work in large academic hospital centers where they are working in a learning environment and have lots of resources and peers and supervisors they can talk to about their self-assessment. It is more difficult in small facilities or a physician office situation.

We suspect that most of the nurses in the state are not putting as much time as the board would like to see into their self-assessment and learning plans. Most of the nurses choose either to do the 30 hours of continuing education or the 15 hours of continuing education and work hours. But, there are nurses who have used national certification, refresher courses, or academic education.

The National Council of State Boards of Nursing is continuing to work on continuing competence, but the member boards are not ready to move forward. There are still nursing boards that have no requirements for relicensure.

Question: Certifiers worry that people will drop out rather than meet recertification requirements. This appears not to be true. What is your drop out rate at a regulatory board?

Burhans: We also worried about a wholesale loss of nurses. We saw a small increase in non-renewals in the first two-year period, but it has stabilized back to the rate we saw before implementing the program.

Question: What is your definition of "active practice?"

Burhans: Active practice means the person is functioning in a nursing role, where the person's job description requires that he or she be a nurse. They do not have to be delivering direct patient care. So, as a regulatory nurse, I am using my nursing knowledge all the time and this is considered my active practice. But, I couldn't be working for IBM developing new operating systems. I might be working for IBM as a nurse consultant working on clinical systems.

Question: It seems intuitive that if nurses keep up their skills and knowledge, assess their needs, and engage in professional development, their practice will be better. How do you think you can measure outcomes from the program?

Burhans: We did not do any pre-assessment and we have not looked at outcomes. We are struggling in any case with how to separate out which clinicians in a team setting are affecting patient outcomes. Anecdotally, we have received calls from nurses who have said they didn't think they needed this program but they are glad they completed the self-assessment because it made them aware of areas where they needed to update their knowledge and skills.

Question: Please expand on what has taken place at the National Council Delegate Assembly.

Burhans: I can't supply details, but I know that some of the discussions have centered on objective measures of continued competence up to and including the development of a new test. Oftentimes, as soon as the word "test" is uttered, resistance increases.

Question: How was the legislative process? Second, does the statute protect the self-assessment and learning plan documents from discovery in the event of a malpractice lawsuit?

Burhans: Adding the continuing competence requirement to our practice act was basically a walk in the park. It was an easy sell in the context of public safety. The nurses association was fully on board.

There is no specific language in the law or the rules that protects the privacy of the self-assessment and the learning plan.

Question: You were ahead of the curve for licensing boards. Have you considered changes in your program to bring it up to the current state of the art?

Burhans: We have always expected the program to evolve. Currently, we are looking at what the board of nursing in Washington State is developing. They have just begun a continuing competence program into which they have incorporated a feedback mechanism. We know that we need to move our program forward in North Carolina, but we haven't decided what shape that will take.

The Assessment Program of the National Certification Corporation

Fran Byrd, Director, Strategic Initiatives, National Certification Corporation

For several years, the NCC Board of Directors believed it is a good idea to tie continuing competence to the maintenance of NCC credentials. The question was not "should it be done?" but "could it be done – and cold it be done in a way that our certificants would embrace lifelong learning as an integral part of their certification maintenance process?"

In 2005, NCC embarked on a demonstration project to validate the need for a continuing competence initiative. Fifteen hundred randomly selected women's healthcare practitioners were asked to do an assessment of where they thought the stood in their practice. They then completed a 100-item multiple-choice tool, which would more objectively assess where they stood. The tool covered three levels: entry to practice, "cutting edge" practice, and a combination of both levels.

The board wanted to determine if nurses could self-assess their areas of weakness. They also wanted to collect data showing whether assessment should relate to entry level or recent practice in a specialty. The pilot was also designed to give nurses feedback regarding their specialty knowledge and competence. Finally, the pilot looked at developing CE to meet identified learning needs.

The pilot results showed that individuals do not correctly assess where they are strong and where they have gaps of knowledge. So, NCC decided to develop a more objective evaluation tool and to keep the assessment at the same level as the current certification exams in specialties. For NPs, that is entry into practice. For other nurses, it is a level of two years' expertise in the field. One reason for this is that there is already a task analysis and content validation for the current core exam.

Based on the pilot, NCC decided to design a system of focused feedback for each certificant, so they can see where gaps exist. The plan was to create content categories reflecting the core competencies for each specialty and to rate the results of the assessment to create a personalized education plan. The plan also called for enhancing the existing NCC self-assessment program modules so the results are coded to help certificants match their education plan to a specific module.

The assessment is a125-item multiple-choice computer-delivered tool based on the knowledge competencies for each specialty. The items are co-related with the competency categories on the certification exam and they are weighted to equal 50 hours of CE across all categories. The competency categories are different for each specialty, such as inpatient obstetric nursing, neonatal intensive care nursing, and the women's health care nurse practitioner specialty.

We developed a platform allowing certificants to access the assessment from their own personal computers. This was important to us because the pushbacks from the profession are concerns about time, cost, and inconvenience. In addition to built-in security features, prior to be allowed access to the assessment, certificants sign an agreement acknowledging that this is a secure evaluation tool to be taken by them alone.

We implemented the program in two stages. The first is an orientation stage, which went live in June 2010. In 2014 the process will become binding.

We mailed an explanatory brochure to every certificant, posted information on the Web site, and mailed reminder post cards prior to each maintenance cycle. There are still people who don't read the material.

The binding stage began in April 2011 for those individuals whose renewal is in 2014. They need to take this assessment to direct what their CE can be to maintain their credentials. The assessment has to be completed prior to their beginning to do CE.

If I were an individual with a June 30, 2011, cycle deadline, I would submit my maintenance assessment this time. I would earn credit for 5 hours of CE for taking the assessment, dropping the requirement from 45 to 40 hours. Having taken my specialty assessment, I have my individualized education plan now and can look for conferences, modules, and other educational opportunities consistent with my education plan.

The Specialty Index Report is issued immediately upon completion of the assessment, plus the corresponding education plan. It is sent to my password-protected account on

the NCC Web site. This is because certificants told NCC it is important to them to have control over where this information goes.

The assessment uses mathematical calculations on a one-to-ten scale in each competency content category. For establishing whether I need additional education in a particular area, NCC set a 7.5 or higher cut off. There is a carrot in the program because if I earn 7.5 or higher, I will not be required to have additional education in that area. However, if I show weaknesses, I will have to complete a CE requirement in addition to the fifteen-hour baseline requirement in my specialty.

NCC doesn't call the assessment a test. People don't pass or fail. We don't use the terms "need" or "weakness." We use terms that are not threatening. If you want buy-in, your constituents have to feel the program is there for positive reasons, rather than to be a club.

The resistance has not been as bad as we feared. We think introducing the program with the "Try it, you'll like it!" orientation phase overcame some resistance. There are no fees. The emphasis is on the assessment/evaluation tool versus an exam or test. Delivery is convenient on one's own computer. The five-hour credit for taking the assessment is a carrot for the current cycle.

Among the lessons learned, no matter how much information you provide, people don't read it. Any process dependent on computer systems will create headaches associated with compatibility, Internet outages, etc.

This has been a dynamic process from the start, and we expect to see refinements in the process, the content of the assessment tool, and in NCC's continuing education resources. We are working toward having a better platform to handle this function. Changes will be based on what we see in content validation and task analysis, what the psychometrician tells us based on a review of the results of an assessment, and feedback from the NCC population.

In terms of NCC's CE, we are working on multi-media formats, podcasts, PowerPoint with audio, avatar-based simulations, and procedural review for advanced practice nurses.

Question: Could you talk more about the security of the assessment, given that it is completed in people's homes?

Byrd: Our IT people can see people's log-in and log-out times and they can tell if more than one person has logged in from the same place. The assessment tool is timed to take 2 hours and 15 minutes. The bottom line is that we are looking to our certificants to embrace lifelong learning. If they can look up answers or have a discussion group in that length of time, more power to them. If security appears to be a big problem, we will look at it further. At this point, we feel it is not a key concern.

Question: What are the requirements for certificants who do not want to participate in the self-assessment piece?

Byrd: We have an "opt-out" process, which will come into effect in stage two because we don't want to deny anyone the right to maintain their certification. It is intentionally an onerous process to discourage its use. If people refuse to take the assessment, it is impossible to say where their strengths and weaknesses are, so they are required to take 50 hours across the five content areas of their specialty. Also, the maintenance fee is higher.

Question: How do you determine how many hours of CE are needed for areas of weakness?

Byrd: It is based on the percentage of items in the core exam for each particular area.

Question: How many items did you decide was necessary to get reliability in each area? How much is the initiative costing?

Byrd: The 125 item exam was based on the spread in the core exam. As to the cost, we had a head start because we have our own testing platform already in place. The additional development of the specialty assessment was about $40,000.00. Our content experts are volunteers.

Assessing the Communications Skills of Physicians in Training as a Condition of Entering a Residency Program

Ann Jobe, Executive Director, Clinical Skills Evaluation Collaboration. National Board of Medical Examiners

Graduates from a U.S. medical school who want to become licensed as a physician, have to take the USMLE and be in a residency program. Graduates from an international school have to have all their credentials verified, take the USMLE and do another residency in the United States.

The USMLE is the product of a partnership between the Federation of State Medical Boards and the National Board of Medical Examiners (NBME), which creates a single pathway for US graduates and international graduates to demonstrate competence to practice without supervision. This replaces state-based exams and separate national exams for U.S. and for foreign medical graduates.

USMLE is a computer-based multiple-choice examination. It assesses medical knowledge, clinical pathology, pharmacology, pathophysiology, and so on. It assesses clinical knowledge and clinical skills. In addition to multiple-choice, there is a small component that is computerized case simulations, similar to those described on occupational therapy.

Licensure usually occurs while graduates are in residencies. Re-licensure is the responsibility of the state licensing authority, not USMLE. Board certification and maintenance of certification is the responsibility of specialty boards. Most medical students take the first two USMLE exams (12CK and clinical skills) before they graduate from medical school and take step three while they are in residency.

USMLE is important because it is a performance assessment, on Miller's scale of Knowledge / Competence / Performance / Action. In other words, candidates "show how" to do something.

Kirkpatrick's criteria are 1) Reaction; 2) Learning; 3) Behavior; and 4) Results. We want to see results, change in organizational practice, benefits to patients and clients. So we look at what assessments we are doing that bring about change in our culture, and why. Because we assess communication, we are assessing something very different than standard computer-based exams assess.

How did the NBME develop its exam? The first exams in 1916 were voluntary and took a week to complete. From 1922-1950, exams included essay questions and observed patient encounters. In the 1950ies, "selective response" (multiple-choice) questions replaced essay questions. The bedside oral examination demonstrated more about the raters than it did about the test-takers. It was eliminated in 1964.

The NBME then started looking for something reliable to assess performance. In 1960, they tried to assess clinical performance using videos in large auditoriums. It didn't work. They tried "latent-image management" problems. That didn't work either. Everything reverted to multiple-choice in the 1980ies, even knowing that this does not get at performance.

The public was saying that physicians don't listen. The most frequent complaints to medical boards related to communication. Litigation was skyrocketing and most malpractice cases involved communication. The Joint Commission agrees that the communication breakdown is the basis for sentinel events. In nearly 3,000 sentinel events the root cause was communication breakdown.

Take home message: high level skills in "bedside medicine" is the cornerstone of safe, quality patient care.

Some medical schools have courses in clinical communication skills. Still, more than 60 percent of medical graduates said they had never been observed doing a complete history and physical.

NBME and the Educational Commission for Foreign Medical Graduates (ECFMG) wanted to assess clinical skills. ECFMG implemented the Clinical Skills Assessment exam in 1998. It is a national standardized assessment using standardized patients. However, it was only for international medical graduates.

The clinical skills evaluation collaboration was created in 2003 by the presidents of NBME and ECFMG who saw no reason for two competing examinations and created the Clinical Skills Evaluation Collaboration (CSEC). The first administration of the clinical skills examination occurred in June 2004.

The state boards and the USMLE composite committee felt this exam would be a national validation of the clinical skills of medical graduates. The medical schools and medical students and the AMA opposed the exam, arguing that schools were already assessing students.

As of May 2011, CSEC has examined 229.091 candidates with 2,749,092 standardized patients. We have five centers in Atlanta, Chicago, Houston, Los Angeles, and Philadelphia that run 5-6 days a week. We have 2 – 3,000 examinees a month, which is about 24 per day at each center. It costs about $1,100.00 per examinee.

The cases include important situations typically found in a clinic, a doctor's office, emergency department, or hospital. There is a blend of cases in each exam for an undifferentiated physician. We try to be sure everyone has a comparable level of difficulty for the exam, regardless of which test site.

We build our blueprint to relate to system, gender, age, and acuity. Every exam involves 12 encounters, which take 25 minutes apiece – up to15 minutes with the standardized patient and 10 minutes to write a patient note.

It is a pass/fail exam and they have to pass all three sections in a single administration. Communication and interpersonal skill are rated by our standardized patients who are people from the lay public representing all different backgrounds. Examinees are assessed on their ability to ask questions and explain and counsel to patients, their professional manner and rapport, respect, privacy, modesty, comfort, empathy.

Spoken English proficiency is included because 43% of examinees are international graduates. The integrated clinical encounter has two pieces. One is data-gathering and the other is patient notes – communication of the findings. For data-gathering, standardized patients use checklists to indicate whether the appropriate questions have been asked and the appropriate physical was done. The patient note is evaluated by physician raters, who evaluate the conclusions and recommendations for what to do next.

The failure rate for U.S. examinees is about 3-4 percent, mostly because of deficiencies in the integrated clinical component. This represents 500-600 individuals. For international graduates, the failure rate is around 25 percent, also because of weakness in the integrated clinical component.

Why do we use standardized patients and not physicians as raters? Because physicians may decide to deviate from the checklist and then there isn't standardization. Standardized patients are less expensive, more available, and easier to train to be standardized. Studies have shown that physicians are unable to distinguish standardized

patients from real patients. Standardized patients are more accurate than physician raters. There is a one-way mirror in the exam rooms, so other observers can look in and assess the accuracy of the standardized patients' rating.

We believe we are enhancing patient protection by assessing communication skills and improving quality and safety. The educational validity of the exam is proven. The majority of medical schools now have clinical skills centers. Most use standardized patients for teaching. Most have clinical skills courses.

What do I worry about? In the exam, we often see "paint-by-the numbers" rote performance by examinees. However, real life situations are unique and test-taking strategies may not apply. Another thing that is concerning is that examinees may short-cut the exam because they know they won't find physical findings, such as a heart murmur. The exam does not effectively assess whether an examinee can discern abnormal findings. The exam is only a snapshot. It is not longitudinal, so I am not sure it will ever be able to assess whether an individual can distinguish abnormal from normal.

But, we are trying to assess whether an individual can synthesize and integrate all the information gathered from a patient. Another thing that is concerning is that this is a high-stakes exam, and just like any other important activity, there are secondary review courses that are money-makers.

We provide feedback in a grid that shows examinee's performance compared to national standards. However, they don't receive this feedback until 4-6 weeks after the test.

What is CSEC working on? Enhancements to the exam, such as counseling patients about behavioral change, delivering bad news, disclosing errors, negotiating a treatment plan which includes patient preferences, starting medication, health literacy, medication reconciliation, functional status assessments, communicating with more than one person in the room, using an interpreter, functioning in a team environment, hand-offs.

What is measured is important. Individuals and organizations change their behavior in the lens of high stakes examinations.

Potential opportunities include collaboration with specialty boards that provide assessments for certification, partnering with graduate medical education, partnering with certification and licensure to administer assessments for other professions.

Question: Please say something more about assessing practice teams.

Jobe: It is on the horizon, but we haven't settled on a protocol. We are thinking of assessing how a physician reacts when challenged by a standardized nurse or other team member. We would welcome input.

Question: What do you think about assessment using simulations?

Jobe: I am a proponent of simulations for educational purposes, but I'm not sure they would be effective in high-stakes exams, especially assessment of communication. I think simulations would be useful for longitudinal assessments.

Question: Please talk a bit about patient-physician communication.

Jobe: There is some literature showing that there are behaviors and communication patterns that lead to increased patient adherence and better outcomes. We are in the process of changing our scale to reflect the behaviors that are being used more consistently across disciplines and specialties. It doesn't take away from individual style, but there are some essential components of communication that we believe we can observe and assess. If a person can easily communicate findings, but is unable to develop respect and foster a relationship of trust, the outcome is not as positive.

We don't have data showing that outcomes are improved with good communication, but the Medical Council of Canada has had a clinical skills exam longer than we have and researchers have shown that there are improved clinical outcomes. The data also links those who did poorly on a communications scale with more substantive complaints to the licensing authority. I would like to do an outcomes study at NBME, but since we are changing the communications scale, it doesn't make sense to do a study based on the old scale.

Question: How do you see clinical skills assessment being used for continuing competence?

Jobe: I have had conversations with several of the specialty boards and encouraged them to use our test for initial certification, let alone recertification. I ask them if they are sure every one of their residency programs is of the same caliber and if they can guarantee every graduate is of the same competency. A few specialty boards are thinking about it. I don't know if they would use the test for recertification, but I think the place to start is initial certification. If we were to assess all the graduates in every specialty, we would probably have to establish some more centers incrementally.

Discussion: Points to Consider When Developing an Assessment Program

Cynthia Miller Murphy, Executive Director, Oncology Nursing Certification Corporation

ONCC is looking at improving our measurement of continuing competency. I am going to walk you through our decision-making process and identify questions we still have to answer.

I like a definition of competence that talks about knowledge and skills in the context of doing something successfully and applying prior experience to new situations with good

effect. Competence helps those around us feel more comfortable and inspires others to seek knowledge.

We can define competence, but how do we reliably measure it? ONCC's mission refers to having the knowledge to practice competently, but we aren't sure we can measure whether our certificants actually do.

When we began in 1986, we were one of the few nursing organizations that required recertification, by passing the test again. The pass rate was high, but the average recertification rate was only 59 percent, implying they weren't re-certifying because they didn't want to take the test.

In 2000, we launched a points renewal option, where nurses can acquire points in 7 or 8 different categories, one being CE, others being publishing a paper, teaching a course, earning academic credit, and so on – in addition to having the required number of practice hours. It has increased our recertification rate up to 74%. We still have 5% choosing to re-test. Those who aren't in active practice have to earn points and take the test.

Of the points, at least 60% must be in the oncology specialty. The problem is that an individual can get all his or her CE in one area or subspecialty. But, their credential says that they are certified broadly.

In 2010, we initiated a Mega-Issue discussion about "How should ONCC implement a more rigorous process for the measurement of continued competency?" We use an approach called "knowledge-based governance," which asks four important questions followed by dialogue about the pros and cons of all available choices.

Question 1: What do we know about our stakeholders' needs, wants and preferences that are relevant to this issue?

Our stakeholders fall into three groups: nurses, employers, and healthcare consumers. We know that nurses want to become certified and remain certified. We know they don't want to take a test again. Paying for certification is considered an obstacle by many of them. Half the nurses have their initial certification paid for by employers, but only 38% have their recertification paid for by their employers. We know that consumers think it is important to verify current competence.

Question 2: What do we know about the current realities and evolving dynamics of our stakeholders' environment that is relevant to the issue?

We looked at the economy, technology trends, and so on. We know there is a nursing shortage, but there are also unemployed nurses. We know computer-based testing and electronic recertification are very popular. The trend, as evidenced by the American Board of Medical Specialties, is toward much more rigorous recertification requirements. There is a drop-off in conference attendance, but an increase in electronic education.

Question 3: What do we know about the capacity and strategic position of our organization that is relevant to this issue?

We have a platform for our online practice tests, but don't have the capacity to administer an assessment tool in house. This will be a huge financial investment, but we are a stable organization. We have the human resources and can retain consultants to supplement.

Question 4: What are the ethical implications of our choices?

There isn't a lot of data to support any particular approach to recertification. We looked at consistency with our mission and the implications for quality and safety. We looked at our certificants' likely perception of our decisions and the effect on access to recertification.

We identified options and looked at the pros and cons of each. One option is to make no changes. Or, we could postpone changes until we have more data. We could require a portfolio, or require re-testing. We considered requiring CE in all areas of the test blueprint.

What we decided to require, with lots of advice and help from NCC, is individual learning needs assessment (ILNA) based on a blueprint and targeted CE related to results. We won't call this self-assessment, because the assessment will be administered and scored by ONCC. ONCC will instruct examinees as to what CE and other professional development activities they need to complete.

We formed another task group including consumers, educators, managers, and nurses in different roles. We decided there were many more benefits than barriers for all our stakeholders. We think if it is communicated well, nurses will think of it as an advantage. Most likely, most of them will need to obtain fewer points, but in targeted areas.

We know we will need many more volunteers for test development in each of our five active programs and two retired programs. It will require psychometrician and test vendors. We are evaluating proposals. We need to address legal issues, such as test security, reliability, and identification of CE sources in all the content areas.

We have a timeline that is fairly rapid. The assessment has to be available to certificants a couple of years prior to when we require them to use the system. New certificants will use the diagnostic score report for their certification exam to identify the CE needed for the first cycle.

Eventually, we will probably have to raise recertification fees because it will cost us more. We will be careful not to raise the fees at the time the ILNA is being launched. Communication and marketing will be very important, beginning in 2012, assuming that the program will be in effect in 2015.

We have a research team that is working on short- and long-term goals for the program and evaluation strategies. We want to be able to collect evidence related to outcomes measures. We may ask certificants to conduct a self-assessment after completing the assessment we administer to see if there is any correlation. It would be good data for us to have to demonstrate to our constituency why we want them to take the ILNA.

We need to develop something equally rigorous for those who refuse to take the assessment and for the holders of our two retired credentials. We want to offer a mechanism for the renewal of more than one credential at a time.

Question: What percent of oncology nurses are certified?

Miller-Murphy: We don't really know the universe, but we estimate that there are about 63,000 oncology nurses of whom we certify 32,000. The membership society has 35,000 members.

Question: Has your 74% recertification figure changed since 2000?

Miller-Murphy: That percentage has drifted to 74% since we put in the point system and as the certificants got used to the program.

Question: Have you thought of ways to incentivize certification and recertification?

Miller-Murphy: Recertification is mostly employer or workplace-driven. There is a program of "magnet recognition" for hospitals that promote professional nursing practice and pay for certification and recertification of their employees. Certified nurses can make up to $10,000.00 more per year. State boards will recognize certification as a way to meet re-licensure requirements. Nevertheless, our surveys show that oncology nurses get certified for intrinsic, not extrinsic reasons.

Question: The conversation today differentiated between pure self-assessment as opposed to more objective types of assessment using a tool. Objective assessment tools have to include feedback so examinees know where they didn't do well. Has anyone considered using volunteers from another geographic area to provide personalized feedback –similar to mentoring – to help people structure their continuing professional development plan?

Comment: The North Carolina Physical Therapy Board began developing a continuing competence program several years ago after hearing a keynote speaker from a Canadian pharmacy board. His view was that if professionals are "engaged" in their profession, it helps ensure competence. Our board developed a menu of activities, including CE, online courses, volunteerism, specialty certification, and so on. This was necessary in our state where development opportunities are not readily available in rural areas.

Miller-Murphy: I think engagement is changing and membership societies are recognizing that there will be fewer face-to-face encounters and more electronic engagement.

Attachment 3

DEPARTMENT OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Survey for Health Licensing Entites

Take the Survey

Office of Statewide Health Planning and Development is required to establish the California Healthcare Workforce Clearinghouse to serve as the central source for collection, analysis, and distribution of information on the healthcare workforce employment and educational data trends for the state. To assist in the collection efforts, the board is providing this voluntary survey to individuals licensed by the board.

This survey does not require disclosure of any personal identification information and is designed to collect information on workforce and education trends, to determine if future needs of the state will be met. The board thanks you for your participation.

This web site contains PDF documents that require the most current version of Adobe Reader to view. To download click on the icon below.

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DEPARTMENT OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Survey for Health Licensing Entities

1. Residence

Completion of survey helps determine health professionals' shortages and improves access to patient care.

Residence Location:

Residence County:

Residence ZIP:

Next

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BOARD OF PHARMACY

Survey for Health Licensing Entities

2. Work Location

If working more than 3 locations, provide information for the 3 locations where you spend the most time.
If not working skip to Page 5 (Education).
Work Location 1:

Number of years you have worked for this employer

Check box if self employed

- Self employed

Work Location

County:

ZIP:

Health Occupation:

Work hours per week at this location:

- 40+
- 30-29
- 20-29
- 10-19
- 1-9

Work setting:

- Acute care hospital
- Durable medical equipment/home care
- Long-term acute care/rehabilitation hospital/sub-acute care
- Skilled nursing facility
- Accredited education program

- Manufacturer/distributor
- Outpatient facility/physician's office/dentist's office
- Clinics/community health center

Other setting, please describe:

Work activities:

% Patient Care

% Research

% Teaching

% Administration

% Other

Prev Next

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BOARD OF PHARMACY

Survey for Health Licensing Entities

3. Work Location

Work Location 2:

Number of years you have worked for this employer:

Check box if self employed

- Self employed

Work Location

County:

ZIP:

Health Occupation:

Work hours per week at this location:

- 40+
- 30-29
- 20-29
- 10-19
- 1-9

Work setting:

- Acute care hospital
- Durable medical equipment/home care
- Long-term acute care/rehabilitation hospital/sub-acute care
- Skilled nursing facility
- Accredited education program
- Manufacturer/distributor

- Outpatient facility/physician's office/dentist's office
- Clinics/community health center

Other setting, please describe:

Work activities:

% Patient Care

% Research

% Teaching

% Administration

% Other

Prev Next

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BOARD OF PHARMACY

Survey for Health Licensing Entities

4. Work Location

Work Location 3:

Number of years you have worked for this employer:

Check box if self employed

- Self employed

Work Location

County:

ZIP:

Health Occupation:

Work hours per week at this location:

- 40+
- 30-29
- 20-29
- 10-19
- 1-9

Work setting:

- Acute care hospital
- Durable medical equipment/home care
- Long-term acute care/rehabilitation hospital/sub-acute care
- Skilled nursing facility
- Accredited education program
- Manufacturer/distributor

- Outpatient facility/physician's office/dentist's office
- Clinics/community health center

Other setting, please describe:

Work activities:

% Patient Care

% Research

% Teaching

% Administration

% Other

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BOARD OF PHARMACY

Survey for Health Licensing Entities

5. Education

List all degrees/certificates obtained

Are you presently pursuing additional credentials or certifications?

- No
- Yes

If so, program name/degree type

Expected year of completion

School/Institution address

School/Institution Name:	
Company:	
Address:	
Address 2:	
City/Town:	
State:	-- select state --
ZIP:	
Country:	

Prev Next

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DEPARTMENT OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Survey for Health Licensing Entities

6. Cultural/ethnic background

(you may select more than one)

Cultural/ethnic background

- ☐ African American/Black/African-Born
- ☐ American Indian/Native American/Alaskan Native
- ☐ Caucasian/White European/Middle Eastern
- ☐ Latino/Hispanic (If Latino/Hispanic, please select one of the following)
- ☐ Central American
- ☐ Cuban
- ☐ Mexican
- ☐ Puerto Recan
- ☐ South American
- ☐ Other Hispanic
- ☐ Asian (If Asian, please select one of the following)
- ☐ Cambodian
- ☐ Chinese
- ☐ Hmong
- ☐ Indian
- ☐ Indonesian
- ☐ Japanese
- ☐ Korean
- ☐ Laotian
- ☐ Malaysia
- ☐ Pakistani
- ☐ Singaporean
- ☐ Thai
- ☐ Vietnamese
- ☐ Other
- ☐ Native Hawaiian/Pacific Islander (If Native Hawaiian/Pacific Islander, please select one of the following)
- ☐ Fijian
- ☐ Filipino
- ☐ Guamanian
- ☐ Hawaiian
- ☐ Samoan
- ☐ Tongan
- ☐ Other Pacific Islander
- ☐ Other (not listed above)
- ☐ Decline to state

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BOARD OF PHARMACY

Survey for Health Licensing Entities

7. Foreign Language

Are you fluent in launguages other than English?
If yes:

- [ ] Verbal
- [ ] Written

Select language

- [ ] Afrikaans
- [ ] Albanian
- [ ] American Sign Language
- [ ] Amharic
- [ ] Apache
- [ ] Arabic
- [ ] Armenian
- [ ] Bantu
- [ ] Bengali
- [ ] Bisayan
- [ ] Bulgarian
- [ ] Burmese
- [ ] Cajun
- [ ] Cambodian
- [ ] Cantonese (Yue Chinese)
- [ ] Chamorro
- [ ] Cherokee
- [ ] Croatian
- [ ] Czech
- [ ] Dakota
- [ ] Danish
- [ ] Dutch
- [ ] Haitian Creole
- [ ] Hebrew
- [ ] Hindi
- [ ] Hmong
- [ ] Hsiang (Xiang Chinese)
- [ ] Hungarian
- [ ] Ibo
- [ ] Ilocano/Iloko
- [ ] Indonesian
- [ ] Italian
- [ ] Japanese
- [ ] Kannada
- [ ] Keres
- [ ] Korean
- [ ] Kru
- [ ] Kurdish
- [ ] Lao
- [ ] Lettish
- [ ] Lithuanian
- [ ] Macedonian
- [ ] Malayalam
- [ ] Mandarin
- [ ] Pashto
- [ ] Patois
- [ ] Persian
- [ ] Polish
- [ ] Purtuguese
- [ ] Rumanian
- [ ] Russian
- [ ] Samoan
- [ ] Sebuano
- [ ] Serbian
- [ ] Serbo-Croatian
- [ ] Sinhalese
- [ ] Slovak
- [ ] Spanish
- [ ] Swahili
- [ ] Swedish
- [ ] Syriac
- [ ] Tagalog
- [ ] Tamil
- [ ] Telugu
- [ ] Thai
- [ ] Tonga

- [ ] Farsi
- [ ] Fijian
- [ ] Finnish
- [ ] Formosan (Amis)
- [ ] French
- [ ] French Creole
- [ ] German
- [ ] Greek
- [ ] Gujarati
- [ ] Mande
- [ ] Marathi
- [ ] Marshallese
- [ ] Mien (Lu Mien)
- [ ] Mon-Khmer
- [ ] Norwegian
- [ ] Navajo
- [ ] Nepali
- [ ] Panjabi (Punjabi)
- [ ] Turkish
- [ ] Ukrainian
- [ ] Urdu
- [ ] Vietnamese
- [ ] Yiddish
- [ ] Yoruba
- [ ] Other (not listed)
- [ ] Decline to state

Prev Next

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BOARD OF PHARMACY

Survey for Health Licensing Entities

8. Retirement

I plan to retire:

- Within the next 2 years
- Within the next 5 years
- Within the next 10 years
- Not planning to retire within the next 10 years
- Already retired
- Retired, work part time
- Plan to work part time

Prev Done

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Attachment 4

Board of Pharmacy Licensing Statistics - Fiscal Year 2011/12

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	153	144	105										402
Pharmacist (initial licensing applications)	149	449	90										688
Intern pharmacist	36	474	389										899
Pharmacy technician	929	1127	1054										3110
Pharmacy	23	35	27										85
Pharmacy Exempt	0	0	0										0
Pharmacy - Temp	11	14	6										31
Sterile Compounding	0	9	2										11
Sterile Compounding - Exempt	0	0	0										0
Sterile Compounding - Temp	0	4	0										4
Nonresident Sterile Compounding	1	1	2										4
Clinics	3	3	9										15
Clinics Exempt	0	0	0										0
Hospitals	1	1	0										2
Hospitals Exempt	0	0	0										0
Hospitals - Temp	0	0	0										0
Drug Room	0	0	0										0
Drug Room Exempt	0	0	0										0
Nonresident Pharmacy	4	5	5										14
Nonresident Pharmacy - Temp	1	0	3										4
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	0	2	0										2
Hypodermic Needle and Syringes Exempt	0	0	0										0
Nonresident Wholesalers	7	11	7										25
Nonresident Wholesalers - Temp	1	0	0										1
Wholesalers	5	8	10										23
Wholesalers Exempt	0	0	0										0
Wholesalers - Temp	1	1	0										2
Veterinary Food-Animal Drug Retailer	0	0	1										1
Veterinary Food-Animal Drug Retailer - Temp	0	0	0										0
Designated Representatives	53	53	67										173
Designated Representatives Vet	0	1	1										2
Total	1378	2342	1778	0	0	0	0	0	0	0	0	0	5498

Board of Pharmacy Licensing Statistics - Fiscal Year 2011/12

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Issued													
Pharmacist	125	437	113										675
Intern pharmacist	40	229	296										565
Pharmacy technician	554	730	1200										2484
Pharmacy	18	22	27										67
Pharmacy - Exempt	0	0	1										1
Pharmacy - Temp	0	0	0										0
Sterile Compounding	2	2	2										6
Sterile Compounding - Exempt	0	0	0										0
Sterile Compounding - Temp	0	0	0										0
Nonresident Sterile Compounding	2	2	4										8
Clinics	1	2	7										10
Clinics Exempt	1	0	0										1
Hospitals	1	0	0										1
Hospitals Exempt	0	0	0										0
Hospitals - Temp	0	0	0										0
Drug Room	0	0	1										1
Drug Room Exempt	0	0	0										0
Nonresident Pharmacy	3	1	5										9
Nonresident Pharmacy - Temp	0	0	0										0
Licensed Correctional Facility	1	0	0										1
Hypodermic Needle and Syringes	3	2	2										7
Hypodermic Needle and Syringes Exempt	0	0	0										0
Nonresident Wholesalers	9	10	6										25
Nonresident Wholesalers - Temp	0	0	0										0
Wholesalers	4	5	10										19
Wholesalers Exempt	0	1	0										1
Wholesalers - Temp	0	0	0										0
Veterinary Food-Animal Drug Retailer	0	0	0										0
Veterinary Food-Animal Drug Retailer - Temp	0	0	0										0
Designated Representatives	30	51	65										146
Designated Representatives Vet	0	0	2										2
Total	794	1494	1741	0	0	0	0	0	0	0	0	0	4029

Board of Pharmacy Licensing Statistics - Fiscal Year 2011/12

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending													
Pharmacist (exam applications)	721	538	566										566
Pharmacist (eligible)	1407	1218	163										163
Intern pharmacist	146	358	475										475
Pharmacy technician	4712	4701	4681										4681
Pharmacy	80	89	84										84
Pharmacy - Exempt	0	0	0										0
Pharmacy - Temp	0	0	0										0
Sterile Compounding	8	15	15										15
Sterile Compounding - Exempt	0	0	0										0
Sterile Compounding - Temp	0	0	0										0
Nonresident Sterile Compounding	13	12	10										10
Clinics	7	8	10										10
Clinics - Exempt	7	7	9										9
Hospitals	2	2	3										3
Hospitals - Exempt	0	0	0										0
Hospitals - Temp	0	0	0										0
Drug Room	2	2	1										1
Drug Room - Exempt	0	0	0										0
Nonresident Pharmacy	44	45	45										45
Nonresident Pharmacy - Temp	0	0	0										0
Licensed Correctional Facility	0	0	0										0
Hypodermic Needle and Syringes	7	7	5										5
Hypodermic Needle and Syringes - Exempt	0	0	0										0
Nonresident Wholesalers	77	79	81										81
Nonresident Wholesalers - Temp	0	0	0										0
Wholesalers	52	55	55										55
Wholesalers - Exempt	2	1	1										1
Wholesalers - Temp	0	0	0										0
Veterinary Food-Animal Drug Retailer	0	0	1										1
Veterinary Food-Animal Drug Retailer - Temp	0	0	0										0
Designated Representatives	237	230	237										237
Designated Representatives Vet	4	5	2										2
Total	7528	7372	6444	0	0	0	0	0	0	0	0	0	6444

Board of Pharmacy Licensing Statistics - Fiscal Year 2011/12

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Change of Pharmacist-in-Charge***													
Received	95	145	122										362
Processed	167	152	66										385
Pending	423	416	472										472
Change of Exemptee-in-Charge***													
Received	5	13	14										32
Processed	11	23	1										35
Pending	179	169	182										182
Change of Permits													
Received	33	70	68										171
Processed	43	40	28										111
Pending	209	239	279										279
Discontinuance of Business***													
Received	4	0	0										4
Processed	37	2	0										39
Pending	146	144	144										144
	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY*	JUN*	FYTD
Renewals Received													
Pharmacist	1238	1811	1472										4521
Pharmacy technician	1875	2871	2235										6981
Pharmacy	112	246	290										648
Pharmacy - Exempt	0	0	53										53
Sterile Compounding	8	15	16										39
Sterile Compounding - Exempt	0	0	2										2
Nonresident Sterile Compounding	7	11	13										31
Clinics	63	90	71										224
Clinics - Exempt	3	2	21										26
Hospitals	14	23	23										60
Hospitals - Exempt	0	0	35										35
Drug Room	2	1	0										3
Drug Room - Exempt	0	1	3										4
Nonresident Pharmacy	32	34	22										88
Licensed Correctional Facility	0	0	16										16
Hypodermic Needle and Syringes	14	27	0										41
Hypodermic Needle and Syringes - Exempt	0	0	0										0
Nonresident Wholesalers	38	45	22										105
Wholesalers	32	52	33										117
Wholesalers - Exempt	0	0	2										2
Veterinary Food-Animal Drug Retailer	1	2	2										5
Designated Representatives	165	248	179										592
Designated Representatives Vet	6	8	1										15
Total	3610	5487	4511	0	0	0	0	0	0	0	0	0	13608

Attachment 5

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

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING
MINUTES

DATE: September 26, 2011

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT:
Greg Lippe, Public Member, Chair
Ryan Brooks, Public Member
Rosalyn Hackworth, Public Member
Deborah Veale, RPh

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, Supervising Inspector
Kristy Shellans, DCA Staff Counsel
Tessa Miller, Staff Analyst

Call to Order

Committee Chair Greg Lippe called the meeting to order at 9:35 a.m.

Chair Lippe conducted a roll call. Committee Members Lippe, Veale, Brooks, and Hackworth were present.

Board President Stanley Weisser was in attendance in the audience.

The committee discussed agenda items out of order.

2. Discussion Concerning Proposed Modifications to California Business and Professions Code Section 4209 Regarding Reporting of Intern Hours to the Board of Pharmacy

Chair Report

Chair Lippe provided that Business and Professions Code (B&PC) section 4209 specifies that an intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination. He stated that this section also specifies that an intern pharmacist shall submit proof of his or her experience on a board-approved affidavit and established the criteria for submission.

Chair Lippe provided that until last year, the board accepted intern hours earned in another state, if the hours were either:

1. Verified by the state board of pharmacy in which the hours were earned or
2. Submitted board affidavits from each pharmacy where the intern has worked.

Chair Lippe provided that after recent review of this policy, it was noted that this intern hour verification was contrary to legal requirements established in B&PC section 4209(b). The result using only option #2 is a significant increase in staff resources to review the intern affidavits, not only regarding the separate hours earned by each intern, but also each pharmacist providing verification of the experience earned.

Chair Lippe provided that that staff recommends an amendment to 4209(b) to allow the board to accept verification from other state boards of pharmacy which will streamline our application process. He reviewed the proposed text provided below:

> 4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam
>
> (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.
>
> (2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.
>
> (b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. <u>Intern hours earned in another state may be certified by the licensing agency of that state to document proof of such hours.</u>

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

Discussion
Committee Member Deborah Veale offered a proposal to recommend to the board to sponsor legislation to modify the section as proposed.

Public Comment
Steve Gray, representing Kaiser Permanente, expressed concern regarding subdivision (c) regarding experience obtained by an applicant licensed as a pharmacist in another state. He discussed that licensure in another state does not necessarily indicate that the applicant has experience working in a pharmacy. Dr. Gray suggested that an additional affidavit be required to certify that these individuals have experience working in a pharmacy.

Executive Officer Virginia Herold indicated that there are at least two states that do not require intern hours.

Assistant Executive Officer Anne Sodergren discussed that intern hour requirements vary by state. She advised that accreditation requirements for schools of pharmacy in all states include a specified amount of hours working in a pharmacy. Ms. Sodergren discussed that if an additional affidavit is required as suggested, applicants licensed in another state would have an additional criterion to meet that is not required for applicants in California.

Ms. Sodergren clarified that the amendment does not impact the current requirements under Section 1728 that prior to receiving authorization from the board to take the pharmacist licensure exam, applicants must submit proof of 1500 hours of pharmacy practice. She indicated that this requirement must be satisfied with a minimum of 900 hours of pharmacy practice experience obtained in a pharmacy and a maximum of 600 hours of pharmacy practice experience substantially related to the practice of pharmacy.

Discussion continued regarding the importance of training and experience earned in a pharmacy. Ms. Veale amended her proposal to expand the proposed modification to subdivision (c).

MOTION: Recommend to the board to sponsor legislation to modify Business and Professions Code section 4209 as provided below.

4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam

(a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of such hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

M/S: Veale/Hackworth

Support: 4 Oppose: 0 Abstain: 0

3. Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Chair Report

Chair Lippe provided that at several prior meetings of the board or its committees, there has been general discussion about developing requirements for pharmacists to earn continuing education (CE) in specific subject matter areas. He stated that to establish such a requirement would take either a legislative or regulation change.

Chair Lippe provided that prior discussions have included possible mandatory CE in emergency/disaster response, patient consultation, drug abuse or in maintaining control of a pharmacy's drug inventory. He stated that any topic the board determines as appropriate for mandatory CE should have generally broad-based applicability for pharmacists.

Chair Lippe provided that at the February 2011 Board Meeting, the board directed that the committee continue its discussion about such a requirement and specified that if the recommendation is approved, authorize staff to investigate implementation.

Chair Lippe provided that B&PC section 4231 requires a pharmacist to earn 30 hours of approved continuing education credit every two years as a condition of renewal.

Chair Lippe provided that B&PC section 4232 specifies that content of courses that will be acceptable including the following:

- Pharmacology
- Biochemistry
- Physiology
- Pharmaceutical chemistry
- Pharmacy Administration
- Pharmacy Jurisprudence
- Public health and communicable diseases
- Professional practice management
- Anatomy
- Histology

Chair Lippe provided that the committee has heard a presentation from two pharmacy directors of California counties' emergency response team and how such a topic would be applicable as an appropriate mandatory CE course. He stated that additional suggested topics also brought to the committee for consideration included the following:

- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Patient Consultation
- Ethics
- Drug Abuse
- Defined Content Areas
- Certification in a pharmacist specialty by a accreditation agency

Chair Lippe provided that the committee has also heard comments about content specific course mandates and CE in general, and whether a portion of CE be obtained in specific manner (e.g. live, web-based, journal, etc.).

<u>Discussion</u>
Ms. Herold suggested that the board consider pursing this change by regulation rather than by statute. She also suggested that preferential credits can be awarded to encourage licensees to earn CE in specific content areas of higher importance.

Ms. Veale indicated that the California Pharmacists Association (CPhA) has indicated that they are in opposition to mandating CE in specific content areas. She asked if specific CE is required in any other state.

Ms. Herold indicated that several states require specific CE coursework. She provided that the Medical Board has also required specific CE. Ms. Herold discussed that specific content areas should be broad, such as ethics or substance abuse, in order to benefit pharmacists practicing in a variety of settings.

Ms. Veale and Committee Member Rosalyn Hackworth spoke in support of considering substance abuse as a specific content area to address the board's discipline cases in this area.

Ms. Veale suggested that licensees be able to choose one or two content areas from a specified list.

DCA Staff Counsel Kristy Shellans provided that she disagrees with the recommendation to pursue this change by regulation. She stated that mandating CE in specific content areas will require statutory change.

Ms. Shellans discussed that incentivizing specific CE is an option the board can explore.

Ms. Veale offered a proposal that the board direct staff to research implementing incentives for licensees who earn CE in specific content areas. She also suggested that the board reconsider and possibly decrease the amount of CE a licensee can earn by attending meetings of the board.

Public Comment
Steve Gray, representing Kaiser Permanente, spoke in support of the proposal and also encouraged the board to also consider pursuing a statutory change to require CE in specific content areas.

Committee Member Ryan Brooks asked if the board can provide guidance on recommended content areas without pursing a statutory change.

Ms. Shellans provided that Section 4232 provides flexibility with respect to the subject matters of the courses and the board can provide guidance in this area. She clarified that a statutory change is needed to mandate specific content areas.

Mr. Brooks requested that board staff explore this option.

Ms. Herold discussed that the board can encourage specific content areas in *The Script.*

MOTION: Direct staff to research implementing incentives for licensees who earn CE in specific content areas including ethics, substance abuse, emergency/disaster response and patient consultation. Recommend that the board reconsider and possibly decrease the amount of CE a licensee can earn by attending meetings of the board.

M/S: Veale/Hackworth

Support: 4 Oppose: 0 Abstain: 0

The committee discussed CE formats including live, web-based, etc. It was clarified that requiring that licensees earn CE in a specific format would require a statutory change.

Ms. Shellans expressed concern regarding restricting how licensees can obtain CE as this issue has lead to a lawsuit for another board in the department. She advised that the board should be cautious about approaching this option.

Additional Public Comment
Steve Gray provided comment regarding the increasing degradation of the quality and value of CE. He discussed that CE, whether it is live or by another means, can be abused. Dr. Gray suggested that CE include an assessment to encourage active participation. He also suggested that the board consider proctored CE and encouraged the board to continue discussions to address this issue.

1. Review of Requests for Board Action to Become a Board of Pharmacy Approved Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies

Background
California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are:
1. already licensed pharmacies, and
2. compound injectable sterile drug products.

These specialized pharmacies may be either hospital pharmacies or community pharmacies. As a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. This is the only category of board licensure that requires annual inspections as a condition of renewal.

The board has over 240 such licensed facilities in California, and approximately 90 nonresident pharmacies with such permits.

However, there is an exemption in existing law from this specialty category of board licensure for pharmacies if:
- the pharmacy is licensed by the board or the Department of Public Health

AND

- the pharmacy is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

There are three accreditation agencies approved by the board: 1. Accreditation Commission for Health Care, Inc (ACHC), 2. Community Health Accreditation Program (CHAP), and Det Norske Veritas (DNV).

The board also has specific regulation requirements to be followed by all pharmacies that perform sterile injectable compounding duties whether licensed by the board or accredited by one of three accreditation agencies. At the beginning of 2010, the board modified its regulations for pharmacies that compound medication. Included in these requirements are modified requirements for pharmacies that compound sterile injectable medication.

In 2003, the Licensing Committee developed criteria for approval of accreditation agencies for sterile injectable compounding pharmacies under Business and Professions Code section 4127.1, and generally that these criteria should assess the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors:

1. Periodic inspection -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years. (Note during 2011 discussions with the accrediting agencies, the board urged annual inspections during the review process.)
2. Documented accreditation standards -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. Evaluation of surveyor's qualifications -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. Acceptance by major California payers -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. Unannounced inspection of California accredited sites -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. Board access to accreditor's report on individual pharmacies.
7. Length of time the accrediting agency has been operating.
8. Ability to accredit out-of-state pharmacies. Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

During prior reviews of the accrediting agencies, board staff were directed to (1) review and assess all accreditation agencies seeking board approval as accrediting agencies for sterile injectable compounding pharmacies, (2) bring staff’s report to a future

Licensing Committee Meeting, and (3) bring the committee's recommendations to the board for action at a future meeting.

Discussion

Supervising Inspector Janice Dang reviewed requests from two additional organizations seeking to become board-approved accrediting agencies for sterile injectable compounding pharmacies. She introduced Michael Zarski and Andrew Lowe, representing the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP), and Joe Cabaleiro, representing Pharmacy Compounding Accreditation Board (PCAB).

Mr. Zarski and Mr. Cabaleiro each provided an overview of their request and of their resepective organizations.

Dr. Dang provided an overview of her findings from an application review for both organizations. A copy of this review is attached, following this meeting summary.

Dr. Dang reviewed results of random inspections of two pharmacies accredited by each organization. She discussed that three of the four inspections were good with only minor corrections ordered. Dr. Dang reviewed her concerns with the inspection of the second pharmacy accredited by HFAP. She explained that this pharmacy had not addressed any discussion points pointed out during a previous inspection by the board about three months prior to her inspection. She stated that these issues were also not addressed by the HFAP survey team during their survey a week prior to Dr. Dang's inspection of the pharmacy.

Ms. Veale requested that HFAP research Dr. Dang's findings of the second HFAP accredited pharmacy and submit a written analysis to the board.

The committee discussed these findings and considered the organizations currently recognized by the board and the requirements set forth prior to their recognition as an accreditation agency. Both organizations were asked to respond to the following requirements:

- Survey teams will include a pharmacist.

  Mr. Zarski discussed that he believes that an organization already recognized by the board does not have a pharmacist on the survey team. He asked that the standards for all organizations be fair and consistent. Mr. Zarski indicated that it would take some time to restructure its survey teams to include a pharmacist.

  Mr. Cabaleiro provided that PCAB surveyor teams consist of all pharmacists.

  The committee discussed whether other organizations have committed to having a pharmacist on the survey team. Ms. Herold indicated that she will confirm and report back to the committee.

- Agency agrees to provide the board access to accreditation reports.

  Mr. Zarski discussed that HFAP will report deficiencies, serious noncompliance and denial or withdrawls of accreditation to the board.

  Mr. Cabaleiro provided that PCAB will notify the board regarding noncompliance and situations where a pharmacy's accreditation is denied or revoked.

  Ms. Herold provided comment on the importance of communication between the board and accreditation agencies, specifically regarding issues impacting patient safety.

  Ms. Shellans discussed that access to accreditation reports is critical to ensure patient safety and to verify that the accreditation agency is operating appropriately. She advised that the board needs to have access to these reports.

  The committee requested clarification regarding whether the other organizations currently recognized by the board have committed to sharing access to these reports.

- Agency agrees to conduct an annual inspection of each pharmacy.

  Mr. Zarski discussed that routine inspections will impact efficiency and lead to additional costs for the pharmacies. He stated that HFAP will conduct annual inspections if required by the board.

  Mr. Cabaleiro also discussed that annual inspections would increase costs for accreditation. He suggested that the board consider random inspection of ten percent of the pharmacies each year. He questioned whether other organizations have agreed to this annual inspection requirement.

  Ms. Herold discussed that the board requires annual inspections of accredited pharmacies to ensure a comparable standard of licensure by the board.

The committee discussed that clarification is needed regarding the requirements agreed to by other accreditation agencies recognized by the board. Staff agreed to research and report back to the committee.

Mr. Brooks suggested that the board establish clear guidelines for all accreditation agencies to follow.

Ms. Veale suggested that board staff develop a comparison of the current accreditation agencies and HFAP and PCAB to review and compare all criteria assessed during the application review and the requirements agreed to prior to recognition. She requested that the comparison be reviewed by the board at the October 2011 Board Meeting.

Ms. Hackworth provided comment in support of this comparison and stated that all organizations should be held to the same standard.

Chair Lippe advised that the board may approve accreditation of HFAP and PCAB after confirmation that they meet the same standards as required by the other accreditation agencies.

Mr. Brooks thanked Mr. Zarski and Mr. Cabaleiro for appearing before the committee. He indicated that the board will send a letter to notify them of the board's decision once the review is completed and the board approves each as a recognized accreditation agency.

Ms. Shellans recommended that the board establish guidelines for accreditation agencies prior to granting approval.

Mr. Cabaleiro provided comment regarding the variance in programs and procedures of the various accreditation agencies. He requested that the board takes this variance into consideration when conducting its comparison.

No public comment was provided.

MOTION: Direct board staff to develop a comparison of the current accreditation agencies and HFAP and PCAB to review and compare all criteria assessed during the application review and the requirements agreed to prior to recognition to be reviewed by the board at the October 2011 Board Meeting.

M/S: Veale/Hackworth

Support: 4 Oppose: 0 Abstain: 0

MOTION: Recommend to the board to conditionally approve HFAP and PCAB as accreditation agencies pending confirmation that they meet the requirements of other accreditation agencies recognized by the board and the guidelines established for all accreditation agencies to follow at the October 2011 Board Meeting.

M/S: Brooks/Veale

Support: 4 Oppose: 0 Abstain: 0

4. Discussion Concerning DCA's Focus on Continuing Competency

Discussion
Chair Lippe provided that the Department of Consumer Affairs has asked all boards to evaluate how they can ensure the continued competency of their practitioners.

Ms. Shellans advised that the board will be evaluated in this area during the upcoming sunset review process.

Ms. Herold provided that the National Association of Boards of Pharmacy (NABP) is developing an assessment for the board to use to evaluate competency. She advised that this assessment will be available in 2012 and will satisfy the department's requirement for continuing competency.

It was the consensus of the committee to defer this item to be discussed at the upcoming Board Meeting in October 2011.

No public comment was provided.

5. Office of Statewide Health Planning and Development's Manpower Assessment and Survey of Licensees

Background
As part of Senate Bill 139 (Chapter 522, Statutes of 2007) the Office of Statewide Health Planning and Development (OSHPD) was directed to establish the California Healthcare Workforce Clearinghouse (Clearinghouse) to serve as the central source for collection, analysis, and distribution of information on the healthcare workforce employment and educational data trends for the state.

Chair Report
Chair Lippe provided that the Licensing Committee of the board has discussed possible implementation strategies to assist OSHPD with their collection efforts. He stated that as the board has neither a statutory or regulatory mandate to collect this data, nor are licensees required to provide this information as a condition of licensure or renewal, implementation efforts are limited.

Chair Lippe provided that the committee was advised in March 2011 that the department was working with OSHPD on the development of a survey and that the board could provide a link via our website. He advised that board staff was advised that the department is no longer moving towards such implementation. Chair Lippe explained as a result, this item will be brought back to the Licensing Committee and the full board to discuss alternate implementation strategies.

Chair Lippe stated that as mandating submission of this information would require either a regulation and/or statutory change, board staff recommends that the board consider

development of a survey that could be accessed from the board's Web site. He discussed that an on-line resource such as Survey Monkey, could serve as an easy collection method that would have minimal impact on board staff.

Chair Lippe reviewed the following data to be collected:
(a) The current supply of health care workers, by specialty.
(b) The geographical distribution of health care workers, by specialty.
(c) The diversity of the health care workforce, by specialty, including, but not necessarily limited to, data on race, ethnicity, and languages spoken.
(d) The current and forecasted demand for health care workers, by specialty.
(e) The educational capacity to produce trained, certified, and licensed health care workers, by specialty and by geographical distribution, including, but not necessarily limited to, the number of educational slots, the number of enrollments, the attrition rate, and wait time to enter the program of study.

Discussion
Mr. Brooks suggested that survey participation be incentivized to increase participation.

Ms. Sodergren discussed that this issue will also be addressed during the Board's sunset review. She asked the committee to consider first deploying the survey to begin collecting that data and then to later create an incentive for participation.

Ms. Shellans discussed that in this case, California law prohibits collection of personal data if it can be linked back to the individual who provided the data. She recommended that the survey not record the participant's license number or any other personal data.

Mr. Brooks recommended that a disclosure regarding voluntary participation be added to the survey.

Ms. Shellans offered to identify possible disclosure language for the survey.

Ms. Sodergren stated that she will work with board counsel on the survey to be reviewed by the board at the October 2011 Board Meeting.

No public comment was provided.

6. Competency Committee Report

Chair Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Chair Lippe provided that the board instituted a quality assurance review of the CPJE effective August 8, 2011. He stated that this process is done periodically to ensure the reliability of the examination. Chair Lippe indicated that as of the date of this report, the quality assurance review is still under review. He stated that the board anticipates releasing results by the beginning of October 2011.

Examination Development

Chair Lippe provided that both Competency Committee workgroups met in August 2011 at the annual meeting to discuss examination development. He stated that each Competency Committee workgroup will also meet once in the fall of 2011 for examination development.

There was no committee discussion or public comment.

7. Licensing Statistics

Chair Lippe referenced the licensing statistics that were provided to the committee. A copy of the statistics are attached, following this meeting summary.

There was no committee discussion or public comment.

8. Public Comment for Items Not on the Agenda

Steve Gray, representing Kaiser Permanente, provided comment regarding fraud and licensing of pharmacies. He suggested that this issue be discussed at a future meeting.

The meeting was adjourned at 12:22 p.m.

Attachment 6

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within three working days of a completed application by June 30, 2011.
Measure:	Percentage of licenses issued within three work days.
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt.

	# of Apps. Received:				Average Days to Process:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	402				34			
Pharmacist (initial licensing)	668				9			
Pharmacy Intern	899				12			
Pharmacy Technician	3,110				67			
Pharmacies	85				20			
Non-Resident Pharmacy	14				25			
Wholesaler	23				29			
Veterinary Drug Retailers	1				1			
Designated Representative	175				33			
Out-of-state distributors	25				32			
Clinics	15				19			
Hypodermic Needle & Syringe Distributors	2				20			
Sterile Compounding	15				18			
Change of Permit	171				30			
Pharmacist in Charge	362				30			
Designated Representative in Charge	32				30			
Discontinuance of Business	39				30			

2. Process 100 percent of all deficiency documents within five work days of receipt.

	Average Days to process deficiency:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	3			
Pharmacist (initial licensing)	3			
Pharmacy Intern	2			
Pharmacy Technician	24			
Pharmacies	5			
Non-Resident Pharmacy	6			
Wholesaler	6			
Veterinary Drug Retailers	6			
Designated Representative	6			
Out-of-state distributors	6			
Clinics	5			
Hypodermic Needle & Syringe	6			

3. Make a licensing decision within three work days after all deficiencies are corrected.

	Average Days to Determine to Deny/Issue License:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	2			
Pharmacist (initial licensing)	2			
Pharmacy Intern	5			
Pharmacy Technician	2			
Pharmacies	5			
Non-Resident Pharmacy	5			
Wholesaler	5			
Veterinary Drug Retailers	5			
Designated Representative	5			
Out-of-state distributors	5			
Clinics	5			
Hypodermic Needle & Syringe	5			

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

	Licenses Issued:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	675			
Pharmacy Intern	565			
Pharmacy Technician	2,484			
Pharmacies	70			
Non-Resident Pharmacy	9			
Wholesaler	20			
Veterinary Drug Retailers	0			
Designated Representative	148			
Out-of-state distributors	25			
Clinics	11			
Hypodermic Needle & Syringe	7			
Sterile Compounding	14			

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	121			
Pharmacies	0			
Non-Resident Pharmacy	5			
Clinics	0			
Sterile Compounding	0			
Designated Representative	6			
Hypodermic Needle & Syringe	0			
Out-of-state distributors	0			
Wholesaler	0			
Veterinary Drug Retailers	0			
Registered Pharmacist	0			
Intern Pharmacist	0			

6. Deny applications to those who do not meet California standards.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	2			
Intern Pharmacist	0			
Pharmacy Technician	14			
Pharmacies	0			
Non-Resident Pharmacy	1			
Clinics	0			
Sterile Compounding	0			
Designated Representative	1			
Hypodermic Needle & Syringe	0			
Out-of-state distributors	0			
Wholesaler	0			

7. **Responding to e-mail status requests and inquiries to designated e-mail addresses.**

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	2,501			
Pharmacy Technicians	3,653			
Site licenses (pharmacy, clinics)	1,002			
Site licenses (wholesalers, nonresident pharmacies)	1,159			
Pharmacist in Charge	257			
Renewals	372			

8. **Responding to telephone status request and inquiries.**

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	*			
Pharmacy Technicians	*			
Site licenses (pharmacy, clinics)	468			
Site licenses (wholesalers, nonresident pharmacies)	122			
Pharmacist in Charge	93			
Renewals	2,380			

* Voicemail status requests have been suspended to allow staff time to focus on processing applications and issuing licenses

Objective 2.2	Cashier 100 percent of all revenue received within two working days of receipt by June 30, 2011.
Measure:	Percentage of revenue cashiered application within 2 working days.

Tasks:

	Revenue Received:				Average Days to Process:			
	*Qtr 1	Qtr 2	Qtr 3	Qtr 4*	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Applications	457,041				4			
Renewals	1,607,099				4			
Cite and Fine	223,625				5			
Probation/ Cost Recovery	69,591				5			
Request for Information/ License Verification	3,375				7			
Fingerprint Fee	26,775				5			

* 1st quarter reflects July and August 2011 data available at the time of report development.

Objective 2.3	Update 100 percent of all information changes to licensing records within five working days by June 30, 2011.
Measure:	Percentage of licensing records changes within five working days.
Tasks:	

	Requests Received:				Average Days to Process:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Address/Name Changes	3,378				1			
Off-site Storage Applications (approved)	24				20			
Transfer of Intern Hours to Other States	45				6			

Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	1. Determine why 26 states do not allow the use of a CA license as the basis for transfer of pharmacist license to that state. *Jan. 2007:* *Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated.* *March 2007:* *Pennsylvania agrees to accept California NAPLEX scores.* *May 2007:* *At National Association of Boards of Pharmacy meeting several states agree to reconsider their position against accepting California scores.* 2. Evaluate the drug distribution system of clinics and their appropriate licensure. *1st Qtr 09/10:* *Continued to advise clinics and their advocates about the barrier the Capen decision places on surgicenters/clinics from obtaining a board clinic permit. A legislative solution is needed.* *3rd Qtr 09/10:* *Board hears presentation by Fort Sutter Surgery Center discussing the issue.* 3. Work with the Department of Corrections on the licensure of pharmacies in prisons. *June 2007:* *Meet with the Department of Corrections Receiver to discuss possible regulatory structures for drug dispensing and distribution within correctional facilities.* *Oct. 2008:* *Board staff meet with Department of Corrections staff to develop regulatory structure for prisons.* *Dec. 2008:* *Met with receiver for correctional facilities to discuss regulatory structure.* *1st Qtr 10/11:* *Governor includes provisions for pharmacy services in prisons.* *3rd Qtr 10/11:* *Legislation introduced to include some changes. (AB 389, Lowenthal)* *4th Qtr 10/11:* *AB 389 amended and no longer addressing licensure issue.* 4. Work with local and state officials on emergency preparedness and planning for pandemics and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. *2nd Qtr 09/10:* *Board votes that in declared emergencies where a board meeting cannot quickly be scheduled, a subcommittee of three members can make decisions for patient safety under provisions of Business and Professions Code section 4062 and the board's emergency response policy.* *4th Qtr 09/10:* *Licensing continued reviewing requests from CDPH seeking clarification on board disaster response policy.* *2nd Qtr 10/11:* *Discussion of the California Hospital Association's repopulation after hospital evacuation guidelines and checklist at Licensing Committee Meeting.* *3rd Qtr 10/11:* *Board discussed its role in repopulation of hospitals in working with the CDPH to inspect the pharmacy to validate that there are appropriate safeguards to ensure the safety of the drugs.* *Licensing Committee hosts a presentation on emergency preparedness during quarterly meeting. Committee discusses need for possible mandatory CE in this area.* 5. Evaluate the need to issue a provisional license to pharmacy technician trainees. *Dec. 2010:* *Update on the board's psychometric evaluation for the ExCPT and PTCB at the Licensing Committee.*

	6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. *Sep. 2006:* *Committee hears presentation on ExCPT exam approved for certification of technicians by five states. Committee directs staff to evaluate exam for possible use in California.* *Dec. 2006:* *DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.* *March 2007:* *DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.* *May 2007:* *Board seeks private contractor to evaluate both ExCPT and PTCB exams for job validity.* *Sep. 2007:* *Board required to check with other state agencies to ensure that state-employed PhD psychometricians are not able to perform this review before the board can contract for services. Committee recommends delay until CSHP and CPhA complete their review of pharmacy technician training and knowledge.* *Oct. 2007:* *Board postpones work on this topic until CSHP and CPhA complete their review.* *March 2009:* *Board executive staff meet with the executive director of the ExCPT exam.* *April 2009:* *Board directs staff to secure a psychometric review of both the PTCB and ExCPT exams, in wake of AB 418 being stalled in the legislature.* *2nd Qtr 09/10:* *Board initiates discussions with DCA regarding use of their Ph.D to evaluate the validation studies.* *2nd Qtr 10/11:* *DCA psychometric expert initiates review of PTCB and ExCPT exams.* *3rd Qtr 10/11:* *Board staff reports interagency agreement has been signed with OPES. The DCA psychometric expert has begun its review of the PTCB and ExCPT examinations.* 7. Review requirements for qualifications of pharmacy technicians with stakeholders *4th Qtr 07/08:* *Future work on the training of technicians will occur as joint activities of the pharmacist associations.* *Legislation to require an exam and continuing education for pharmacy technicians is dropped (AB 1947)* *Board participates in CSHP sponsored stake holder meeting.* *2nd Qtr 08/09:* *Executive officer participates in a meeting with CPhA and CSHP to provide technical advice on proposed legislation to be introduced next year. Attend CSHP sponsored stakeholder meeting.* *3rd Qtr 08/09:* *Senate Bill 418 introduced to add new requirements for technicians. SB 418 is later dropped for the year.*

8. Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008.

Note: I-Licensing system has been cancelled and the BreEZe system will take its place.

July 2006: *Executive officer becomes executive sponsor of program.*

Nov. 2006: *Board completes system identification of parameters for each licensing program.*

Dec. 2006 - Jan. 2007: *Preparatory work and pilots completed; board staff initiates transfer to ATS system as sole platform for applicant tracking for all licensing programs.*

3rd Qtr 08/09: *Request for Proposal for I-Licensing system modified to contain revised parameters. Staff changes in the Office of Information Services cause additional delay in moving the project forward.*
ATS project implemented.

2nd Qtr 09/10: *Board advised of new initiative to facilitate online applicant submission and renewal.*

4th Qtr 09/10: *Board analyst temporarily assigned to assist on BreEZe project.*

1st Qtr 10/11: *Assistant Executive Officer chairs forms design workgroup to consolidate forms for all boards (reducing programming costs).*
Executive staff continue on BreEZe execution steering committee.

2nd Qtr 10/11: *Board analyst continues to work with the department on the BreEZe project.*

3rd Qtr 10/11: *Executive staff and analyst continue to work with DCA on implementation issue.*

4th Qtr 10/11: *Board has assigned two analysts to work with DCA two days a week on the implementation of BreEZe.*
Executive Officer nominated to key position on change board.
Assistant Executive Officer assumes role as project manager over forms consolidation.
Two Board staff loaned to the project on a part-time basis.

1st Qtr 11/12: *Board staff met with BreEZe staff to conduct final review of board requirements and work flow*

9. Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards.

3rd Qtr 06/07: *Board attends 3 day-long working sessions convened by California's schools of pharmacy to develop list of skills students should possess by end of basic intern level experience (about 300 hours).*

Oct. 2007: *Board considers basic internship competencies developed under the program and develops letter of support.*

Oct. 2008: *California Pharmacy Council meets to discuss Intern requirements.*

Dec. 2009: *Licensing Committee again discusses the requirements given that other states are no longer transferring intern hours.*

10. Implement new test administration requirements for the CPJE.

March 2007:	*Board advised about new exam vendor for CPJE effective June 1, 2007. Board notifies all CPJE eligible candidates of pending change, advises California schools of pharmacy graduating students and applicants in general.*
June 2007:	*Shift to new exam vendor, PSI, takes place. New Candidates Guide is printed and distributed. Some transition issues to new vendor exist and are being worked on.*
4th Qtr 09/10:	*Board approves new job content outline submitted by the Competency Committee as a result of the job analysis with an effective date of 4/1/2011.*
2nd Qtr 07/08:	*Transition efforts to PSI continue.*
3rd Qtr 07/08:	*New security procedures put in place and corresponding revisions to the Candidates' Guide are published and released.*
1st Qtr 09/10:	*Competency Committee develops occupational analysis survey.*
2nd Qtr 09/10:	*Competency Committee develops new content online for CPJE.*
3rd Qtr 09/10:	*Board approves new job content outline submitted by the Competency Committee as a result of the job analysis with an effective date of 4/1/2011.*
2nd Qtr 10/11:	*Documents advising applicants of new exam structure developed and released.*
3rd Qtr 10/11:	*Board staff updated CPJE Candidate Information Bulletin and Web site for new Content Outline effective April 1, 2011.*
4th Qtr 10/11:	*New CPJE Content Outline implemented.*

11. Participate in ACPE reviews of California Schools of Pharmacy.

Oct. 2007:	*Board participates in review of California Northstate College of Pharmacy.*
Jan. 2008:	*Board participates in review of UCSF.*
March 2008:	*Board participates in review of Touro.*
3rd Qtr 08/09:	*Board participates in three ACPE reviews of the schools of pharmacy at USC, Touro and California Northstate.*
3rd Qtr 09/10:	*Board participates in ACPE review of the school of pharmacy at UOP.*

12. Initiate review of Veterinary Food Animal Drug Retailer Designated Representative training.

Sept. 2007:	*Licensing Committee initiates review of training requirements for Designated Representatives and notes problems with unavailability 40-hour course specified in board regulations.*
Oct. 2007:	*Board evaluates options for training of designated representatives.*
Sept. 2008:	*Licensing Committee hears testimony regarding program.*
June 2009:	*Evaluation of designated representative training scheduled for September.*

13. Convene Committee to evaluate drug distribution within hospitals.

2nd Qtr 08/09: *Executive Officer presents information at CSHP Seminar on failure of the recall system to remove Heparin from nearly 20% of California hospitals months after recall.*

3rd Qtr 08/09: *Board establishes subcommittee to initiate review.*

March 2009: *First meeting convened.*

June 2009: *Second meeting convened in San Francisco.*

Sept. 2009: *Third meeting convened in Sacramento.*

Dec. 2009: *Work of Hospital Subcommittee nearly completed. Board to review parameters for recalls at January 2010 meeting.*

2nd Qtr 09/10: *Document finalized.*

14. Improve reporting of and accounting for intern hours.

4th Qtr 08/09: *Licensing Committee discusses how intern hours are reported to the board and specifics of where intern hours can be earned.*

2nd Qtr 10/11: *The new Intern Hours Affidavit form was approved by legal counsel.*

3rd Qtr 10/11: *New Intern Hours Affidavit form made available on the board's Web site.*

4th Qtr 10/11: *Intern hours affidavit form modified to more specifically detail compliance with statutory requirements.*

15. Participate in initiatives to increase the number of pharmacists in California to meet demand.

4th Qtr 08/09: *Board executive staff attend forums aimed at ensuring continual growth in the number of pharmacists and pharmacy technicians in California.*

16. Assess the operations of specialty pharmacy services.

4th Qtr 08/09: *Board initiates review of refill pharmacies.*

2nd Qtr 10/11: *Board considers request from PETNET Solutions for a waiver of security requirements for pharmacies to permit after hours maintenance of equipment without a pharmacist present. The board lacks the authority to waive California pharmacy law in the manner requested.*

4th Qtr 10/11: *Board staff work with Radio Pharmaceutical Company to address specific licensing requirement challenges.*

17. Encourage use of technology where it benefits the public.

June 2009: *Presentation to Licensing Committee of new robotic technology to compound drugs in hospitals.*

Oct. 2009: *Automation equipment demonstrated to Board that would facilitate unit dose packaging in hospitals and allow for barcoding.*

Jan. 2010: *Demonstration to Board if patient medication instructions in various languages accessible by emerging software available to pharmacies.*

4th Qtr 10/11: *Board takes a support if amended positive on AB 377 (Solorio) which would include the use of barcode technology in a hospital that was a centralized hospital pharmacy for repackaging and compounding.*

18. Secure the implementation of e-prescribing in California by the earliest possible date.

4th Qtr 08/09: *Licensing Committee sees presentation on e-prescribing pilot programs sponsored by the California HealthCare Foundation and CalPERS.*

2nd Qtr 10/11: *Board hears presentation by CalERx on the status of e-prescribing in California.*

Executive Officer provides presentations on e-prescribing at annual CalERx meeting.

Board establishes an ad hoc task force to develop a guidance document on the e-prescribing of controlled substances.

3rd Qtr 10/11: *Guidance document prepared and reviewed by board.*

4th Qtr 10/11: *Medical Board to review the section for prescribers.*

19. Ensure the public receives necessary pharmaceuticals in emergency response activities to the H1N1 pandemic.

4th Qtr 08/09: *Board assists the California Department of Public Health in responding to distribution of Tamiflu and Relenza. Pharmacy law requirements regarding labeling and dispensing not waived as standard and necessary pharmacists care could still be provided.*

2nd Qtr 09/10: *Board continues to work with Department of Public Health on H1N1 distribution issues.*

20. Automate fingerprint background results with the Department of Justice.

2nd Qtr 09/10: *Began working with the DCA to implement automation of background results for applicants to be automatically imported into the board's Applicant Tracking System (ATS).*

3rd Qtr 09/10: *Continued working with the DCA on developing programming specifics in order to go live on February 17, 2010.*
Board staff develops the procedures.

4th Qtr 09/10 : *Final revision to the procedures, trained staff, and assigned job task to staff.*
Board staff continues to manage automated process and resolve issues.

4th Qtr 10/11 : *Key staff position filled to manage automated responses and resolve issues.*

21. Evaluate pharmacy technician, pharmacist, and intern pharmacist application process to identify areas for improvement and to modify the application requirements to require "Self-Query" reports from the National Practitioners Data Bank – Healthcare Integrity and Protections Data Bank (NPDB-HIPDB).

3rd Qtr 09/10: *Staff reached out to pharmacy technician programs to advise them of statutory changes to the application fee.*
Staff revised pharmacy technician application after reviewing most common deficiencies for legal review.

4th Qtr 09/10: *Staff reached out to pharmacy technician programs educating them on the most common application deficiencies.*

1st Qtr 10/11: *Staff finalized the draft pharmacy technician, pharmacist, and intern pharmacist application.*
Legal approved the draft pharmacy technician and intern pharmacist application.

2nd Qtr 10/11: *Legal approved the pharmacist application.*
Proposal to initial a regulation change to update the pharmacy technician application at the Licensing Committee meeting.
Licensing Committee made recommendations for board to pursue the changes to the pharmacy technician application.
Licensing Committee made recommendations for board to pursue the changes to require "Self-Query" reports from the National Practitioners Data Bank – Healthcare Integrity and Protections Data Bank (NPDB-HIPDB) for the pharmacy technician, pharmacist, and intern pharmacist application for licensure.
At the recommendation of the Licensing Committee, the board authorized the Executive Officer to take all steps necessary to initiate a rulemaking update to the pharmacy technician application form and NPDB/HIPDB self-query report.

	3rd Qtr 10/11: *Regulation change noticed to require self-query report with technician application.* *The board approved to initiate a rulemaking file to add 1727.2 and to amend 1728 related to requiring an intern pharmacist and pharmacist applicant to submit a Self-Query from the NPDB-HIPDB.* *The board approved to modify the Pharmacy Technician Application and direct staff to take all steps necessary to complete the rulemaking process.* *The pharmacist examination and licensure application and intern pharmacist application was updated and made available on the board's Web site in a fillable format, which includes the new Intern Hours Affidavit form.* *4th Qtr 10/11:* *The rulemaking package was submitted to DCA on June 29, 2011 for California Code of Regulations section 1793.5 pharmacy technician application.* *1st Qtr 11/12:* *The rulemaking package was approved by OAL with an effective date of October 1, 2011.* *The new pharmacy technician application was made available on the board's Web site.* *Pharmacy technician programs were notified of the new application and requirements.* 22. Implement Fingerprint Requirement for Pharmacist Renewal. *4th Qtr 09/10:* *Regulation approved by Office of Administrative Law (effective date of regulation is December 7, 2010).* *Department drafted programming changes to accommodate requirement.* *Board staff tested changes in a testing environment.* *2nd Qtr 10/11:* *Obtained FBI approval through DOJ for job title on Live Scan for licensed pharmacists.* *Board staff working with the department to implement importing automated fingerprint response into ATS.* *Implementation delayed due to hiring freeze and approval by FBI of new category for reprinted pharmacists.* *3rd Qtr 10/11:* *Staff added to the board's Web site the pharmacist renewal fingerprinting requirements for those licensed prior to 2001. Included on the Web site is the Live Scan form and instructions required for renewal. Staff developed the letter notifying pharmacist licensees that have been identified as to comply with this renewal requirement and forwarded to Legal for review and approval. Board staff continues to work with the DCA on programming requirements to facilitate implementation.* *4th Qtr 10/11:* *Staff worked with DOJ and DCA to establish procedures for implementation in July 2011.* *Letter finalized. Article included in The Script advising registered pharmacists of the requirement.* *1st Qtr 11/12:* *Procedures implemented to import fingerprint responses directly from DOJ into the board's database.* *Board notified pharmacists impacted by implementation of CCR 1702.*

23. Evaluate licensing requirements for businesses seeking licensure that are under common ownership.

4th Qtr 09/10 : *Board staff developed standards for common ownership requirements.*

24. Evaluate Continuing Education Requirement for Pharmacists

2nd Qtr 10/11: *Board discussed a proposal to specify continuing education credit for pharmacists in specific content areas and forwarded to Licensing Committee.*
Licensing Committee discussed multiple specific areas for optional continuing education. The committee decided to amend the regulation 16CCR 1732.2. to allow for continuing education hours for various specified activities.
Regulation 16CCR 1732.2. was noticed for public comment on Nov. 22, 2010.

3rd Qtr 10/11: *Board approved based on Licensing Committee recommendation to pursue specific content areas for continuing education and authorized staff to investigate implementation.*
Subcommittee of the Licensing Committee discussed possible course content and methods of requiring continuing education.

25. Improve pharmacy technician application forms to reduce deficiencies and require HIPDB.

1st Qtr 10/11: *Identify changes and initiate rulemaking process to adopt changes to application forms.*

2nd Qtr 10/11: *Additional enhancements identified, and returned to board for approval.*

3rd Qtr 10/11: *Regulation change initiated to require new application form.*
Board adopts changes to implement via promulgation of regulations.

4th Qtr 10/11: *The rulemaking package was submitted to DCA on June 29, 2011 for California Code of Regulations section 1793.5 pharmacy technician application.*

1st Qtr 11/12: *The rulemaking package was approved by OAL with an effective date of October 1, 2011.*
The new pharmacy technician application was made available on the board's Web site.
Pharmacy technician programs were notified of the new application and requirements.

26. Require a self query HIPDB report as a condition for applying for a pharmacists intern and pharmacist license and as part of the application process to take the CPJE.

1st Qtr 10/11: *Board approves concept and staff readies regulation changes to implement.*

2nd Qtr 10/11: *Board approves language to initiate rulemaking process.*

4th Qtr 10/11: *Rulemaking process initiated.*