

**ENFORCEMENT AND COMPOUNDING COMMITTEE
MEETING MATERIALS
SEPTEMBER 9, 2015**

Amy Gutierrez, PharmD, Chair, Board President

Greg Lippe, Public Member, Vice Chair

Stan Weisser, Professional Member

Allan Schaad, Professional Member

Rosalyn Hackworth, Public Member

Greg Murphy, Public Member

I. PUBLIC COMMENT FOR ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to recommend whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

II. ENFORCEMENT MATTERS

a. Update on the CURES 2.0 Prescription Monitoring Program

The California Department of Justice is continuing to work on upgrading the CURES system. On June 30, the DOJ had a “soft launch” of CURES 2.0 as the new system is called. Since then the DOJ has been working to pilot test the new system and install upgrades that will permit conversion to the new, enhanced system.

Below is the update prepared in late June on the soft launch from the DOJ’s press release:

CURES 2.0 Soft Launch and Phased Rollout

Update from July 1, 2015:

The Department of Justice (DOJ) and the Department of Consumer Affairs (DCA) are pleased to announce that the state’s new Controlled Substance Utilization Review and Evaluation System – commonly referred to as “CURES 2.0” – went live on July 1, 2015. This upgraded prescription drug monitoring program features a variety of performance improvements and added functionality.

In order to ensure a smooth transition from the current system, CURES 2.0 will be rolled out to users in phases over the next several months, beginning with early adoption by a select group of users who currently use CURES and meet the CURES 2.0 security standards, including minimum browser specifications. DOJ is currently identifying prescribers and dispensers who meet these criteria and will contact and coordinate their enrollment into CURES 2.0. For all other current users, access to CURES 1.0 will not change and no action is needed at this time. For users and entities not currently enrolled in CURES, further notification will be provided in August as to the enrollment/registration process.

Practitioners and health systems should begin to prepare for universal adoption of the system by January 2016, at which point all users will be required to meet CURES 2.0's security standards. If you have any questions please contact cures@doj.ca.gov.

Thank you for your continued support of the CURES program.

Note: CURES 2.0 users will be required to use Microsoft Internet Explorer Version 11.0 or greater, Mozilla FireFox, Google Chrome, or Safari when accessing the system.

At this meeting, Robert Sumner of the California Department of Justice will provide an update on the transition to the new CURES 2.0 system. We have asked for an update as well as information about the new registration system and the number of California pharmacists who are registered to use the system. Under CA law, all pharmacists with active licenses need to be registered to access CURES by January 1, 2016.

b. Update by the University of California, San Diego on Its Pilot Program to Permit Patients to Access Medication from an Automated Storage Device not Immediately Adjacent to a Pharmacy

Attachment 1

At the Board of Pharmacy's April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the UCSD School of Pharmacy involving use of an automated storage device for prescription medication for which staff and their families of a Sharp Hospital in San Diego, who opt in, may pick up their outpatient medications from this device located in a hospital, instead of having to go to the community pharmacy. Consultation will be provided via telephone before medication can be dispensed to a patient.

This study was planned to start in June or July, 2015. However, in scheduling items for this committee meeting, we learned that the project is running a bit behind.

An update report will be provided at this meeting via telephone with UCSD Researcher Jan Hirsch, BS Pharm, PhD. Dr. Hirsch will provide this presentation and respond to questions of the committee. A copy of her presentation is attached.

c. Discussion Regarding the Board's Proposed Regulations for the Take Back of Prescription Medication

Attachment 2

Since the July Board Meeting, work has continued on refining the board's proposed requirements for drug take back programs. The current iteration is provided in **Attachment 2**.

Meanwhile, additional counties have established requirements to permit/require take of unwanted pharmaceuticals from the public often involving pharmacies.

Additionally, on September 26, the DEA will conduct another national Drug Take Back day. The board has released a subscriber alert and posted information about this collection day on the board's web site.

After discussion at this meeting, staff will incorporate comments into the draft and bring to the October Board Meeting.

Board staff respectfully suggests a motion from this meeting for a recommendation that staff complete work on the proposed regulation, including incorporating comments made at this meeting, and bring the draft to the board meeting with a recommendation for the board to initiate a rulemaking by releasing the requirements for the 45-days of public comment.

d. Discussion on Enforcement Options for Patient Consultation Violations

Attachment 3

Background:

Nearly 25 years ago, the Board of Pharmacy promulgated regulations to require pharmacists to consult with patients every time they receive a medication for the first time. The board included in the regulation additional occasions where a pharmacist must consult a patient – where the patient has questions or the pharmacist believes a medication warrants consultation. A copy of the requirement is provided in **Attachment 3**.

Sometimes California's requirements are confused with national requirements enacted about the same time by CMS for Medicare patients in what was known as "OBRA 90." However, California's requirements were actually adopted before OBRA 90's requirements. The OBRA 90 requirements provided that Medicare patients be offered consultation when they receive medication for the first time. So California's requirements, requiring the pharmacist to initiate consultation, were stronger and broader than the OBRA 90 requirements in that they pertained to all patients, not just those whose medications were paid for by Medicare, establishing one standard of care for all patients in California.

After approval of California's patient consultation requirements, the board also delayed implementation of patient consultation at the request of the profession because pharmacists stated they could not provide consultation without the aid of pharmacy technicians. So the approved patient-consultation regulation was delayed so that the board could secure statutory authority and then promulgate regulations to establish the licensure of pharmacy technicians to "free" the pharmacist to provide consultation.

California's requirement is for the pharmacist to consult the patient – not to offer to consult. When doing the consultation rulemaking, the board emphasized that consultation was to be initiated by the pharmacist, and that any denial of the consultation must be made directly to the pharmacist, other staff (e.g., pharmacy technicians or ancillary staff) were not to screen for consultation by asking if the patient wanted to speak to the pharmacist or had questions about the medication. Consultation was required whenever the patient or the patient's agent was present in the pharmacy to receive the consultation.

Over the years, the board has added other enhancements to help ensure patients receive meaningful consultation, including a notice to consumers poster that must be posted in a

pharmacy that specifically states the pharmacist must consult with each patient about his or her new medication, and lists the 5 questions a patient should understand before taking a prescription medication.

More recently in promulgating the requirements for patient-centered labels, the board required that oral consultation services be available in 12 languages to aid limited-English speaking patients in better understanding how to take their prescription medication.

Over the years, the board has enforced its patient consultation requirements in various ways. Initially it was one of the first violations for which the board used its citation and fine authority. In recent years, the board has typically assessed fines of approximately \$1,000 when it observes failure to consult during an inspection. Where a medication error has occurred and consultation was not provided, the board generally issues a higher fine.

In 2011, board staff began working on a project with three California district attorneys' offices to aid in the board's enforcement of patient consultation. Using the state's unfair business practices statute in Business and Professions Code section 17200, the DAs' offices were able to assess higher fines for failure to consult. Additionally, the DAs' offices used undercover investigators to pass prescriptions, an action the board has not done.

The DAs' investigations have resulted in more substantial fines to three pharmacy chains where investigations have been completed – CVS (2013, \$658,500), Rite Aid (2014, \$498,250) and recently Walgreens (2015, \$502,000). A press release for each of these settlements is provided in **Attachment 3**.

At the July Board Meeting, the board heard a report summarizing the results of a short survey monkey questionnaire conducted by the board involving patient consultation. A summary of the 1,006 results of this survey are provided in **Attachment 3**.

At this meeting:

At this meeting the committee will discuss enforcement of the patient consultation requirements.

Additionally Fred Mayer and Aglaia Panos have asked for an opportunity to provide information about enforcement of patient consultation from their perspective as part of the committee's discussion.

e. Discussion of the Proposed Regulation for Pharmacies and Clinics Aimed at Reducing Losses of Controlled Substances

Attachment 4

At the July Board Meeting, the board approved initiation of a rulemaking to establish inventory requirements for controlled drugs for pharmacies and clinics. This regulation will be

noticed before the October Board Meeting. A copy of this proposed regulation is provided in **Attachment 4**.

The regulation requires perpetual inventories of all federal Schedule II drugs, with a physical count every 90 days. Additionally, the board will establish a list of one or several additional controlled drugs from Schedules III – V that are reported as frequently stolen to the board and/or DEA.

Provided below is a list of the top non-Schedule III-V drugs reported lost or stolen to the board in the last year. For ease of comparison, all drugs listed have been converted into administration dosage units (i.e., liquids have been converted into 5 mL teaspoons to identify a dose). On the basis of this list, the board would require the inventory monitoring of alprazolam and promethazine with codeine.

Top Ten: FY 2014 – 2015 CS Schedules III-V Losses by Quantity

Drug	Quantity In Actual Dosage Equivalents
Alprazolam	160,169
Promethazine/Codeine	77,862*
Carisoprodol	38,579
Tramadol Hydrochloride	34,801
Acetaminophen/Codeine	27,903
Lorazepam	26,864
Zolpidem Tartrate	18,657
Diazepam	17,139
Clonazepam	14,628
Phentermine	10,820

*mLs converted into 5mL dosage units

The board’s staff also developed the following list of Schedule II controlled drugs reported lost or stolen within the last year.

Top Ten: FY 2014 – 2015 CS Schedule II Losses by Quantity

Drugs	Quantity In Actual Dosage Equivalents
Hydrocodone and Combos	402,377*
Oxycodone and Combos	73,756*
Amphetamine/Salts/Methamphetamine	26,368
Hydromorphone/Oxymorphone	20,885
Dex/Methylphenidate	19,212
Methadone	9,817
Fentanyl Citrate	6,822
Diphenoxylate/Atropine	4,130
Tapentadol Hydrochloride	2,062
Meperidine HCl	831

*total dosages (mLs converted into 5mL dosage units and added to solids)

f. Tracking of Automated Drug Delivery Devices in Use in California

Pharmacies are able to operate automated dispensing machines or devices in various settings away from the licensed pharmacy. This includes in:

- Skilled nursing homes and other health care facilities licensed under Health and Safety Code section 1250 (c), (d) or (k) (the devices are authorized under section 1261.6 of the Health and Safety Code, authority for pharmacies to do this in specific locations is specified in Business and Professions Code section 4119.1)
- Clinics licensed under section 4180 of the Business and Professions Code (the devices are authorized under section 4186) – these include licensed, nonprofit community or free clinics defined under Health and Safety Code 1204(a)(1), a clinic operated by a federally recognized Indian tribe or tribal organization referred to in Health and Safety Code section 1206(b), a clinic operated by a primary care community or free clinic operated on a separate premises from a licensed clinic and that is open no more than 20 hours per week as referred to in Health and Safety Code section 1206(h), a student health center clinic operated by a public institution of higher education such as college health center as referred to in Health and Safety Code section 1206(j).
- Hospitals may use Pyxis or Pyxis-type machines throughout a hospital to store medication under application of provisions in Title 22 that allow drugs to be stored in nursing stations. The Pyxis and like devices are considered secured storage units for drugs.

The board has no idea how many of these machines are in use, and where they are in use, or which pharmacy is responsible for the machines.

The demand for additional use of devices is growing. As scheduled earlier at this meeting, a pilot study is underway that if proven valuable, would allow patients to pick up medication from machines not specifically located in a pharmacy.

Staff suggests that a simple registration be established for pharmacies that operate each of these machines that identifies their locations, as a beneficial step in board oversight and enforcement. The list could be updated as needed via form submission to the board by a pharmacy adding, moving or removing a machine. This registration could operate much like the off-site storage waivers for records waivers. Then at annual renewal of the pharmacy, the pharmacy would update or confirm the list of machines it operates and where each is located.

A regulation or statutory amendment is likely needed to establish this requirement.

III. COMPOUNDING MATTERS

a. Discussion on Medicare's Pharmacy Practice Expectations for Critical Access Hospitals

Attachment 5

At this meeting, time has been set aside to allow a discussion of these practice guidelines for hospital pharmacies. This item is for discussion and information purposes.

There are two related documents provided in **Attachment 5**. Various excerpts from the ASHP article are provided below:

The “CMS document officially establishes United States Pharmacopeia (USP) Chapter 795 as the minimum standard for practices related to nonsterile compounding and USP chapter 797 for compounded sterile products.”

“USP chapter 795 has been an enforceable standard since 2001, meaning that state boards of pharmacy and other organizations can use it as the basis for fines and other adverse actions against noncompliant regulated entities. Chapter 797 has been enforceable since 2004.”

The article later goes on to quote ASHP as stating: “only by a pharmacist or other personnel authorized in accordance with State and Federal law’ may pose compliance problems for sparsely staffed critical access hospitals.”

“According to the CMS document, critical access hospitals that contract for compounding activities must have access to the vendor’s quality assurance data to verify compliance with USP chapters 795 and 797. Each hospital must document that it obtains and reviews the data. CMS also expects vendors to demonstrably follow state laws and meet the requirements of 503A of the Food, Drug and Cosmetic Act that relate to the compounding of human drug products.”

The article then goes on to discuss outsourcing facilities and their potential future role in providing compounded drugs for hospitals. It notes that CMS’s policy acknowledges FDA’s preference for hospitals to use official outsourcing facilities to obtain compounded sterile products. But then the article notes that outsourcing facilities are not meeting FDA’s expectations when information from the FDA’s Web site is reviewed. The FDA Web site lists all licensed outsourcing facilities and the number of FDA inspection report findings (on form 483) and 12 warning letters issued by the FDA to outsourcers. As of late January, only 1 of the 42-registered outsourcing facilities that had been inspected by the FDA had “no significant objectionable conditions” identified by the FDA.

b. Warnings about Becton-Dickinson Syringes and Loss of Medication Potency from the Federal Food and Drug Administration and Institute for Safe Medication Practices

Attachment 6

Several weeks ago, the FDA and Institute for Safe Medication Practices released warnings about the loss in potency detected for certain medications stored in 3mL, 5mL or perhaps additional larger Becton–Dickinson syringes. **Attachment 6** contains these two warnings,

which were distributed by the board as subscriber alerts. A copy of the Becton-Dickinson public notice is also provided in this attachment.

This item has been added to the agenda so the committee can discuss the situation, and make a determination about whether the board needs to initiate additional actions or warnings to clinicians. We know of one recall that was initiated following release of these warnings. The executive officer has also learned that several outsourcers may have identified this loss in potency prior to these releases and took steps to notify their customers.

A proposed additional warning is:

The California State Board of Pharmacy is resending the following subscriber alert that was recently sent involving IV medications stored in BD syringes in the interests of ensuring that all pharmacy practitioners are aware of this potential public safety issue. Please review this cautionary information carefully. The issue seems to be isolated to 3 and 5 mL BD syringes at this time, although the FDA has concerns with larger syringes. Pharmacists need to make certain all of their clinicians are aware of this situation so they can report any therapy failures/nonresponses to drug therapy when administering drugs that have been stored in syringes to the pharmacy and to FDA's MedWatch.

c. Discussion on Compounding for Prescriber Office Use

This item has been added to the Enforcement and Compounding Committee agenda for discussion.

Section 4052(a)(1) of the California Business and Professions Code provides that: Notwithstanding any other law, a pharmacist may furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

This "reasonable quantity" of compounded drug product has been defined in 16 California Code of Regulations section 1735.2(c) as:

- (c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of a compounded drug product that:
 - (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 compounded drug product.

The recent proposed modifications to the compounding regulation take out the 72-hour supply for that could be distributed to patient. Other changes have also been made to this section which as currently proposed reads:

- (c) A “reasonable quantity” that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:
- (1) Is ordered by the prescriber or the prescriber’s agent and paid for by the prescriber or the prescriber’s agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber’s office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and
 - (2) Is delivered to the prescriber’s office and signed for by the prescriber or the prescriber’s agent; and
 - (3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and
 - (4) That the pharmacist has a credible basis for concluding the quantity provided for office use is reasonable considering the intended use of the compounded medication and the nature of the prescriber’s practice; and
 - (5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and
 - (6) Does not exceed an amount the pharmacy can reasonably and safely compound.

Thus if the currently proposed compounding regulation changes take effect, pharmacies will be able to compound for prescriber office use, but not in quantities for prescribers to dispense to a patient.

d. Comments on the Food and Drug Administration’s Guidance Document #230 on Compounding Animal Drugs from Bulk Drug Substances

Attachment 7

The Board of Pharmacy has previously expressed interest in submitting comments on the FDA's Guidance Document 230, "Compounding Animal Drugs from Bulk Substances."

During this meeting, the committee will have the opportunity to discuss this guidance document and the comments it wishes to submit to the FDA. **Attachment 7** contains this guidance document.

The following provides an overview and summary of the guidance provided in the FDA's document. The guidance supports and reinforces the regulatory framework developed by FDA for pharmacies and outsourcers who compound human drugs with several exceptions.

- For pharmacies that compound medications for animal use, the FDA guidance states that a veterinarian's prescription is required for the specific animal. The prescription must contain the standard information required on all prescriptions but also must include:
 1. The name and species of the animal
 2. A statement that the animal is not a food-producing animal
 3. If a manufactured drug exists, a statement that the compounded product would make a clinical difference from the manufactured product

The guidance provides that pharmacies that compound such drugs must do so pursuant to USP 795 and 797 standards, by or under the supervision of a pharmacist, and such compounded products may not be distributed by wholesalers.

Finally, the guidance allows a pharmacy to compound for future furnishing but is limited to the maximum quantity of that drug dispensed in a 14-day period within the last six months.

- For outsourcing facilities that compound animal drugs from bulk substances, the FDA is developing a list (which is not yet completed) of approved drug substances that an outsourcing facility must use when compounding for animals, linked to the species and the condition.

The compounding must be done in accordance with cGMP standards by or under the supervision of a pharmacist. Outsourcing facility-compounded drugs may not be used on or in food producing animals, and must be expressly labeled to state this prohibition.

The veterinarian must note on the order or prescription that the veterinary drug is intended to treat a specific condition and specific species, and this must match the listing on the FDA's bulk drug substances list. The guidance specifies labeling requirements and a statement on the label that the product is not for resale. The guidance

also requires that any drugs compounded by an outsourcing facility must be reported on the biannual lists of products compounded that must be sent to the FDA, with a notation of the products intended for animals.

The guidance also permits compounding by a veterinarian.

The committee may wish to provide general comments to include in the written comments that will be submitted later this month to the FDA.

e. Discussion on the Compounding Services provided by Sterile Compounding Pharmacies and Outsourcing Facilities

The November 2013 enactment of the DQSA created a new type of entity authorized to compound medications – the outsourcing facility. These generally large-scale production facilities are authorized to compound large quantities of medications for use by other entities. The medications must be prepared under current good manufacturing practices (or cGMPs), which are more stringent than compounding requirements for pharmacies, since many patients in multiple locations can receive these medication that are not usually linked to a patient-specific prescription.

The legislation essentially creates a new entity, with the results that there are three types of drug producers.

1. Manufacturers who are regulated by the FDA, and for facilities located in a specific state, often by a unit of the state's Department of Health (this occurs in CA). Manufacturers are required to perform extensive drug testing trials before receiving authorization to market a drug. Their physical plants are inspected by the FDA and must comply with rigorous cGMPs.
2. Outsourcers are regulated more like drug manufacturers and are regulated under cGMPs, but outsourcing facilities are exempted from performing drug approval testing like manufacturers must do for their products. In the future, the FDA has stated they plan on developing specific cGMP requirements for outsourcing facilities, but these specialized requirements are not yet available.
3. Pharmacies, which are authorized to compound pursuant to a patient-specific prescription, are regulated by state boards of pharmacy. Because pharmacies generally do not compound drugs in quantities the size of those produced by outsourcing facilities or manufacturers, pharmacies are regulated under lesser standards. Sterile compounding pharmacies, however, are generally regulated at a level closer to that of manufacturers and outsourcers because of heightened concerns about sterility, integrity, potency and quality of the compounded medication.

For a number of years, the board and other agencies have grappled with the issue of at what point does a pharmacy compounding medications in large quantities in anticipation of receiving a prescription, actually become a manufacturer because the pharmacy is compounding so much medication, or compounding not specific to received prescriptions. The board, the CA Department of Public Health and the FDA have all studied and discussed this issue in CA over the years, and similar discussions have gone on in other states and federally.

With the advent of outsourcing facilities, the issue is simplified;

- An outsourcing facility (aka a 503B facility) licensed by the FDA (and in the future by the CA Board of Pharmacy if located or shipping into the state), shall function under the supervision of a pharmacist and operate according to cGMPs, to produce compounded drug products for multiple entities without a prescription.
- A pharmacy (aka a 503A facility) may compound a medication pursuant to patient-specific prescription order or in very limited quantities based on normal dispensing patterns in anticipation of a prescription, and dispense pursuant to a patient-specific prescription.
- A specially licensed sterile compounding pharmacy may compound a sterile medication pursuant to a patient-specific prescription or in limited quantities based on normal dispensing patterns in anticipation of a patient-specific prescription, but dispense pursuant to a patient-specific prescription.
- A pharmacy may compound medication or sterile medication for administration in a physician's office (but after implementation of California's new compounding requirements, not for dispensing to patient in 72-hour quantities).

f. Review of Sterile Compounding Statistics Identified by the Board

At this meeting, Supervising Inspector Christine Acosta will provide an overview of statistics compiled by the board from inspections and investigations of California-licensed compounding.

IV. December 2015 Meeting Dates

The Enforcement Committee will meet December 14, 2015 in Sacramento. Committee meeting dates for 2016 are provided below.

- March 2, 2016
- June 1, 2016
- August 31, 2016

Attachment 1

Study of Expanded Use of an Automated Delivery Device

UPDATE 9-09-15

Jan D. Hirsch, BPharm, PhD

UCSD Skaggs School of Pharmacy & Pharmaceutical Sciences



Update

- ScriptCenter Kiosk Installation
 - Location
 - Progress and timeline
- Update on Study
 - Reminder of Research Questions
 - Updated Timeline

ScriptCenter Kiosk Location Sharp Memorial Hospital

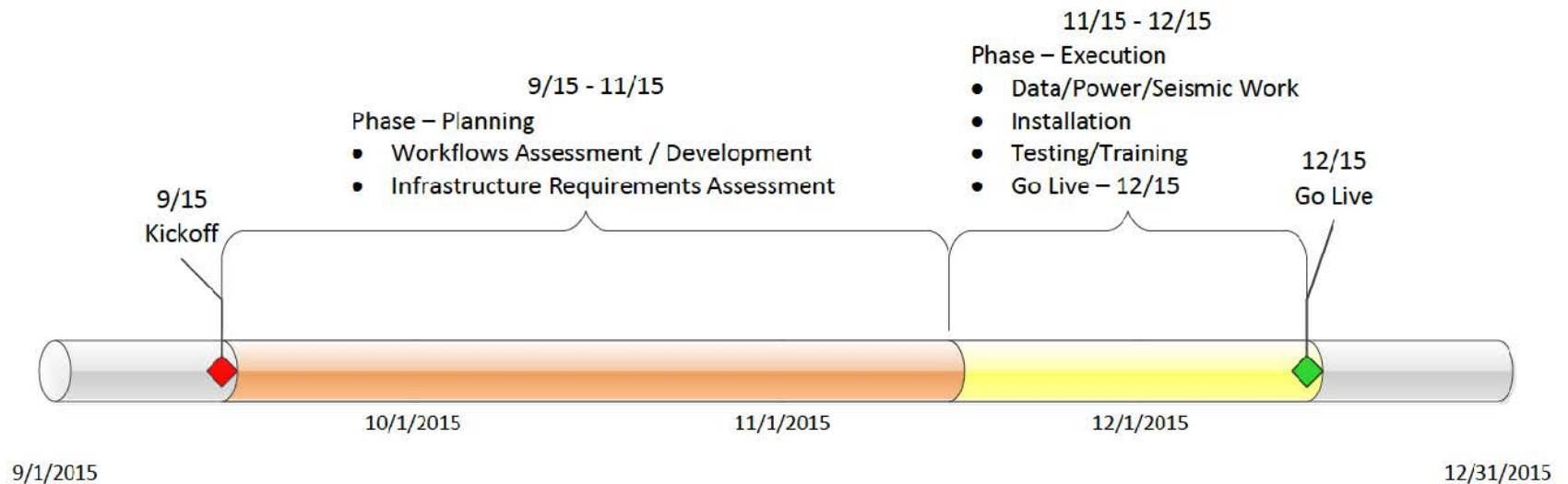


Sharp Memorial Hospital employee entrance located on ground floor. Secure access only.

ScriptCenter Kiosk Installation



Asteres ScriptCenter Implementation, Sharp Memorial Hospital



Study Research Questions

Primary: Is patient *primary adherence* (prescription retrieval rate; all prescriptions) greater for kiosk vs.

- Historical and concurrent regular counter rate?
- Rx retrieval rate based on Return to Stock (RTS) rate per month

RTS rate = # Rxs RTS after 14 days/# Rxs filled

Secondary: Kiosk vs. Regular Counter Patients

- Is number or nature of questions for pharmacists during consultation for new prescriptions different? (*consultation log*)
- What is mean time from fill (RPh verified) to pick up?

Kiosk patients:

- Satisfaction with access to pharmacist for questions & convenience

Sharp Memorial Hospital employees:

- Would kiosk be beneficial and increase primary adherence?

Study Design

Quasi-experimental with
non-randomized control group

- Pre-Kiosk Implementation Survey (Sharp Employees)

Kiosk Start

6 months pre-kiosk

Month 1

Month 6

Regular Counter

- RTS rate*

Kiosk

- RTS rate
- Consultation Log
- Time to Pick-up
- Kiosk Patient Satisfaction

Regular Counter

- RTS rate*
- Consultation Log (1 week sample pts w/ new Rx)
- Time to Pick-up*

RTS = Return to Stock

* For employees and dependents

Updated Projected Study Timetable

- Q4 2015 Pre-kiosk 6-month data collection phase begins

- Q1 2016 Implement Kiosk device (12/15/15)
Refine data collection tools & process
Deployment of program/enroll patients

- Q2 & Q3 2016 Post-kiosk implementation
Data collection and analysis

- Q4 2016 Report Results to Board

Questions?

Attachment 2

Article 9.1

Prescription Drug Take-Back Programs

Revised: 9/4/15 by Virginia Herold

Section 1776

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and licensed skilled nursing facilities may offer, under the requirements in this article, specified prescription drug-take back services to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.

All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods. Federal, state and other law prohibit the deposit in drug take-back receptacles of the following: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).

Section 1776.1 Pharmacies

- (a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription medication as provided in this article. Provision of such services is voluntary.
- (b) Pharmacies may provide take-back services to patients as provided in sections 1776.1 - 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under Health and Safety Code section 1250(c).
- (c) There are multiple federal and state requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.
- (d) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.
- (e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic

drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage shall be placed on collection receptacles as referenced in section 1776.3.

- (f) Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by a pharmacy or practitioner to a patient or patient's agent. Dangerous drugs that have not been dispensed to patients (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in pharmacy drug take-back programs.
 - 1. Pharmacy staff shall not review, accept, count, sort, or handle prescription medication returned from the public.
 - 2. A pharmacy shall not accept or possess prescription medication returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
 - 3. A pharmacy shall not dispose of quarantined, recalled or outdated prescription drugs which it must return to a reverse distributor in a drug take-back collection receptacle.
- (g) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or who has had a DEA permit denied, surrendered or revoked.
- (h) Any pharmacy that operates a drug take-back collection program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:
 - 1. Any pharmacy that ceases to operate a drug take-back program shall notify the board within 30 days on a form designated by the board.
 - 2. Any pharmacy operating a mail back program or maintaining collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
 - 3. Any tampering with a storage receptacle or theft of deposited drugs shall be reported to the board with 30 days.
 - 4. Any tampering, damage or theft of a removed liner shall be reported to the board with 30 days.

1776.2 Mail Back Services from Pharmacies

- (a) Pharmacies that provide prescription drug take-back services may do so by establishing mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.
- (b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.

- (c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription medication. Postage shall be prepaid on each envelope or package.
- (d) The preaddressed envelope and package shall contain a unique identification number for each package, and certain instructions for users to mail back drugs.
- (e) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.
- (f) Once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return, processing or holding.

1776.3 Collection Receptacles in Pharmacies

- (a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas. In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care.
- (b) A pharmacy that establishes a collection receptacle must also establish a separate collection to collect sharps, unwanted syringes or needles, so that these items are not deposited into the drug collection receptacle.
- (c) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription medication returned from the public, but instead direct the public to deposit the medication into the container themselves.
- (c) Before establishing a collection receptacle, the pharmacy must obtain collector status from the federal Drug Enforcement Administration. If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.
- (d) Within 30 days of establishing a collection receptacle, the pharmacy must notify the board that it has installed a collection receptacle and the location of the receptacle on a form designated by the board. The pharmacy shall annually report all receptacles it operates at time of renewal. Removal of any collection receptacle shall be reported to the board within 30 days.
- (e) The receptacle shall be locked and have a removable inner liner to contain the deposited prescription drugs. The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the

prescription drug or item cannot be removed or counted. The liner into which a drug is deposited shall be provided to a reverse distributor as provided in this article within three business days.

- (f) The liner shall be made of antineoplastic material that is waterproof, tamper evident and tear resistant. The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the bag by the manufacturer.
- (g) A liner may be removed from a locked receptacle by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle. Removed liners shall not be opened, x-rayed, analyzed or penetrated.
- (h) Liners that have been filled and removed from a collection receptacle must be stored in a secured, locked location in the pharmacy no longer than three days.
- (i) The pharmacy shall maintain a log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:
 - 1. The unique identification number of the liner
 - 2. The date the liner is placed in the collection receptacle,
 - 3. The date the liner is removed from the collection receptacle,
 - 4. The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and
 - 5. The date the liner was provided to a licensed DEA-registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor.
- (j) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed distributor pick-up at the licensed pharmacy's premises.
- (k) The collection receptacle shall contain signage developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not Schedule I drugs. Labeling shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle.

1776.4 Collection in Skilled Nursing Facilities

Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article.

- (a) Skilled nursing facility personnel may dispose of a current resident's unwanted or unused prescription medication by using mail back packages or envelopes based upon a request by the resident patient. The mail back package shall conform to the requirements specified in section 1776.1. Records shall be kept by the skilled nursing

facility noting the specific quantity of each prescription drug mailed back, the serial number of the mail back package and the address to which the mail back envelope is sent.

- (b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs.
 - 1. Any pharmacy and hospital/clinic with an onsite pharmacy operating collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.
 - 2. Any pharmacy or hospital/clinic with an onsite pharmacy that operates a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.
 - 3. Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to operate a collection site at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
 - 4. Any pharmacy operating a collection site at a skilled nursing facility shall list all collection receptacles it operates annually at the time of renewal of the pharmacy license.
- (c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.
- (d) Every pharmacy and hospital/clinic pharmacy that operates a collection site at any skilled nursing facility shall notify the board within 14 days of any loss from the collection receptacle or secured storage location for the storage of removed liners.
- (e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.
- (f) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed.
- (h) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removal inner liner.
- (i) The outer container shall include a small opening that allows deposit of drugs into the inside of the outer container and directly into the inner liner.
- (j) The outer container shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
- (k) Once deposited, the prescription drugs shall not be counted, inventoried or otherwise individually handled.

- (l) The installation, removal, transfer and storage of inner liners shall be performed only by:
 - 1. One employee of the authorized collector and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
 - 2. By or under the supervision of two employees of the authorized collector pharmacy.
- (m) Upon removal from the collection receptacle, the liner shall be immediately sealed. Sealed inner liners may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.
- (n) Liners may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.
- (o) Records of the destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transferred each liner.

1776.4 Reverse Distributors

- (a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.
- (b) A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately DEA-licensed distributor.
- (c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.
- (d) A reverse distributor shall not employ as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.
- (e) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.
- (f) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/package, including the:
 - 1. Date of acquisition

2. Number and the size (e.g., five 10-gallon liners, etc.)
3. Inventory number of each liner or envelope/package
4. The date and place and method of destruction
5. Number of packages and inner liners received
6. Number of packages and inner liners destroyed
7. The number and signature of the two employees of the registrant that witnessed the destruction.

1776.5 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services







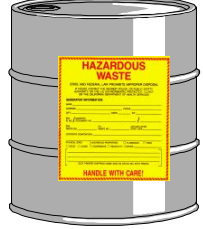

Each entity authorized by this article to collect unwanted prescription medication from patients shall maintain the following records.

- (a) When obtaining unused mail-back packages and envelopes for future distribution:
 1. The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.
 2. For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.
- (b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.
- (c) For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,
- (d) For sealed mail back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.
- (e) For pharmacies using collection receptacle, for each liner:
 1. Date each unused liner was acquired, its unique identification number and size (e.g., five gallon, 10-gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.
 2. Date each liner is installed in a receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10-gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
 3. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees

that witnessed each removal.

4. Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
5. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor.

MASTER WASTE MATRIX

Requirements	Medical Waste 	Sharps Waste 	Trace Chemo 	Pathology Waste 	Controlled Substances 	Pharmaceutical Waste 	Hazardous Waste 	Universal Waste 
Regulatory Reference	Medical Waste Management Act (H&S Code 11760-118360)	Medical Waste Management Act (H&S Code 11760-118360)	Medical Waste Management Act (H&S Code 11760-118360)	Medical Waste Management Act (H&S Code 11760-118360)	DEA, RCRA and California Medical Waste Mgt. Act	Medical Waste Management Act (H&S Code 11760-118360)	Title 40, Code of Federal Regulations and Title 22, California Code of Regs	California Health & Safety Code 25150.6
Container and labeling requirements	Initially in red biohazard bag labeled with the words "Biohazardous Waste" or with biohazard symbol and the word "BIOHAZARD". Secondarily in rigid, leak resistant container with tight fitting lids of any color, labeled with "Biohazardous Waste" or biohazard symbol and the word "Biohazard" on lid and sides so as to be visible from any lateral direction.	Rigid puncture-resistant container that, when sealed, is leak resistant and cannot be opened without great difficulty. Containers should be labeled with the words "sharps waste" or with the biohazard symbol and the word "BIOHAZARD"	Yellow BD Chemo/Sharps container marked "Chemotherapy Waste", "CHEMO", or other label approved by the DHS on the lid and sides.	Rigid, leak resistant container with tight fitting lids of any color. Labeled with the words "Pathology Waste", "PATH" or other label approved by the DHS on lid and sides so as to be visible from any lateral direction.	Depends on classification of controlled substances. For the majority that are California only hazardous pharmaceutical wastes, "Incineration Only" or other label approved by the DHS on lid and sides so as to be visible from any lateral direction.	Rigid, leak resistant container with tight fitting lid of any color. Labeled with the words "Incineration Only" or other label approved by the DHS on lid and sides so as to be visible from any lateral direction. <u>Sharps with non-RCRA Pharmaceuticals may go in sharps/pharm container labeled "Incineration Only"</u>	Vary by waste type-and volume but must be leakproof and compatible with the waste. "Hazardous Waste" label stating chemical hazard, "Accumulation Start Date" and Facility/Department generating waste.	Vary by waste type (see Tables 1-4)
What can go in the container?	<ul style="list-style-type: none"> • Cultures and stocks of infectious agents • Items soaked or caked with blood or other infectious materials • Suction canisters • ET tubes • Culture plates • Bloody disposable gowns/gloves 	<ul style="list-style-type: none"> • Devices and implements that could potentially puncture or cut the skin, and/or otherwise cause percutaneous injury, e.g. • Sharps with or without engineered injury protection • All disposable needles • All disposable syringes with needles • Scalpels/ blades 	<ul style="list-style-type: none"> • Empty (non-pourable or scrapable in any orientation)vials, empty IV tubing from chemo administration • Gowns and gloves contaminated from chemo administration. • Sharps Trace Chemo should be segregated in separate container from non-sharps if there is a risk of needlestick when introducing waste 	<ul style="list-style-type: none"> • Surgery specimens or tissues which have been fixed in formalin or other fixatives. Fixatives must be decanted off prior to disposal. • Fetal remains cannot go in these containers. They must be placed in ziplock or sealable plastic containers for disposal to crematorium. 	<ul style="list-style-type: none"> • DEA Schedule 2-5 narcotics. Most diluted injectables classified as pharmacy waste and must be sent for incineration. Some solids are P&U listed and must be sent as RCRA wastes. Some very dilute are non-hazardous and can be wasted to sewer if POTW approves after witnessing. 	<ul style="list-style-type: none"> • All non-RCRA pharmaceuticals except list of 24 tested by Kaiser and found to not be California Haz Wastes. Contact local POTW to receive approval for sewerage. • Partial vials and IV bags containing medications. • Sharps go in red sharp's container. • Live and attenuated vaccines • Diluted chemo agents 	<ul style="list-style-type: none"> • All chemical wastes that are characteristically hazardous or listed • All RCRA P&U Listed Bulk Chemotherapy Agents • All Pharmaceuticals that are RCRA Characteristic or listed wastes (see RCRA Table). 	<ul style="list-style-type: none"> • Batteries except Lead Acid, which are haz waste. • Mercury containing thermostats, switches (including motor vehicle light switches), thermometers, dental amalgam, pressure or vacuum gauges, GI dilators, gas flow regulators and more. • Lamps, (including all fluorescent), neon, high intensity discharge, sodium vapor and metal halide • Consumer electronic devices including CRTs, TVs, computers, telephones, answering machines, etc.
Storage requirements	May not be stored longer than 7 days	May not be stored when full longer than 30 days as of 1/1/2007.	May not be stored when full longer than 7 days	May not be stored when full longer than 7 days	Can accumulate for up to 1 year. Storage for 90 days when ready for disposal (30 days if sharps).	Can accumulate for up to 1 year. Storage for 90 days when ready for disposal (30 days if containing sharps).	Storage time limits vary with generator status and TSDF distance.	1 year maximum storage time limit.

Attachment 3

1707.2 Duty to Consult.

- (a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:
 - (1) upon request; or
 - (2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.
 - (b) (1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:
 - (A) whenever the prescription drug has not previously been dispensed to a patient; or
 - (B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.
 - (2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice: of his or her right to request consultation; and a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.
 - (3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.
- (c) When oral consultation is provided, it shall include at least the following:
 - (1) directions for use and storage and the importance of compliance with directions; and
 - (2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.
- (d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:
 - (1) the name and description of the medication;
 - (2) the route of administration, dosage form, dosage, and duration of drug therapy
 - (3) any special directions for use and storage;
 - (4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
 - (5) prescription refill information;
 - (6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;
 - (7) action to be taken in the event of a missed dose.
- (e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

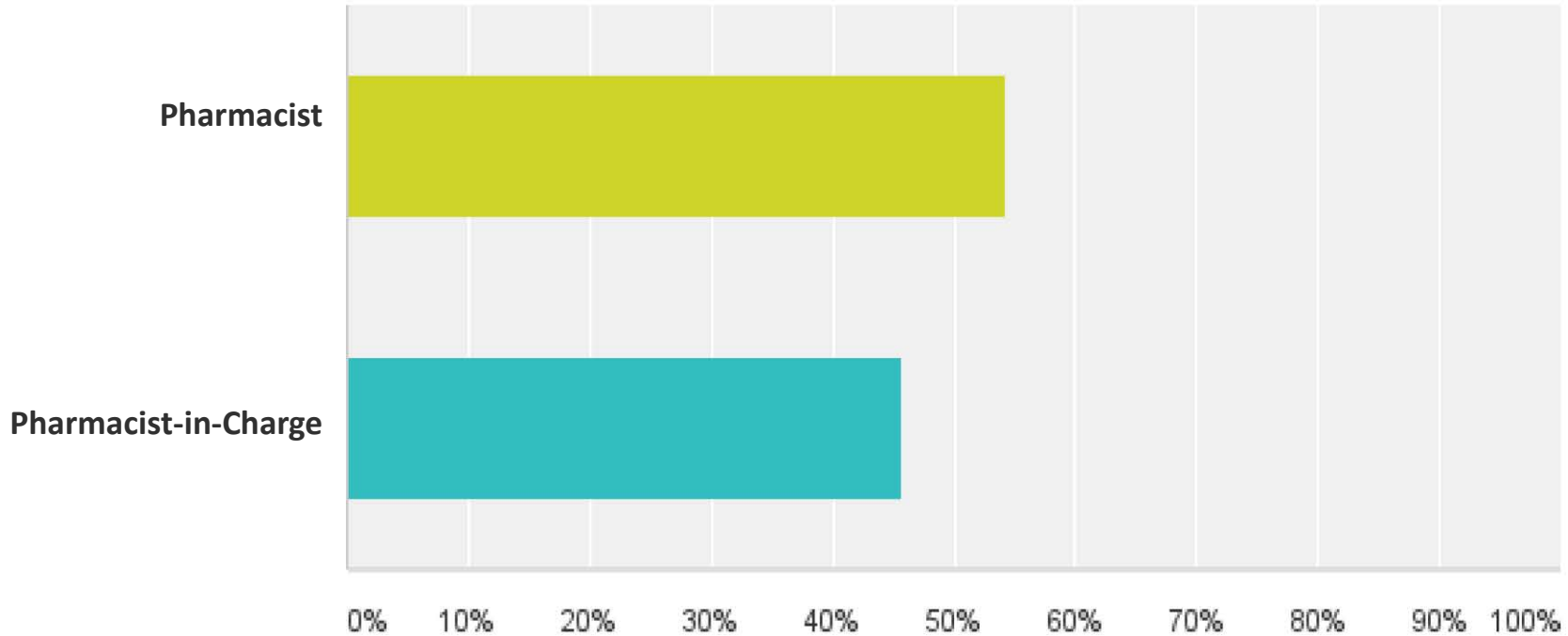
Survey for Pharmacists

1,006 total responses

Survey Date: July 20-24, 2015

Question 1: I am a licensed California_____.

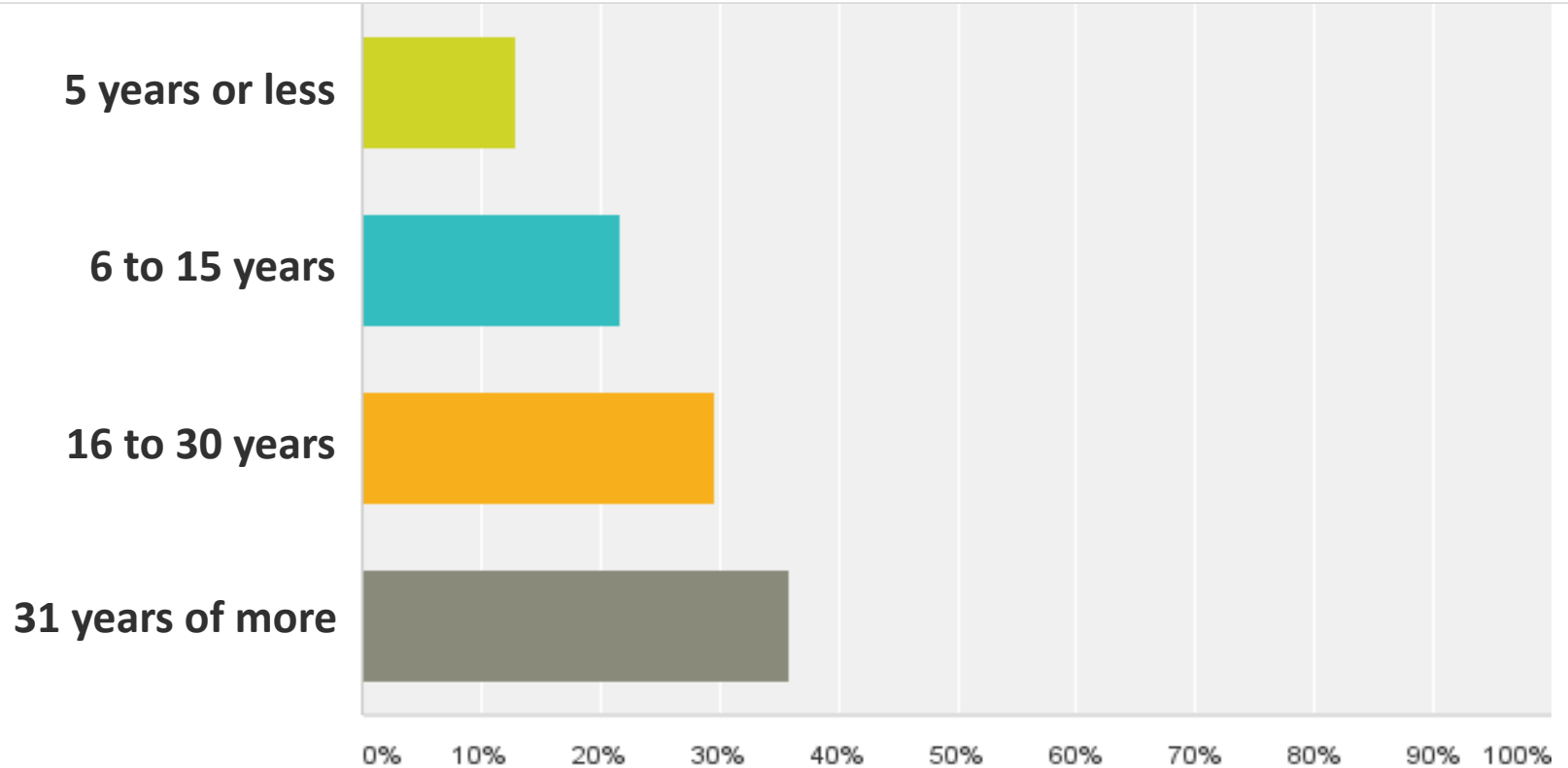
Answered: 998 Skipped: 8



Question 2: How long have you been a pharmacist?

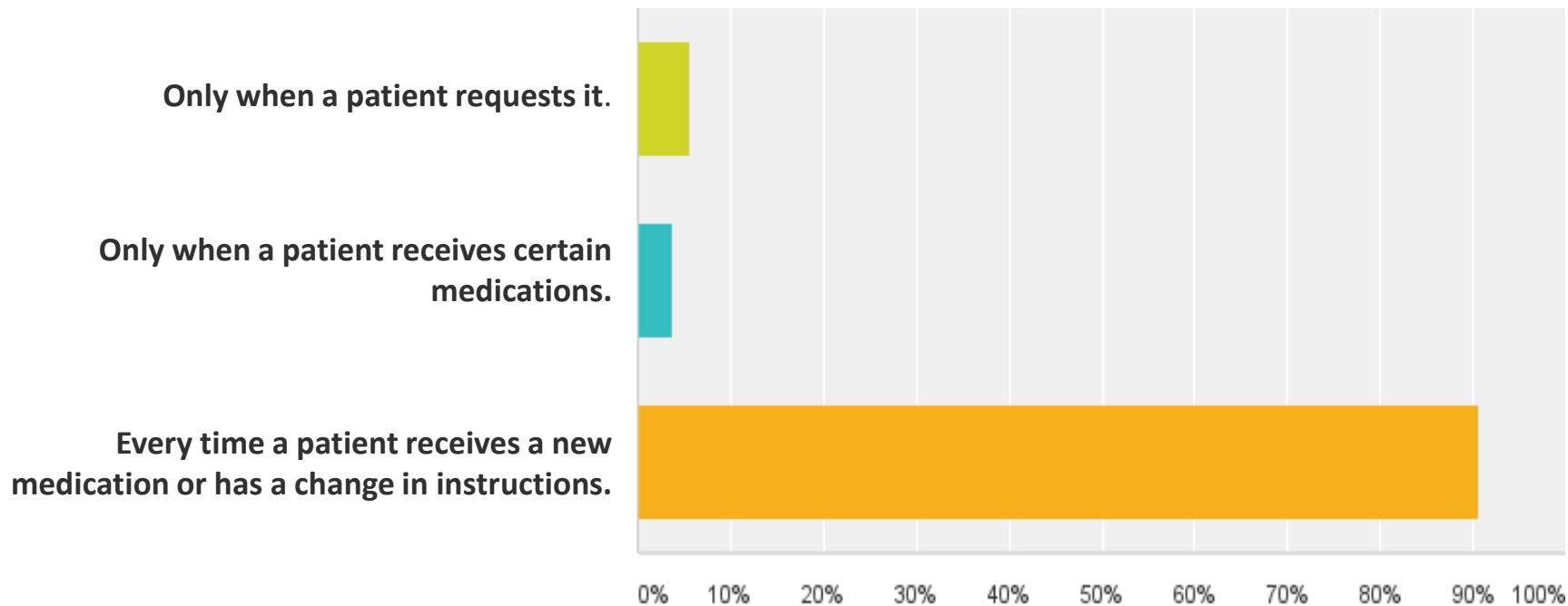
Answered: 1,004

Skipped: 2



Question 3: I consult....

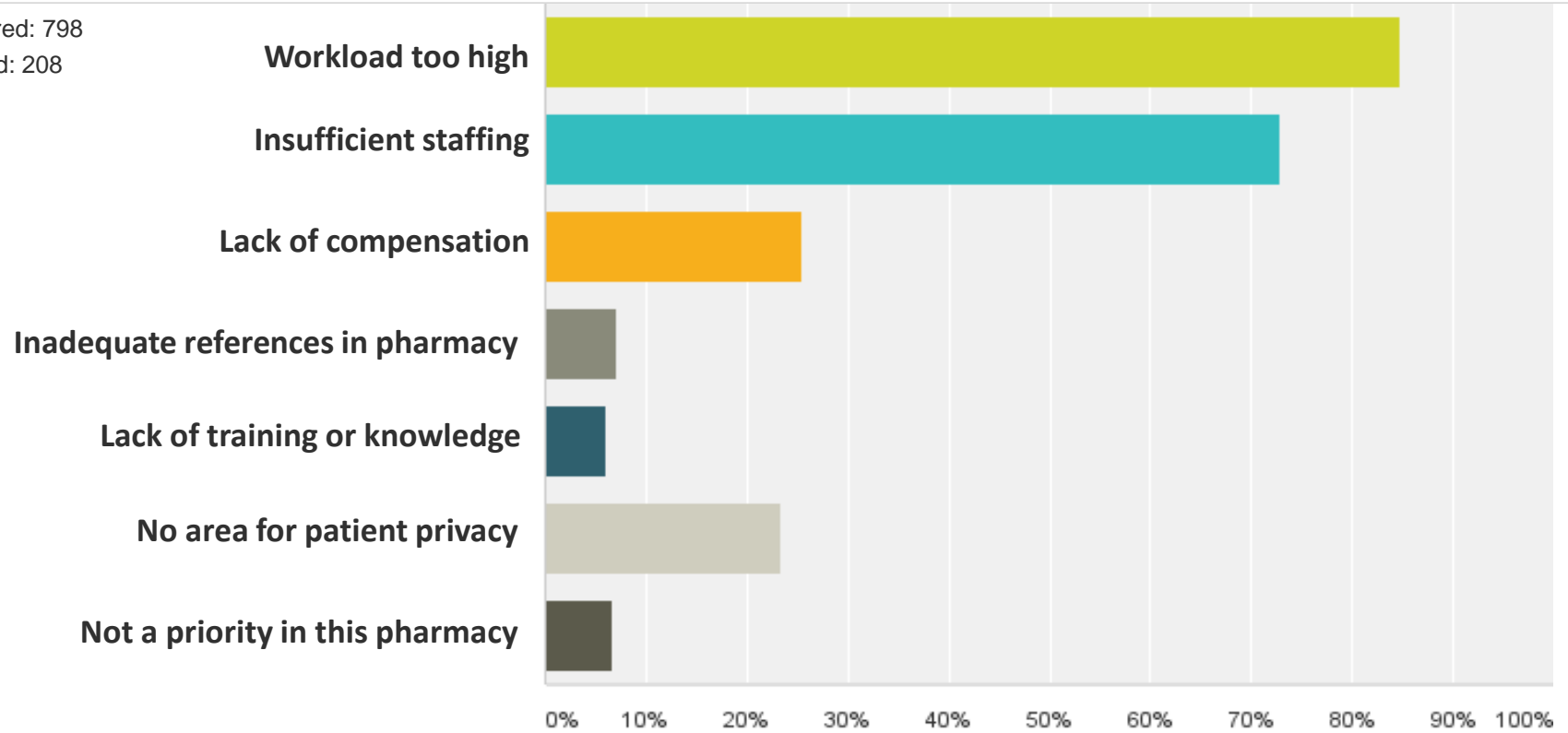
Answered: 897 Skipped: 109



Question 4: What barriers exist to a pharmacist initiating consultation (mark all that apply):

Answered: 798

Skipped: 208



Answers to the question: What barriers exist to a pharmacist initiating a consultation?	
None, I make it a priority to consult.	53
Patients in are in hurry and will not wait for consultation.	37
Doesn't apply to my practice setting.	30
The pharmacist is too busy / pressure from employer to fill prescriptions quickly even if that means not consulting.	24
No reimbursement for consultation.	12
Language or other communication barriers.	12
Lack of privacy to provide consultation.	9
The clerk or technician is the one working with the patient initially and they do not tell the patient they need to wait to talk to the pharmacist.	8
Ratio of technicians to pharmacists is too low.	6
Lack of training or experienced staff.	2



Riverside County District Attorney

NEWS RELEASE

PAUL E. ZELLERBACH
DISTRICT ATTORNEY

For Immediate Release
Dec. 23, 2013

John Hall
Senior Public Information Specialist
Contact: 951.955.8662

CVS PHARMACY, INC ORDERED TO PAY \$658,500 CONSUMER PROTECTION SETTLEMENT

RIVERSIDE – Today, Dec. 23, 2013, District Attorney Paul Zellerbach announced that a judge has ordered Rhode Island-based CVS Pharmacy, Inc., to pay a \$658,500 settlement in a consumer protection lawsuit brought against the owners of the CVS pharmacy chain in California.

The civil complaint, filed in San Diego Superior Court under California's unfair competition laws, alleges that CVS pharmacists throughout the state frequently failed to comply fully with the California Board of Pharmacy's (Board) rules requiring personal pharmacist consultations when prescription drug customers receive new prescriptions or new dosages of existing prescriptions. Defendants Garfield Beach CVS, LLC, and Longs Drugs Stores, California, LLC, are California limited liability companies owned by parent company CVS Pharmacy, Inc. These CVS defendants own and operate the 850 CVS-branded pharmacies in California. There are 45 CVS stores in Riverside County.

In 2011, the Board brought to the District Attorney's Offices in Riverside, San Diego and Alameda counties the problem of health risks to California pharmacy customers when pharmacists fail to properly provide needed personal consultation to prescription drug customers. Uninformed or improper use of prescription drugs harms an estimated 150,000 Californians each year and contributes to an estimated \$1.7 billion statewide in economic loss. Regulations enforced by the Board require that a pharmacist must provide personal consultation to a patient receiving a prescription drug not previously dispensed to that patient, or a prescription drug in a different dosage, form, or strength, or on the patient's request.

Working with the Board, the three District Attorneys' Offices conducted an undercover investigation of the consultation practices of a number of the major pharmacy chains in California. Today's enforcement action is the first of several such actions anticipated as a result of that investigation. The Board provided the District Attorney's Offices copies of 22 citations issued to CVS by the Board between March 2008 and September 2012 showing a continuing pattern of violations of the consultation requirement. Subsequent undercover investigations by the District Attorney's Offices in the three counties in 2011 and 2012 found a number of instances where CVS pharmacies offered consultations by improper personnel and other instances where the pharmacies did not offer or did not provide the required consultations at all.

Under the terms of the judgment, signed on Dec. 20, 2013, by San Diego Superior Court Judge Lisa Schall -- which was entered without admission of liability by CVS -- CVS is permanently enjoined to comply with California's standards for patient consultations and must fully implement an internal compliance program that CVS began once it learned of prosecutors' concerns. In the stipulated final judgment, CVS entities also agreed to pay agency investigative costs of \$97,500 and civil penalties totaling \$561,000. The Riverside County DA's Office will receive one-third, or \$187,000, of those civil penalties and \$19,166 of the costs. CVS worked cooperatively with the prosecutors to promptly resolve the matter and to implement the new compliance procedures.

The case was handled in Riverside County by Deputy DA Elise Farrell of the DA's Consumer Fraud Unit.



<http://pleasantonweekly.com/news/print/2014/06/30/rite-aid-pays-nearly-500000-in-pharmacy-consultation-lawsuit>

Updated: Tue, Jul 1, 2014, 6:54 am

Uploaded: Mon, Jun 30, 2014, 3:08 pm

Rite Aid pays nearly \$500,000 in pharmacy consultation lawsuit

Pleasanton drug store one of 582 in California suit

by Jeb Bing

Alameda County District Attorney Nancy E. O'Malley announced this week that the Office's Consumer and Environmental Protection Division, along with Riverside and San Diego District Attorneys' Offices and the California State Board of Pharmacy, has settled a \$498,250 lawsuit against the owners of the Rite Aid pharmacy chain in California.

Rite Aid operates a pharmacy at Hopyard Road and Valley Avenue in Pleasanton.

The civil complaint, filed in San Diego Superior Court, alleges that California Rite Aid pharmacists frequently failed to comply fully with the board's rules requiring personal pharmacist consultations when prescription drug customers receive new prescriptions or new dosages of existing prescriptions.

In 2011 the California State Board of Pharmacy contacted the three District Attorneys' offices concerning health risks that may arise when pharmacists fail properly to provide needed personal consultation to prescription drug customers. Working with the Board of Pharmacy, the three DA offices conducted an undercover investigation of the consultation practices of a number of the major pharmacy chains in California.

Under the terms of the judgment, which was entered without admission of liability, Rite Aid is permanently enjoined to comply properly with California's standards for patient consultations, and must fully implement an internal compliance program. The Rite Aid entities also agreed to pay agency investigative costs of \$78,250 and civil penalties totaling \$420,000.

Alameda County will receive one-third, or \$140,000, of those civil penalties and \$18,500 of the costs.

Rite Aid and its counsel worked cooperatively with the prosecutors to promptly resolve the matter and to implement the new compliance procedures.

"The collaboration of the three D.A. Offices and the State Board of Pharmacy resulted in today's settlement," O'Malley said.

"Pharmacist consultations are imperative to safeguard that prescriptions have been filled according to a doctor's order, as well as to advise the patient of proper and safe usage of the medication. My Office remains dedicated to ensuring that the public has access to knowledge and education regarding the use of all prescription drugs."

Thrifty Payless, Inc., a California corporation, is the wholly-owned subsidiary of Pennsylvania-based Rite Aid Corporation, a Delaware corporation. Payless owns and operates the 582 Rite Aid-branded pharmacies in California, including the one in Pleasanton, on behalf of the Rite Aid Corporation.

OFFICE OF
THE DISTRICT ATTORNEY
COUNTY OF SAN DIEGO

San Diego
330 West Broadway
San Diego, CA 92101
(619) 531-4040

BONNIE M. DUMANIS
DISTRICT ATTORNEY

San Diego County District Attorney

August 17, 2015
For Immediate Release

Contact: [Steve Walker](#) (619) 531-3890
[Tanya Sierra](#) (619) 531-3315
En Español [Barbara Medina](#) (619) 531-3305

Walgreens Pharmacy to Pay \$502,200 to Resolve Consumer Protection Case

Pharmacists failed to Provide Patient Consultations

San Diego County District Attorney [Bonnie M. Dumanis](#) announced today that Consumer Protection Unit, working with the Riverside and Alameda District Attorneys' Office and the State Board of Pharmacy, has obtained a \$502,200 settlement in a consumer protection lawsuit brought against the owners of the Walgreens pharmacy chain in California.

The civil complaint, filed in San Diego Superior Court under California's unfair competition laws, alleges that Walgreens pharmacists throughout the state frequently failed to comply fully with the state Board of Pharmacy's rules requiring personal pharmacist consultations when prescription drug customers receive new prescriptions or new dosages of existing prescriptions.

“Pharmacist consultations prevent drug errors and ensure that patients have the right prescription for their condition,” DA Dumanis said. “Without these checks and balances, dire consequences could result.”

Defendant Walgreen Co. (known as “Walgreens”) is an Illinois corporation headquartered in Deerfield, Illinois, that owns and operates the 620 Walgreens-branded pharmacies in California.

In 2011, the California State Board of Pharmacy brought to the three District Attorneys' Offices the problem of health risks to California pharmacy customers when pharmacists fail to properly provide needed personal consultation to prescription drug customers. Uninformed or improper use of prescription drugs harms an estimated 150,000 Californians each year and contributes to an estimated \$1.7 billion in economic losses throughout the state.

Regulations enforced by the California State Board of Pharmacy require that a pharmacist must provide personal consultation to a patient receiving a prescription drug not previously dispensed to that patient, or a prescription drug in a different dosage, form, or strength, or on the patient's request.

Follow the District Attorney's Office on



Working with the Board of Pharmacy, the three District Attorneys' Offices conducted an undercover investigation of the consultation practices of a number of the major pharmacy chains in California. Today's enforcement action is the third of several such actions anticipated in this statewide project, and follows our December 2013 judgment against CVS pharmacies (injunction and \$658,500 in monetary relief) and our June 2014 judgment against Rite Aid (injunction and \$498,250 in monetary relief).

With regard to the Walgreens chain, the Board provided the District Attorneys with copies of 21 administrative citations issued to Walgreens by the Board of Pharmacy between 2010 and 2014 showing ongoing violations of the pharmacists' consultation requirement. Subsequently, in 28 undercover purchases at Walgreens stores conducted by the District Attorneys in late 2013 in San Diego, Riverside, and Alameda counties, district attorney investigators found a significant pattern of failures to provide the required consultations and/or failures to offer patient consultations by proper personnel.

Under the terms of the judgment, which will be entered without admission of liability, Walgreen Co. will be subject to an injunction requiring full compliance with California's standards for proper patient consultations, and must fully implement an internal compliance program. In the stipulated final judgment, the Walgreens entities have also agreed to pay \$502,200, including agency investigative costs of \$79,200 and civil penalties of \$423,000. (San Diego DA will receive one-third, or \$141,000, of those civil penalties and \$18,600 of the costs.) Walgreens and its counsel worked cooperatively with the prosecutors to resolve this case and to implement new consultation compliance procedures.

The stipulated final judgment in this case was signed by Judge Lisa Schall and finalized by the court last Friday.

The case was handled for the San Diego District Attorney's Office by Deputy District Attorney Tom Papageorge, head of the Consumer Protection Unit (619-531-3971), and Deputy District Attorney Steve Spinella (619-515-8160).

Attachment 4

1715.55 Reconciliation and Inventory Report of Controlled Substances

Revision Date: July 28, 2015 by the Full Board

- (a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.
- (b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.
- (c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.
 - (1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.
 - (2) The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:
 - a. A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.
 - b. The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.
- (d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
- (e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
 - (1) Losses shall be identified in writing and reported to the board and, when

appropriate, to the Drug Enforcement Administration.

- (2) Likely causes of overages shall be identified in writing and retained.
 - (3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.
- (f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.
- (1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.
 - (2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.
 - (3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.
- (g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.
- (h) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing


Attachment 5

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Pharmacy News

Medicare Updates Pharmacy Practice Expectations for Critical Access Hospitals

[March 15, 2015, AJHP News]

Kate Traynor

BETHESDA, MD 02 Mar 2015—A January 16 directive to state survey agencies gives new details about Medicare's expectations for compounding practices and other pharmacy activities at critical access hospitals.

But the Centers for Medicare and Medicaid Services (CMS) communication—an update to interpretive guidelines for state surveyors—has wider ramifications, said Patricia C. Kienle, director of accreditation and medication safety for Cardinal Health Innovative Delivery Solutions.

That's because CMS is mandating well-established pharmacy practices that ASHP, the Institute for Safe Medication Practices, the United States Pharmacopeial Convention, and other professional groups have endorsed for years, Kienle said. And she expects CMS to ultimately require the same practices at all hospitals.

Kienle said the directive is good news.

"I think it's a very positive thing for patients, because it's incorporating minimum standards, for everybody, that we know are the safe ways of practicing," she said. "And they need to remember, it's a minimum standard."

A substantial portion of the 93-page CMS communication addresses pharmacy practice, including sterile and nonsterile compounding; infection prevention and control; medication safety, handling, administration, and storage; and contracted operations.

"It's not really necessarily any different from what we had been doing already," said clinical pharmacist Todd Lemke of CentraCare Health, a critical access hospital in Paynesville, Minnesota. "I kind of see a lot of this as just regulation catching up with practice, at least for us."

Lemke said that although meeting the Medicare-required practice standards isn't really difficult for critical access hospitals, finding time to document compliance with those practices can be a concern.

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For questions, comments, or more information on this article, please contact the ASHP News Center at newscenter@ashp.org.

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The clear path to BPS review & recertification for clinical pharmacists



"The part that I struggle with the most is just making sure that our policies are up to date," Lemke said. "That just doesn't always seem to be something that's actually doable, as a critical access pharmacist, because we have to also do the day-to-day stuff."

David T. Caron, Jr., director of pharmacy at Martha's Vineyard Hospital in Oak Bluffs, Massachusetts, likewise said that finding time to document compliance with changing standards and regulations is difficult for critical access hospitals, in general.

Nevertheless, he said, "I think we all know, as pharmacists, it's the right thing to do. And we all want to do the right thing . . . It's just that getting there is the monumental task."

Surveys. State survey agencies—the CMS document's official audience—are responsible for certifying that hospitals not accredited by a so-called deeming organization, such as the Joint Commission, meet the Medicare program's conditions of participation (CoPs).

CoPs, Keinle noted, "drive everything in the hospital."

According to CMS, 83% of hospitals overall but just 33% of critical access hospitals in fiscal year 2013 were Medicare-certified through a deeming agency, suggesting that state survey agencies play a large role in ensuring that critical access hospitals meet Medicare's CoPs.

But federal regulations require accrediting organizations with deeming authority to employ survey procedures that are comparable to those used by state survey agencies, including new requirements imposed by CMS.

A Joint Commission spokesperson stated that the accrediting agency revised its standards for critical access hospitals last year to reflect regulatory changes in CMS's state operations manual for critical access hospitals.

She said the Joint Commission is currently "reviewing the details" of the new CMS directive to examine how the compounding provisions compare against the accrediting agency's medication management standards for critical access hospitals.

Lemke's Minnesota hospital is certified by Medicare through his state survey agency, and Caron's Massachusetts hospital is accredited by the Joint Commission.

ASHP Engages on Compounding

ASHP's Bona Benjamin said ASHP has been providing technical expertise on safe compounding practices for many years and has long supported the principles contained in *United States Pharmacopeia (USP) chapter 797*. She said ASHP "will continue to engage with the Centers for Medicare and Medicaid Services, as we always have, to support their efforts to improve oversight of sterile compounding and better their understanding [of] USP 797 requirements as they develop surveyor training materials."

ASHP recently issued a [regulatory alert](#) that summarizes CMS's compounding requirements for critical access hospitals. ASHP's "[Guidelines for Outsourcing Sterile Compounding Services](#)" and the ASHP Research and Education Foundation's "[Outsourcing Sterile Products Preparation: Contractor Assessment Tool](#)" are being revised to reflect current regulatory requirements.

Compounding. The CMS document officially establishes *United States Pharmacopeia (USP)* chapter 795 as the minimum standard for practices related to nonsterile compounding and USP chapter 797 for compounded sterile products.

USP chapter 795 has been an enforceable standard since 2000, meaning that state boards of pharmacy and other organizations can use it as the basis for

fining and other adverse actions against noncompliant regulated entities. Chapter 797 has been enforceable since 2004.

Bona Benjamin, ASHP's director for medication-use quality improvement, said the CMS communication means that critical access hospitals, regardless of whether they are accredited by a deeming organization or surveyed by a state agency, should expect "additional scrutiny of sterile and nonsterile compounding services."

Lemke said the CMS requirement that compounding be performed "only by a pharmacist or other personnel authorized in accordance with State and Federal law" may pose compliance problems for sparsely staffed critical access hospitals.

"Sometimes we only have seven people in the hospital, so it's not economically feasible to always have a pharmacist onsite," Lemke explained. He noted that some critical access hospitals have no staff pharmacists and rely on a local community pharmacist or other contract arrangement for compounding services.

Kienle said the CMS provisions that relate to contracted operations, including offsite compounding, "may be something that needs some attention" from pharmacy departments at critical access hospitals.

"For any contracted service, the hospital needs to have a written agreement—it can't just be a handshake—and they need to have written expectations and a way of monitoring what these places are doing," Kienle said.

According to the CMS document, critical access hospitals that contract for compounding activities must have access to the vendor's quality assurance data to verify compliance with USP chapters 795 and 797. Each hospital must document that it obtains and reviews this data. CMS also expects vendors to demonstrably follow state laws and meet the requirements of Section 503A of the Food, Drug, and Cosmetic Act that relate to the compounding of human drug products.

Hospitals also have the option to contract with FDA-registered outsourcing facilities to obtain compounded sterile products. Also known as 503B entities, outsourcing facilities are FDA regulated and must use current good manufacturing practices—the same standard to which drug manufacturers are held, with some exceptions.

Lemke said his hospital purchases manufacturers' premixed sterile i.v. solutions and, when those products aren't available, ready-to-mix products that require minimal manipulation by a nurse. Otherwise, he said, one of the three staff pharmacists prepares compounded sterile products onsite.

"We don't have any things that are made by compounding pharmacies here," Lemke said.

Lemke noted that his experiences with product recalls, including Hospira's January recall of ketorolac tromethamine injection, make him hesitant to outsource compounding activities.

"If the big drug companies are having problems with sterility and having foreign material in the vial, I'm really concerned with the compounding pharmacies," Lemke said.

Caron said his hospital purchases some high-use compounded sterile products, such as premixed i.v. pitocin for infusion, from an FDA-registered outsourcing facility.

Caron said he checks information on FDA's website to ensure that the outsourcing facility has "no obvious violations." And the hospital's parent organization, Boston-based Partners HealthCare, evaluates and makes recommendations about vendors.

"Before you use a company like that you have to be sure that all of their quality standards meet yours, . . . that they're 797 compliant, that they have quality indicators that they report to you," Caron said. "In light of all the tragedies that have happened in this state, it's my number-one job to ensure the safety of those products, whether I'm making them or somebody else is making them."

Massachusetts was home to the New England Compounding Center, a compounding pharmacy whose tainted products were blamed for 64 deaths and hundreds of fungal infections during an outbreak that began in 2012.

A 2014 Massachusetts law codified USP chapters 795 and 797 as the standards for pharmacy compounding in the state. In addition, after June 30 of this year, all pharmacies in the state that perform sterile or nonsterile compounding must be licensed by the state to do so.

Caron said his hospital has been preparing for this change in addition to maintaining compliance with federal law and accreditation requirements.

FDA's commissioner in January 2014 urged hospitals and other healthcare facilities to purchase compounded sterile products only from FDA-registered outsourcing facilities. The agency also asked state boards of pharmacy to request that out-of-state pharmacies that ship compounded sterile products into the state register with FDA as outsourcing facilities.

The CMS document acknowledges FDA's preference for hospitals to use official outsourcing facilities to obtain compounded sterile products. But the facilities do not yet appear to be fully meeting federal regulators' expectations.

As of late January, just 1 of the 42 FDA-registered outsourcing facilities that had been inspected by the agency had passed the review with no "significant objectionable conditions," according to FDA. The agency issued warning letters or requested product recalls for 12 of the inspected facilities.

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Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 15-19-CAH

DATE: January 16, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised State Operations Manual (SOM) Appendix W, Critical Access Hospitals (CAHs)

Memorandum Summary

The Centers for Medicare & Medicaid Services (CMS) CAH Conditions of Participation (CoPs) Changed in Two Final Rules:

- CMS-3267-F was published on May 12, 2014 and portions related to CAHs became effective July 11, 2014. Among other provisions, this final rule revised the CAH Conditions of Participation (CoP) requirements related to the responsibilities of doctors of medicine (MDs) and doctors of osteopathy (DOs).
- CMS-1599-F was published August 19, 2013 and became effective October 1, 2013. This final rule revised the CAH CoP requirements related to provision of inpatient acute care services.

SOM Appendix W Updated:

- We are updating the pertinent portions of the CAH interpretive guidelines, found in SOM Appendix W, to reflect these rule changes.
- In addition, we are taking this opportunity to update the guidance for the portions of 42 CFR 485.635 addressing the following topics, in order to bring them into alignment with current accepted standards of practice: pharmacy services; infection prevention and control; dietary services; services under arrangement; nursing services; and rehabilitation services.

Two final rules published by the CMS include changes to the CAH CoPs:

- “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of

Participation; Payment Policies Related to Patient Status,” published August 19, 2013 and effective October 1, 2013 (78 Fed. Reg. 50495).

- “Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II,” published May 12, 2014 and effective July 11, 2014 (79 Fed. Reg. 27105).

Briefly, the new and revised CAH regulations from these two final rules are:

- Designation and Certification of CAHs, §485.606:

The cross-reference to hospital swing bed services found in this CAH regulation was revised to reflect the renumbering of the hospital regulation. This CAH regulation prohibits a State from denying CAH designation to an otherwise eligible hospital solely because the hospital provides swing bed services. The revision has no substantive effect on the current CAH requirement. *This change was effective July 11, 2014.*

- Number of Beds and Length of Stay, §485.620:

The provision at §485.620(a) was revised to remove an outdated reference to a January 1, 2004 effective date, after which a CAH may not maintain more than 25 inpatient beds that may be used to provide either inpatient or swing-bed services. *This change was effective October 1, 2013.* The revision has no substantive effect on the current CAH requirement.

- Staffing and Staff Responsibilities, §485.631:

o §485.631(b)(1)(v) & (vi) were revised, *effective July 11, 2014*, to:

- o Addresses the confusion about the prior rule’s requirements concerning physician review of outpatient records by deleting §485.631(b)(1)(vi) and incorporating its provisions into §485.631(b)(1)(v). The revised requirement calls for a CAH MD or DO to periodically review and sign a sample of outpatient records of those patients cared for by non-physician practitioners (nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants), but only to the extent required under State law where State law requires such record reviews and/or co-signatures by a collaborating physician.

The amended requirement is not substantively different from the previous CAH requirement, but is stated more clearly.

- o Removes the requirement for those reviews which are required under State law to take place at least every two weeks.
- o §485.631(b)(2) was revised, *effective July 11, 2014*, to remove the requirement that an MD or DO must be present in the CAH at least once every two weeks. CAH MDs/DOs are now required to be present for sufficient periods of time to provide medical direction,

consultation, and supervision for the services provided in the CAH. This revision recognizes that many of the MD/DO required functions may be performed remotely via electronic means, and that the time required to be on-site will vary from CAH to CAH, depending on the volume and type of services they offer.

- Provision of Services, §485.635:
 - §485.635(a)(2) was revised to remove the requirement for the CAH’s patient care policies to be developed with the advice of at least one individual who is not a member of the CAH’s professional healthcare staff. *This change was effective July 11, 2014.*
 - §485.635(a)(3)(vii) was revised to remove the conditional language that could have been misunderstood as making it appear optional for a CAH to provide acute inpatient services. *This change was effective October 1, 2013.*
 - §485.635(b)(1) was revised to add a new, explicit requirement at §485.635(b)(1)(ii) for CAHs to furnish acute care inpatient services. After regulation changes adopted in 2012 removed language referring to “direct” services a CAH must provide, as opposed to services a CAH may provide under arrangement, the language remaining could have been misinterpreted to suggest that a CAH must only provide outpatient services. *This change was effective October 1, 2013.*
 - §485.635(c) was revised to remove inpatient hospital care as a service that may be provided under arrangement, to avoid creating the misperception that CAHs are not required to furnish inpatient services. *This change was effective October 1, 2013.*

We have revised our interpretive guidelines in Appendix W of the SOM, to reflect these rule changes.

In addition to the changes based on the revised regulations, we are taking this opportunity to update the guidance in Appendix W for the portions of 42 CFR 485.635 addressing the following topics, in order to bring them into alignment with current accepted standards of practice: pharmacy services; infection prevention and control; dietary services; services under arrangement; nursing services; and, rehabilitation services.

An advance copy of the revised portions of SOM Appendix W is attached. The online SOM will be updated at a later date and may differ slightly from this advance copy.

Revisions have also been made to Tags in the Automated Survey Processing Environment (ASPEN) to correspond to the revised guidance. Note that some tags have been consolidated or address different regulations than previously.

Questions concerning this memorandum should be addressed to CAHSCG@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

/s/
Thomas E. Hamilton

Attachment: 1- Revisions to State Operations Manual Appendix W, related to critical access hospitals.

cc: Survey and Certification Regional Office Management

CMS Manual System

Department of Health &
Human Services (DHHS)

Pub. 100-07 State Operations

Centers for Medicare &
Medicaid Services (CMS)

Provider Certification

Transmittal

(Advance Copy)

Date:

SUBJECT: Revisions to State Operations Manual Appendix W, related to critical access hospitals.

I. SUMMARY OF CHANGES: We are revising: Appendix W, Survey Protocol, Regulations and Interpretive Guidance for Critical Access Hospitals (CAHs) and Swing Beds in CAHs, to reflect recent regulation changes. We are also taking this opportunity to make clarifications and updates to existing guidance.

NEW/REVISED MATERIAL - EFFECTIVE DATE: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix W/Table of Contents
R	Appendix W/C-0211/§485.620(a)
R	Appendix W/C-0260/§485.631(b)(1)(iv) &/§485.631(b)(1)(v)
R	Appendix W/C-0261/§485.631(b)(2)

R	Appendix W/C-0270/§485.635
R	Appendix W/C-0271/§485.635(a)(1)
R	Appendix W/C-0272/§485.631(a)(2) &/§485.631(a)(4)
R	Appendix W/C-0273/§485.631(a)(3)(i)
R	Appendix W/C-0274/§485.635(a)(3)(ii)
R	Appendix W/C-0275/§485.635(a)(3)(iii)
R	Appendix W/C-0276/§485.635(a)(3)(iv)
R	Appendix W/C-0277/§485.635(a)(3)(v)
R	Appendix W/C-0278/§485.635(a)(3)(vi)
R	Appendix W/C-0279/§485.635(a)(3)(vii)
R	Appendix W/C-0280/§485.635(b)(1)(i)
R	Appendix W/C-0281/§485.635(b)(1)(ii)
R	Appendix W/C-0282/§485.635(b)(2)
R	Appendix W/C-0283/§485.635(b)(3)
R	Appendix W/C-0284/§485.635(b)(4)
D	Appendix W/C-0286
R	Appendix W/C-0287/§485.635(c)(1)(i) & /§485.635(c)(2)
R	Appendix W/C-0288/§485.635(c)(1)(ii) & /§485.635(c)(2)
R	Appendix W/C-0289/§485.635(c)(1)(iii)
D	Appendix W/C-0290
R	Appendix W/C-0291/§485.635(c)(3)
R	Appendix W/C-0292/§485.635(c)(4)
D	Appendix W/C-0293
R	Appendix W/C-0294/§485.635(d) & /§485.635(d)(1)
D	Appendix W/C-0295

R	Appendix W/C-0296/§485.635(d)(2)
R	Appendix W/C-0297/§485.635(d)(3)
R	Appendix W/C-0298/§485.635(d)(4)
R	Appendix W/C-0299/§485.635(e)

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2015 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

State Operations Manual

Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospitals (CAHs) and Swing-Beds in CAHs

(Rev.)

[Transmittals for Appendix W](#)

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Regulations and Interpretive Guidelines for CAHs

§485.608 Condition of Participation: Compliance With Federal, State, and Local Laws and Regulations

§485.610 Condition of Participation: Status and Location

§485.612 Condition of Participation: Compliance With CAH Requirements at the Time of Application

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- §485.643 Condition of Participation: Organ, Tissue, and Eye Procurement
- §485.645 Special Requirements for CAH Providers of Long-Term Care Services (“Swing-Beds”)

C-0211

(Rev.)

§485.620(a) Standard: Number of Beds

Except as permitted for CAHs having distinct part units under §485.647, the CAH maintains no more than 25 inpatient beds. *Inpatient beds may* be used for either inpatient or swing-bed services.

Interpretive Guidelines §485.620(a)

Section 1820(c)(2)(B)(iii) of the Social Security Act limits a CAH to a maximum of 25 inpatient beds that can be used for inpatient acute care or swing bed services. The statute also requires CAHs to provide inpatient acute care limited, on an annual average basis, to 96 hours per patient (see interpretive guidelines for §485.620(b)).

Section 1820(c)(2)(E) of the Act also permits a CAH to operate a 10-bed psychiatric distinct part unit (DPU) and a 10-bed rehabilitation DPU, without counting these beds toward the 25-bed inpatient limit.

The limit applies to the number of inpatient beds; not to the number of inpatients on any given day. CAHs that were larger hospitals prior to converting to CAH status may not maintain more than 25 inpatient beds, plus a maximum of 10 psychiatric DPU inpatient beds, and 10 rehabilitation DPU inpatient beds. *Any bed used for inpatient services at any time must be counted when assessing compliance with the 25 inpatient bed limit. Beds used for outpatient services, such as observation services, sleep studies, emergency services, etc. do not count towards the CAH’s 25-bed limit only if they are never used for inpatient services.*

Beds Used for Observation Services

Beds used solely for patients receiving observation services are not included in the 25-bed maximum, nor in the calculation of the average annual acute care patient length of stay. This makes it essential for surveyors to determine that CAHs with observation beds are using them appropriately, and not as a means to circumvent the CAH size and length-of-stay limits. Inappropriate use of observation services also subjects Medicare beneficiaries to an increased beneficiary coinsurance liability that could have been avoided, had the beneficiary been properly admitted as an inpatient. This is the case because, as CAHs are not paid under the hospital Outpatient Prospective Payment System (OPPS), the beneficiary in an observation status will be liable for a coinsurance charge equal to 20 percent of the CAH's customary charges for the services. Further, as CAHs are also not subject to the preadmission payment window, a Medicare beneficiary would be liable for the coinsurance charges for the observation status services even when subsequently admitted. Depending on the terms of their health insurance coverage, other CAH patients may also face similar increased and avoidable costs when inappropriately placed in an observation status.

Observation care is a well-defined set of specific, clinically appropriate services that include ongoing short-term treatment, assessment, and reassessment, that are provided before a decision can be made regarding whether a patient will require further treatment as an inpatient, or may be safely discharged. Observation status is commonly assigned to patients with unexpectedly prolonged recovery after outpatient surgery, and to patients who present to the emergency department and who then require a significant period of treatment or monitoring before a clinical decision is made concerning their next placement. The CAH should ensure that once there is sufficient information to render this clinical decision, the patient should be expeditiously admitted, appropriately transferred, or discharged.

A patient may be in an observation status even though the CAH furnishes the patient overnight accommodation, food, and nursing care.

Observation services are **NOT** appropriate:

- As a substitute for an inpatient admission;
- For continuous monitoring;
- For medically stable patients who need diagnostic testing or outpatient procedures (e.g., blood transfusion, chemotherapy, dialysis) that are routinely provided in an outpatient setting;
- For patients awaiting nursing home placement;
- To be used as a convenience to the patient, his or her family, the CAH, or the CAH's staff;
- For routine prep or recovery prior to or following diagnostic or surgical services; or

- As a routine “stop” between the emergency department and an inpatient admission.

Observation services **BEGIN** and **END** with an order by a physician or other qualified licensed practitioner of the CAH.

- The order for observation services must be written prior to initiation of the service, as documented by a dated and timed order in the patient’s medical record. The order may not be backdated. Orders should be clear for the level of care intended, such as “admit to inpatient” or “place *in* observation.” *(Note: It is not uncommon for hospitals and practitioners to refer to “admitting” a patient for observation. Technically, only inpatients are “admitted,” while patients receiving observation services are in an outpatient status. However, usage of the term “admit” in an order placing a patient in observation status does not violate any CAH CoP and is not cited.)*
- Observation services end when the physician or other qualified licensed practitioner orders an inpatient admission, a transfer to another health care facility, or discharge. The inpatient stay begins on the date and time of the new order.
- Standing orders for observation services are not acceptable, since it is not necessary to employ observation services for every patient in a given category, e.g., every emergency department patient, in order to reach a clinical decision about the appropriate next step in the patient’s care.

Medicare generally will not pay for observation services lasting more than 48 hours. However, *some States may have more stringent limits in their licensure or other regulatory requirements on the length of observation services, e.g., 24 hours. In such cases the State’s more stringent limit on the length of an observation stay applies to Medicare beneficiaries as well, but is not enforced through the Federal survey process, unless the State has taken a final enforcement action.*

The CAHs must provide appropriate documentation upon surveyor request to show that an observation bed is not an inpatient bed. The CAH must be able to document that it has specific clinical criteria for *placing a patient in* and *discharging* from, the observation service, and that these criteria are clearly distinguishable from those used for inpatient admission and discharge. CMS expects a CAH to employ the same type of clinical criteria for observation versus inpatient status for all patients, regardless of their payer status. For example, if a CAH were routinely placing only Medicare beneficiaries in its dedicated observation unit, then this *could* suggest that non-clinical criteria were being used in the decision to admit versus place in observation status. This would not only call the observation bed status into question, but *could also* violate the CAH’s provider agreement *requirement that prohibits differential treatment of Medicare beneficiaries.* (See 42 CFR 489.53(a)(2).)

If a CAH maintains beds that are dedicated to observation services, the CAH must be able to provide evidence, such as the clinical criteria for admission to that unit and how patients in the unit meet those criteria, to demonstrate that its observation beds are not being used for inpatient services. CMS expects there to be a reasonable relationship between the size of the CAH’s inpatient and observation operations. For example, a 10-bed observation unit in a 25-bed CAH

might be disproportionately large, and the surveyor must determine whether the observation unit is actually functioning as an inpatient overflow unit. A CAH observation unit that routinely operates at a high occupancy rate could also be an indicator of the need to probe further.

Other Types of Beds

Other bed types that do not count toward the 25 inpatient bed limit include, *but are not limited to*:

- Examination or procedure tables;
- Stretchers;
- Operating room tables;
- Beds in a surgical recovery room used exclusively for surgical patients during recovery from anesthesia;
- Beds in an obstetric delivery room used exclusively for OB patients in labor *or recovery after* delivery of newborn infants;
- Newborn bassinets and isolettes used for well-baby boarders (*Note: If the baby is being held for treatment at the CAH, his or her bassinet or isolette does count towards the CAHs 25-bed limit*);
- Stretchers in emergency departments; and
- Inpatient beds in Medicare-certified distinct part rehabilitation or psychiatric units.

Beds Used for Hospice Services

A CAH can dedicate beds to a hospice under arrangement, but the beds must count as part of the maximum bed count. The computation contributing to the 96 hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care.

Medicare does not reimburse the CAH for the hospice CAH benefit. Medicare reimburses the hospice. The CAH must negotiate payment for services from the hospice through an agreement.

Survey Procedures §485.620(a)

- Count the number of inpatient beds the CAH maintains, excluding any DPU beds.
- Ask the CAH how frequently it uses observation services, and for its policies and procedures governing use of observation services.

- Verify that patients are never pre-registered for observation services; there should be no scheduled observation stays.
- Check to see if the CAH has specific clinical criteria for *placement in* and discharge from observation *status*, and that these clinical criteria are clearly distinguishable from those used for inpatient admission and discharge.
- If there is a separate unit of observation beds, ask the CAH for evidence of how its criteria for *placement in* the observation unit differ from admission criteria for an inpatient bed. Count the number of beds in the observation unit and compare them to the number of inpatient beds. The higher the proportion of observation beds, the greater is the CAH's burden to prove these are not being used as inpatient beds. Ask for the occupancy rates for the observation unit; the higher the occupancy rate, particularly if there are more than a couple of beds, the greater is the CAH's burden to prove these are not being used as inpatient beds.
- Review the medical records for patients who are in observation status at the time of survey. Verify that the medical record includes an order to place the patient in observation status, including the clinical reason for observation, *e.g.*, as "Place patient in observation to rule out possible myocardial infarction (MI)."
- Select a sample of closed medical records for patients who were in an observation status. Verify that the medical record includes an order to place the patient in observation status, as well as a later order to admit, discharge, or transfer the patient.
 - Verify through medical record review that observation services are not ordered as a standing order following outpatient surgery or prior to admission from the emergency department.

C-0260

(Rev.)

§485.631(b)(1)

(iv) Periodically reviews and signs the records of *all inpatients* cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(v) Periodically reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician.

Interpretive Guidelines §485.631(b)(1)(iv) & (v)

All inpatient records for patients whose treatment is/was managed by a nonphysician practitioner in the CAH, i.e., nurse practitioners, clinical nurse specialists, or physician assistants, must be reviewed periodically by a CAH MD/DO who must sign the records after the review has been completed. The MD/DO review is expected to cover all applicable inpatient records open at the time of the review, as well as all applicable inpatient records closed since the last review.

In the case of inpatients whose care is/was managed by an MD/DO, as evidenced by an admission order, progress notes, and/or medical orders, etc., but who also receive services from a non-physician practitioner, a subsequent MD/DO review of the inpatient record is not required.

In States where State law requires a collaborating physician to review medical records, co-sign medical records, or both for outpatients whose care is managed by a non-physician practitioner, i.e., a nurse practitioner, a clinical nurse specialist, a certified nurse midwife, or a physician assistant, a CAH MD/DO must review and sign a sample of outpatient records. The outpatient medical record sample reviewed must be representative of all non-physician practitioners providing care to patients of the CAH. The CAH determines by policy the size of the sample reviewed and signed; however, CMS recommends, but does not require, a sample size of 25% of the records of all outpatient encounters managed by a non-physician practitioner since the prior MD/DO review. If State law requires MD/DO review or signature of a larger percentage of the outpatient records, the CAH must comply with State law.

In States where no physician record review or physician co-signature is required for patients managed by a non-physician practitioner, an MD/DO is not required to review or sign outpatient records of such patients.

Neither the regulation nor the preamble to the final rule adopting this regulation (79 Fed. Reg. 27105, May 12, 2014) specify a particular timeframe to satisfy the requirement for “periodic” review, but the CAH must specify a maximum interval between inpatient record reviews in its policies and procedures. The CAH is expected to take into account the volume and types of services it offers in developing its policy. For example, a CAH that has only four certified beds and one MD/DO on staff and which does not always have an inpatient in house would likely establish a different requirement for inpatient record review than a CAH with 25 certified beds, multiple MDs/DOs on staff and a high inpatient occupancy rate. Further, there is no regulatory requirement for the review of records to be performed on site and in person. Thus, if the CAH has electronic medical records that can be accessed and digitally signed remotely by the MD or DO, this method of review is acceptable. Therefore, CAHs with and without the capability for electronic record review and signature might also develop different policies for the maximum interval between reviews.

Survey Procedures §485.631(b)(1)(iv) & (v)

Select a sample of inpatient and outpatient records, including both open and closed records.

- *For inpatient records of patients whose care is/was managed by a non-physician practitioner, verify that:*
 - *An MD/DO has reviewed and signed all records that were open at the time of the review, and all inpatient records that were closed since the MD/DO's last review; and*
 - *That reviews take place within the timeframe specified by the CAH's policy.*
- *If State law requires a physician to review or co-sign (or both) any outpatient records of patients whose care is/was managed by non-physician practitioner, determine whether an MD or DO has reviewed and/or co-signed a representative sample of these records within the timeframe specified in the CAH's policies.*
 - *Ask the CAH how many outpatient encounters are managed by non-physician practitioners, what sample size its policy requires to have an MD/DO review, and what timeframe its policy specifies for reviews.*
 - *Ask the CAH to explain how it ensures the sample is representative of the various non-physician practitioners as well as of the various types of outpatient services they provide.*
 - *Ask the CAH to describe the method it uses to make sure that reviews are performed in a timely manner on a sample that complies with the CAH's policy.*
 - *Review selected records from the CAH's outpatient sample to verify that there is evidence of and MD or DO review and/or signature.*

C-0261

(Rev.)

§485.631(b)(2) A doctor of medicine or osteopathy is present for sufficient periods of time to provide medical direction, consultation, and supervision *for the services provided in the CAH*, and is available through direct radio or telephone communication *or electronic communication* for consultation, assistance with medical emergencies, or patient referral.

Interpretive Guidelines §485.631(b)(2)

An MD/DO must be present in the CAH for sufficient periods of time to provide overall medical direction, consultation and supervision of the healthcare services the CAH furnishes. Being "present" in the CAH means being physically on-site in the CAH. The regulation does not specify a minimum amount of time an MD/DO must spend on-site that applies to all CAHs. Instead, CAHs have the flexibility to develop policies appropriate for their circumstances. With the development of technology such as telemedicine, a CAH may use a variety of ways and timeframes for MDs/DOs to provide the necessary medical direction and oversight. For CAHs that offer a range of more complex services, have more than one MD/DO on staff, and have busy

emergency departments and/or extensive outpatient services, an on-site visit by an MD/DO only once every week or every two weeks, for example, would be grossly inadequate. On the other hand, a bi-weekly on-site visit could be unduly burdensome as well as unnecessary for a small CAH in a remote rural area that offers very limited services and has a low patient volume.

CAHs are expected to have adequate staffing to provide the services they have chosen to furnish, including staffing or supervision by MDs/DOs as applicable. CMS expects each CAH to evaluate its services and adjust its MD/DO on-site schedule accordingly, as an appropriate MD/DO schedule must reflect the volume and nature of services offered.

Note that §485.618(d) also establishes a maximum timeframe for an MD, DO, PA, NP, or clinical nurse specialist to be on-call and available to be on-site to provide emergency care, and that §489.20(r)(2) requires the CAH to maintain an on-call list of MDs/DOs who are available to be on-site as part of the CAH's Emergency Medical Treatment and Labor Act obligations. The CAH must consider all pertinent requirements when developing its policies for MD/DO presence on site.

In addition to requiring an MD or DO to be on-site for sufficient periods of time, consistent with the requirement at §485.618(e), the CAH must also ensure an MD/DO is available through direct radio, telephone or other form of electronic communication, such as video conferencing, for consultation, assistance in handling patient medical emergencies and referral of patients to other healthcare facilities. An MD/DO providing telemedicine services to the CAH may be used to fulfill the requirement for availability via telecommunications. Further, consistent with the requirements for CAH provision of emergency services at §485.618(d), unless a PA, NP, or clinical nurse specialist with training in emergency care is immediately available via one of these telecommunication methods and available on site within the timeframe specified at §485.618(d)(1), an MD or DO must fulfill these requirements.

Survey Procedures §485.631(b)(2)

- *Does the CAH have policies and procedures that address the minimum amount of time and frequency of MD or DO presence on-site at the CAH? Can the CAH demonstrate how its policy reflects the volume and type of services the CAH provides such that there is sufficient MD/DO presence on-site to support the services provided?*
- *Is there documentation showing that an MD or DO is on-site for the frequency and duration specified in the CAH's policies?*
- *Can the CAH demonstrate that an MD or DO is always available by telecommunications contact for consultation, assistance and/or patient referral?*

C-0270
(Rev.)

§485.635 Condition of Participation: Provision of Services

Interpretive Guidelines §485.635

This condition establishes requirements related to patient care policies, required CAH services, and CAH services provided through agreements or arrangements. Assessment of the manner and degree of noncompliance with any one of the following standards in this condition is required in order to determine whether there is noncompliance with this condition.

C-0271
(Rev.)

§485.635(a) Standard: Patient Care Policies

(1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

Interpretive Guidelines §485.635(a)(1)

The CAH must have written policies governing the health care services the CAH furnishes and these policies must be consistent with applicable State law. As discussed in relation to the requirements at §485.608, CMS does not interpret or enforce local law; that is the responsibility of State or local government. If surveyors identify practices related to delivery of health care services that they believe are not consistent with State law, they should refer the matter to the appropriate State authorities.

The regulation requires the CAH to furnish its health care services in accordance with its written policies. In other words, the CAH must not only have written policies, but must actually adhere to them in delivering services.

Survey Procedures §485.635(a)(1)

- *Verify that the CAH has written policies covering the health care services that are furnished in the CAH.*
- **Observe staff delivering health care services to patients. *Is the actual provision of services consistent with the CAH's written policies?***

C-0272
(Rev.)

§485.635(a)(2) The policies are developed with the advice of *members of the CAH's professional healthcare staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1).*

§485.635(a)(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

Interpretive Guidelines §485.635(a)(2) & (4)

The CAH's written policies governing patient care services must be developed with the advice of members of the CAHs professional healthcare staff. This advisory group must include:

- *At least one MD or DO; and*
- *One or more physician assistants, nurse practitioners, or clinical nurse specialists, at least one of these non-physician practitioners if these professionals are included in the CAH's healthcare staff, as permitted at §485.631(a)(1). A CAH with no non-physician practitioners on staff is not required to obtain the services of an outside non-physician practitioner to serve on the advisory group.*

The advisory group not only makes recommendations for new CAH patient care policies, but is also expected to review the existing patient care policies at least annually and, if it concludes that changes are needed, recommend those changes. Policies must be reviewed and, as applicable, revised more frequently when required, for example, in response to a change in Federal or State regulations to which the CAH is subject.

The CAH must maintain documentation that provides evidence that the advisory group has conducted its reviews and made recommendations concerning patient care policies. Although a CAH's patient care policies are developed and periodically reviewed with the advice of members of the CAH's professional healthcare staff, the final decision on the content of the written policies is made by the CAH's governing body or individual responsible for the CAH, consistent with the requirement at §485.627(a). If recommendations of the advisory group are rejected, the governing body must include in the record of its adoption of the final written policies its rationale for adopting a different policy than that recommended.

Survey Procedures §485.635(a)(2)

- *Review any meeting minutes for the group of healthcare professionals that advises the CAH's governing body or responsible individual on patient care policies to determine if the group's composition meets the regulatory requirements.*

- Interview *all staff listed as part of the policy development advisory group* to determine if *they had the opportunity to express opinions and make recommendations to the group, for the group's consideration as a group recommendation.*
- *Can the CAH provide documentation that the advisory group developed written recommendations on the CAH's patient care policies for consideration by the CAH's governing body/responsible individual?*
- *Is there evidence that the group reviewed the CAH's existing policies at least annually and indicated whether or not it recommended any changes?*

C-0273

(Rev.)

§485.635(a)(3) The policies include the following:

(i) A description of the services the CAH furnishes, including those furnished through agreement or arrangement.

Interpretive Guidelines §485.635(a)(3)(i)

The CAH's written patient care policies must describe the types of health care services that are available at the CAH, including whether those services are furnished by CAH staff or through agreements or arrangements. The types of health services described must include services provided both on-site and off-site.

Healthcare services provided through agreement or under arrangement include those provided through formal contracts, informal agreements, or lease arrangements. Services furnished under arrangement or by agreement may include both healthcare services provided on-site at the CAH by a contractor, as well as healthcare services provided to the CAH's patients outside the CAH. For example, the CAH may contract with a laboratory to provide certain laboratory services on-site, and others at an off-site laboratory; or it may contract with an imaging center for provision of certain advanced radiologic diagnostic services, such as MRI, to CAH inpatients who are temporarily moved to the center for the test and then returned to the CAH.

The descriptions of the services provided may be brief but informative, for example, statements like "taking complete medical histories, providing complete physical examinations, laboratory tests including" (with a list of tests provided), radiologic tests and their interpretation, surgery (with a list of the types of surgery available) would satisfy this requirement.

Survey Procedures §485.635(a)(3)(i)

Verify that the CAH's healthcare policies identify and describe all healthcare services offered by the CAH, including services provided under arrangement or by agreement.

C-0274
(Rev.)

§485.635(a)(3) [The policies include the following:]

(ii) Policies and procedures for emergency medical services.

Interpretive Guidelines §485.635(a)(3)(ii)

The CAH's written patient care policies must include its policies and procedures for providing emergency services, addressing all of the requirements at 42 CFR 485.618. See the interpretive guidelines for §485.618.

Survey Procedures §485.635(a)(3)(ii)

Verify that written policies and procedures detail how the CAH plans to comply with the requirements of 42 CFR 485.618. Do the written policies and procedures address the following:

- *How the CAH provides 24 hour emergency care to its patients?*
- *What equipment, supplies, medications, blood and blood products are maintained onsite and which are readily available for treating emergency cases by agreement at other facilities?*
- *What types of personnel are available to provide emergency services and what are their required onsite response times?*
- *Do they address how the CAH coordinates with local emergency response systems?*

C-0275
(Rev.)

§485.635(a)(3) [The policies include the following:]

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

Interpretive Guidelines §485.635(a)(3)(iii)

The written policies for the CAH's healthcare services must include guidelines, such as general instructions and protocols, for the medical management of patients' health problems. The guidelines may include directly or reference protocols that are documented elsewhere for the treatment of medical conditions that are commonly presented in the CAH.

Because nurse practitioners, clinical nurse specialists, and physician assistants may play a large role in patient care at a CAH, the CAH's policies must address the circumstances under which consultation with an MD or DO should occur and which situations require them to consult with or refer to an MD/DO for advice on how to treat a patient. The CAH's policies must also address the circumstances under which patient referral outside the CAH should occur.

The policies must also address maintenance of medical records, consistent with the requirements at §485.638. See interpretive guidelines for §485.638.

The policies must also address the CAH's procedures for periodical review and evaluation of its services, consistent with the requirements of §485.641. See interpretive guidelines for §485.641.

Survey Procedures §485.635(a)(3)(iii)

Verify that the CAH's written patient care policies:

- *Address the circumstances under which consultation with other CAH professional healthcare staff, or referral outside the CAH should occur;*
- *Address maintenance of medical records, in a manner consistent with the requirements at §485.638; and*
- *Address periodic evaluation of the CAH's healthcare services, in a manner consistent with the requirements at §485.641.*

C-0276

(Rev.)

[§485.635(a)(3) The policies include the following:]

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

Interpretive Guidelines §485.635(a)(3)(iv)

The CAH must ensure that drugs and biologicals are managed in a manner that is safe and appropriate, and that its pharmacy system provides all drugs and biologicals prescribed by the CAH's practitioners in a timely manner for administration to its patients.

The CAH's written patient care policies must include rules governing pharmacy services within the CAH. The CAH's rules may be in the form of pharmacy services policies and procedures. These CAH rules must address storage, handling, dispensing, and administration of drugs and biologicals within the CAH. The rules must be in accordance with accepted professional principles of pharmacy and medication administration practices. Accepted professional

principles include compliance with applicable Federal and State law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations, including, but not limited to: U.S. Pharmacopeia (www.usp.org), the American Society of Health-System Pharmacists (<http://www.ashp.org/>), the Institute for Safe Medication Practices (<http://www.ismp.org/default.asp>), the National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org); the Institute for Healthcare Improvement (<http://www.ihl.org/ihl>); or the Infusion Nurses Society (<http://www.insl.org>).

Note re: US Pharmacopeia/National Formulary (USP/NF)

According to the Federal Food, Drug and Cosmetic Act (FCDA), the official compendia of the United States for excipients, drug substances, and drug products is the USP/NF. It is published every year in November by the United States Pharmacopeial Convention (<http://www.usp.org/>) and includes two supplements published in February and June.

The USP is a not-for-profit, non-governmental organization that since 1820 has established quality standards for, among other things, drug substances, drug products and compounded preparations. Congress established a role for USP standards in the adulteration provision of the 1906 Food and Drug Act. That role was expanded in the modern Food, Drug and Cosmetic Act (FDCA) beginning in 1938, with a role for USP compendial standards for naming and identity; strength, quality, and purity; and packaging and labeling, in both the adulteration and misbranding provisions of FDCA. (See, for example, §501(b) of the FDCA regarding compendial standards for strength, quality and purity, §502(g) for compendial standards for packaging and labeling). Under the FDCA, a drug with a name recognized in the USP/NF must comply with compendial identity standards, or be deemed adulterated, or misbranded, or both. To avoid being deemed adulterated, such drugs must also comply with compendial standards for strength, quality, and purity, unless labelled to show all respects in which the drug differs.

The CAH's rules must address the following:

- ***Responsibility for pharmacy services.***

The CAH must identify the qualifications for and designate an individual who has overall responsibility for the CAH's pharmacy services, including development of the rules governing pharmacy services. The CAH and the responsible individual must ensure adherence to State law requirements governing who may perform pharmacy services as well as requirements for supervision of pharmacy staff. The CAH and responsible individual are also responsible for assuring that pharmacy practices adhere to accepted professional principles. The CAH is expected to be able to identify the sources of accepted professional pharmacy practices that it relies upon in developing the CAH's pharmacy rules, policies and procedures.

- ***Storage of drugs and biologicals, including the location of storage areas, medication carts, and dispensing machines.***

Consistent with accepted professional principles, CAHs must demonstrate appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

- ***Proper environmental conditions***

Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for storage of drugs, the CAH is expected to follow the labelled conditions. Absent the manufacturer's labelled conditions, USP indicates that storage of drugs and biologicals be done according to USP/NF, or the food chemicals codex (FCC) monograph requirements. CAHs must exercise caution in dispensing or using any drug or biological that is not labelled to indicate proper storage conditions or that may have been stored under inadequate conditions.

- ***Security***

The CAH must have policies and procedures that are consistent with State and Federal law to address who is authorized access to the pharmacy or drug storage area. Drugs and biologicals must be stored in a secure manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional (for example, ambulatory infusion), they are generally considered secure. Areas restricted to authorized personnel only would generally be considered "secure areas."

CAHs are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff are actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked.

Medication carts, anesthesia carts, epidural carts and other non-automated medication carts containing drugs or biologicals (hereafter, all referred to as "carts") must be secured when not in use. A CAH's policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety.

If a cart containing drugs or biologicals is in use and unlocked, someone with authorized 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 CAH policy is authorized access to the drugs and biologicals in

the cart. That individual 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.

- ***Handling drugs and biologicals.***

“Handling” includes reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug’s manufacturer. “Handling” also includes compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either CAH staff or a contracted pharmacy service. CAHs use many medications that need to be reconstituted, mixed or compounded. Whether furnishing the services via CAH staff or a contractor, the CAH is responsible for proper handling of drugs and biologicals.

Except in emergencies or when not feasible (for example, when the product’s stability is short), only the pharmacy performs reconstituting, mixing, admixing or compounding.

Compounding

All compounding of medications used or dispensed by the CAH must be performed consistent with accepted professional principles which are equivalent to or more stringent than those described in the compounding-related chapters in the USP/NF, which are recognized as authoritative standards regarding minimum standards of safe practice applicable to both sterile and non-sterile compounding.

The definition of compounding as that term is used in the USP is found in USP Chapter <795> (USP <795>):

“The preparation, mixing, assembling, altering, packaging and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

- *Preparation of drug dosage forms for both human and animal patients*
- *Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns*
- *Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients*
- *Preparation of drugs or devices for the purposes of, or as incident to, research (clinical or academic), teaching or chemical analysis*
- *Preparation of drugs and devices for prescriber’s office use where permitted by federal and state law”*

Compounded medications, whether non-sterile or sterile, may be subject to physical and chemical contamination and unintended variations in strength. Microbial contamination and bacterial endotoxins are particularly hazardous with respect to compounded medications that are intended to be sterile.

A CAH pharmacy must be administered in accordance with accepted professional principles, and therefore must be able to demonstrate how it assures that all sterile and non-sterile compounded preparations dispensed and/or administered to the CAH's patients are being compounded consistent with accepted professional standards to ensure safety. The applicable standards for safe compounding are, at a minimum, the standards published in USP Chapters <795> ("Pharmaceutical Compounding – Nonsterile Preparations"), <797> ("Pharmaceutical Compounding – Sterile Preparations") and other relevant USP-NF Chapters. The CAH must be able to provide evidence that the CAH's standard operating procedures for compounding, if performed in-house, and for quality oversight of compounding, regardless of source, are consistent with accepted professional principles.

USP <797> outlines minimum standards of practice to be followed by all health care personnel in any setting when preparing, storing and transporting "compounded sterile preparations" (CSPs). Its stated objective is "to describe conditions and practices to prevent harm, including death, to patients that could result from...microbial contamination...excessive bacterial endotoxins...variability of intended strength of correct ingredients...unintended chemical and physical contaminants...and ingredients of inappropriate quality...." Contaminated CSPs are especially hazardous if administered into body cavities, the central nervous system, vascular system, eyes, joints, and/or used as baths for live organs and tissues. "All compounded dosage forms that must be sterile when they are administered to patients" are considered by USP <797> to be CSPs, including but not limited to:

- "Aqueous bronchial and nasal inhalations;*
- Baths and soaks for live organs and tissues;*
- Injections [and infusions];*
- Irrigations for wounds and body cavities;*
- Ophthalmic drops and ointments;*
- Tissue implants."*

USP <797> specifies differing standards for the physical layout and structure of the locations in which compounding takes place as well as processes, precautions and quality assurance practices to be implemented during the preparation, transport and storage of CSPs. The standards differ in part based on the level of risk of microbial contamination of the CSP, and the risk level has implications for whether a CSP must be terminally sterilized before being dispensed and for how long a CSP may be stored before use. The risk categories and accompanying standards are based on specific criteria, including but not limited to factors such as:

- *The structural design, environmental controls, air quality levels (based on International Organization for Standardization (ISO) standards for particulate matter in air) and air flow patterns in and surrounding the environment to which the contents of the CSP as well as the surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs are exposed.*
- *The sterility of the original ingredients and/or device(s) used in compounding, the number of containers that need to be entered, how many times they need to be entered, the nature and complexity of the manipulations and length of time required to prepare the CSP.*
- *Whether compounding personnel are appropriately garbed and gloved.*
- *Whether multiple doses of sterile products are pooled to produce a CSP that will be administered on more than one occasion or to more than one patient.*

The goal of the USP <797> standards is to prevent and/or minimize the risk of microbial contamination of CSPs, whether by direct contact, exposure to particles in air generated by personnel or objects, or other mechanisms. A major concern is preventing contamination of “critical sites,” which include “any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed or at risk of direct contact with air...moisture...or touch contamination.”

USP <797> describes two basic structural designs for the physical layout and environmental controls intended to minimize airborne contamination of critical sites during preparation of CSPs. The risk level of the CSPs a facility can produce depends, in part, on which USP <797> environmental quality and control/facility design standards the CAH (or its vendor) is able to meet (low-risk level, medium-risk level and high-risk level are discussed here; see §485.635(d)(3) for a discussion of “immediate-use” CSPs):

- *Some facilities may only prepare low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient, and administration must commence within the lesser of 12 hours of preparation or as recommended in the manufacturer’s package insert. Such a facility would have a designated, demarcated room or space that is the “segregated compounding area (SCA),” which contains a device that provides unidirectional airflow of International Standards Organization (ISO) Class 5 air quality (quality class ranges from class 0, the most stringent, to class 9, the most relaxed). The SCA may not be in an area with unsealed openings/potential openings to high traffic locations, the outdoors and other proscribed environmental conditions, and the SCA area may not contain any materials or be the site of any activities unrelated to preparing low-risk CSPs.*
- *If a facility is preparing high- or medium-level risk CSPs or low-risk CSPs with a beyond-use date of greater than 12 hours, it must meet additional environmental design and monitoring/testing standards in the buffer and ante-areas.*

- *USP<797> contains separate standards for the safe compounding of hazardous medications (defined as “...if studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive toxicity, or harm to organs...”), radiopharmaceuticals and allergen extracts.*

In addition, USP <797> includes standards for various processes, precautions and quality assurance practices required and recommended for the safe preparation of all risk levels of CSPs. These address issues such as:

- *The responsibilities of compounding personnel and their supervisors to implement and maintain proper procedures and quality assurance checks.*
- *Issues specific to “immediate use” CSPs; single- and multiple-dose containers; CSPs containing hazardous drugs; radiopharmaceuticals; allergen extracts; and automated compounding devices used for parenteral nutrition compounding.*
- *Methods for sterilization, depyrogenation and for verifying compounding accuracy and sterility.*
- *Specifications for environmental quality and control, including but not limited to:*
 - *Specifications and related personnel training, including competency assessment and evaluation of skill in aseptically preparing CSPs using visual observation as well as bacterial sampling of glove fingertips and “media-fill testing” at specified intervals.*
 - *Evaluation and monitoring/testing of the environment in which compounding takes place and, if applicable, the adjacent “ante-” and “buffer” areas, including facility layout, design, environmental controls, restricted access, air quality standards and testing, surface characteristics, furnishings, cleaning and disinfection procedures, and standards for personnel health, attire/cosmetics, cleansing/garbing/gloving, aseptic work practices, etc.*
- *Suggested standard operating procedures to protect the quality of the environment in which CSPs are prepared.*
- *Quality control related to ingredients, devices and equipment used in relation to CSPs.*
- *Quality checks to be performed before CSPs are dispensed or administered.*
- *Issues related to beyond-use dating and packaging, storage and transportation conditions for CSPs.*
- *Protecting dispensed and distributed CSPs.*

- *Patient education issues.*
- *Monitoring for and reporting adverse patient events related to CSPs.*
- *Requirements for a formal quality assurance program to be maintained by providers of CSPs.*

For Information – Not Required/Not to be Cited

USP <797> Appendices I and III-V contain summaries and assessment tools that CAHs may find helpful. However, there is no requirement to use specific forms or materials as long as the CAH and/or its external sources of CSPs are implementing plans, procedures, testing and documentation consistent with applicable standards for safe compounding. These USP <797> suggested materials are referenced here only as examples:

- *“Appendix I: Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required...and Recommended in USP Chapter <797>”*
- *“Appendix III: Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel”*
- *“Appendix IV: “Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel”*
- *“Appendix V: “Sample Form for Assessing Cleaning and Disinfection Procedures”*

Compounding may take place in the CAH’s pharmacy on-site and/or the CAH may obtain some or all of its compounded medications from external sources. Regardless of the source, if accepted standards for safe compounding are not met, compounded medications may contain less or more than the intended dose and/or may be chemically or microbiologically contaminated, with potentially serious adverse consequences for the patients who receive them.

Use of Outside Compounders (also known as Outsourcing Facilities)

The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an “outsourcing facility.” The law defines an “outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA. Facilities that elect to register as outsourcing facilities:

- *Must comply with the FDA’s Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA’s publishes the most current versions of its draft and final regulations and guidance related to compounding on its website: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm> ;*
- *Will be inspected by FDA according to a risk-based schedule; and*
- *Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.*

In a January 2014 letter to purchasers of compounded medications (available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm>), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that, “[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling.”

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at:

<http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm>

Note that these registered outsourcing facilities are also popularly referred to as “503B pharmacies.”

Use of Compounding Pharmacies

If a CAH obtains compounded medications from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the CAH must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

- *Ensuring that the CAH has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements, and can the CAH document that it obtains and reviews such data?*

- *Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?*

Note that these types of compounding pharmacies are also popularly referred to as “503A pharmacies” and generally are subject to oversight only by their State pharmacy board.

For Information – Not Required/Not to be Cited

ASHP Research and Education Foundation™ “Outsourcing Sterile Products Preparation: Contractor Assessment Tool”

*The ASHP Research and Education Foundation™ offers a tool that CAHs may find useful for assessing vendors that provide compounded sterile preparations.
<http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx> and click on "Start using Sterile Products Outsourcing Tool now."*

- ***Dispensing drugs and biologicals.***

CAHs must comply with applicable State law that governs the qualifications, certification, or licensure of staff who dispense drugs and biologicals. There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery.

Medications must be dispensed in a timely manner. The CAH must have a system that ensures medication orders get to the pharmacy promptly and medications are available for administration to patients when needed, including when the pharmacy is not open. Methods to accomplish this when the pharmacy is not open could include, but are not limited to, one or more of the following: automated dispensing units outside the pharmacy, night cabinets, contracted services after hours via telepharmacy contracting, on-call pharmacists, etc.

Concerns, issues or questions pharmacy staff have about any medication order must be clarified with the prescribing practitioner or another practitioner responsible for the care of the patient before dispensing.

A CAH may utilize a unit dose system, individual prescription, floor stock system or a combination of these systems, properly stored.

- *Automated Dispensing Cabinets (ADCs) for medications are a secure option for medication storage since they ensure locked storage of medications and allow for electronic tracking of controlled substances and other drugs. These cabinets often have embedded security features, such as login and password or biometric identification so that they can only be accessed by authorized personnel.*

- *Policies and procedures must address who can access medications during after-hours.*

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In addition to the required pharmacy policies and procedures above, a well-designed pharmacy service would have policies and procedures addressing medication safety practices such as:

- *Implementation of a do-not-use abbreviation list. CAHs may wish to refer to lists offered by the Institute for Safe Medication Practices (<http://www.ismp.org/tools/errorproneabbreviations.pdf>) or The Joint Commission (http://www.jointcommission.org/assets/1/18/Do_Not_Use_List.pdf);*
- *A high alert drug list. CAHs may wish to refer to a high alert drug list offered by the Institute for Safe Medication Practices (<https://www.ismp.org/tools/institutionalhighAlert.asp>);*
- *For specific high alert medications designated by the CAH, having two health professionals independently check doses CAHs may wish to refer to guidance from the Institute for Safe Medication Practices concerning appropriate use of double-checks (<http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=51>);*
- *Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;*
- *Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit doses that have been repackaged by the pharmacy;*
- *The CAH consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system; and*
- *The American Society of Health-System Pharmacists (ASHP) recommends that floor stocks of medications should be limited to medications for emergency use and routinely used safe items (e.g. mouthwash, antiseptic solutions).*

When utilizing automated dispensing cabinets (ADCs), the Institute for Safe Medication Practices recommendations include the following: (See: <http://www.ismp.org/Newsletters/acutecare/articles/20090212.asp> and http://www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf) Security processes are established to ensure adequate control of medications outside of the pharmacy and to reduce the potential for medication diversion from ADCs.

- *Utilize biometric user identification or, at a minimum, change user passwords quarterly.*

- *Link the ADC to the pharmacy computer to allow for patient “profiling,” so that a pharmacist can review each medication order and screen it for safety before the drug is dispensed or accessed by the nurse or other healthcare professional.*
- *Limiting the availability of overrides to the ADC system.*
- *Limiting access to drugs based on the patients profile so to decrease medication selection errors.*
- *Store each medication and strength in an individual lidded ADC compartment that opens only when the specific medication is selected.*
- *Document the destruction of medication waste at the time of removal of the medication whenever possible. Record this waste via the ADC, and match the administered dose with ordered dose. Have a process to routinely review/reconcile the documented medication waste*
- *Return all medications to a common secure one-way return bin that is maintained by pharmacy, not to an individual pocket or bin within the ADC.*

- ***Administration of drugs and biologicals to patients.***

CAHs must comply with applicable State law that governs the qualifications, certification, or licensure of staff who administer drugs and biologicals and must adhere to accepted standards of practice for medication administration. See the guidance for §485.635(d)(3) concerning medication administration by CAH nursing staff.

- ***Record keeping for the receipt and disposition of all scheduled drugs.***

The U.S. Department of Justice Drug Enforcement Administration (DEA) classifies drugs that are controlled in accordance with the Controlled Substances Act into five “schedules”, ranging from Schedule I substances, which have a high potential for abuse and no currently accepted medical use in treatment, to Schedule V substances, which have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. The CAH is required to accurately track the receipt and disposition of all scheduled drugs used in the CAH. Components of a record system for scheduled drugs would include:

- *Locked storage of scheduled drugs when not in use.*
- *Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.*
- *The record system 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.

- *Any discrepancies in count are reconciled promptly. The CAH 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.*
- ***Ensuring that outdated, mislabeled, or otherwise unusable drugs are not used for patient care.***

The CAH 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 patient use. This would include drugs that are the subject of a manufacturer’s recall.

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer’s approved labeling.

A drug or biological is also outdated after its “beyond-use date” (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available. The CAH must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer. The policies and procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the United States Pharmacopeia-National Formulary (USP).¹

According to Chapters <795> and <797> of the USP, the BUD must be safe for patients, and determined conservatively. The section in USP <797> entitled “Determining Beyond-Use Dates”, which addresses sterile compounding, notes that “the truly valid evidence for predicting beyond-use dating can be obtained only through product-specific experimental studies.” It provides an example of testing considered more appropriate for certain types of

¹ All references to “USP” herein are from: United States Pharmacopeial Convention. *USP on Compounding: A Guide for the Compounding Practitioner. Current with USP 37-NF32 through First Supplement.* Rockville, MD: United States Pharmacopeial Convention, 2014.

compounded sterile preparations (CSPs) such as “CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity....” It also provides examples of important issues that a pharmacist must be able to critically interpret and evaluate when consulting literature sources in the process of determining a BUD; and distinguishes between reviewing literature specific to a particular drug, composition, concentration of ingredients, fill volume, container, storage conditions and duration of use, etc., versus merely reviewing available publications or tables. The former is the preferred approach, while the latter results in a “theoretical BUD,” which has an inherent likelihood of inaccuracy or error.

For individual drug containers: each floor stock drug container is expected to be labelled with the name and strength of the drug, lot and control number equivalent, and expiration date. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD. It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., need-punctured), the USP standard is that the BUD is 28 days, unless otherwise specified by the manufacturer. In addition, where applicable, each patient’s individual drug container is expected to be labelled with the patient’s full name and quantity of the drug dispensed.

If the unit dose system is utilized, each single unit dose package is expected to be labelled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.

For Information Only

Certain provisions of the FDCA address the labeling of prescription drugs generally (e.g., section 503(b)(2) of the FDCA). Section 503B of the FDCA includes labeling requirements for drugs compounded by registered outsourcing facilities (see section 503B(a)(10)). Although CAHs are expected to comply with these requirements, surveyors conducting a Medicare survey do not assess compliance with other Federal law.

Assessing Adverse Drug Reactions & Medication Administration Errors

In accordance with §485.635(a)(3)(v) the CAH must have a system for staff to report adverse drug reactions and medication administration errors. The pharmacy services is expected to assess all such reports to determine if problems or errors in pharmacy services caused or contributed to the adverse reaction or medication administration error. Where such problems or errors are identified, the CAH is expected to take effective action to address the identified issues.

Survey Procedures §485.635(a)(3)(iv)

- *Has the CAH adopted pharmacy rules that were developed with the advice of the CAH’s professional healthcare staff?*

- *Has the CAH identified the qualifications of and designated an individual who is responsible for developing and implementing the rules for the CAH's pharmacy services, consistent as applicable with State and Federal law?*
 - *Review the qualifications of the responsible individual to verify that they satisfy the CAH's written criteria.*
- *Ask CAH practitioners, nursing and pharmacy staff whether the CAH's pharmacy service dispenses prescribed drugs and biologicals in a timely manner. If there is evidence in medical records reviewed of late administration of prescribed medications, probe to determine whether delays are due to pharmacy dispensing delays..*
- *Ask the individual responsible for CAH pharmacy services what sources of accepted professional principles of pharmacy practice the CAH relies upon in developing and implementing its CAH pharmacy rules, policies and procedures. Is the source(s) a nationally recognized source?*
- *Are drugs and biologicals stored in a secure manner?*
 - *Are drugs stored in areas not accessible to unauthorized personnel?*
 - *When drugs or biologicals are kept in a patient care area during hours when patient care is not provided, are they locked up?*
- *Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for.*
- *Determine if the CAH has a system that tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient, destruction of the drug, or return to the manufacturer.*
 - *Does this system provide documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs?*
 - *Review records of scheduled drugs over a recent time period. Is there evidence of discrepancies, and if so, of efforts by the CAH to reconcile and address the discrepancies?*
 - *Interview the person responsible for pharmacy services as well as other CAH staff to determine their understanding of the CAH's controlled drug policies.*
- *Verify that only a pharmacist or other personnel authorized in accordance with State and Federal law compound, label and dispense drugs or biologicals, regardless of whether the services are provided by CAH staff or under arrangement.*

- *Interview pharmacy and CAH staff to determine how drugs and biologicals are dispensed;*
- *Observe on-site dispensing operations;*
- *Review records to see if drugs and biologicals are removed from the pharmacy by unauthorized personnel;*
- *Do the CAH's pharmacy rules address ADCs, if used within the CAH? Are the ADCs being used in the manner prescribed by the CAH's rules?*
- *Can the CAH demonstrate that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices equivalent to or more stringent than the standards described in USP <795> and <797>?*
- *Does the individual responsible for the pharmacy service, including compounding policies, practices and quality assurance within the CAH, and selecting and overseeing any external sources of compounded medications, have the expertise to conduct effective quality oversight consistent with USP <795> and <797> (or equivalent/more stringent) standards?*
- *Can the individual responsible for the pharmacy services explain the risk level(s) of the CSPs being produced in-house and/or obtained from external sources? Can he or she demonstrate that the assigned risk levels are consistent with USP <797> or equivalent/more stringent standards?*
- *If any CSPs are produced in the CAH:*
- *Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the CAH and/or to assess how this is done by external source(s) of CSPs. Is there evidence that the BUDs are determined consistent with the CAH's rules, policies and procedures?*
- *Interview staff who engage in sterile and non-sterile compounding. Are they knowledgeable about applicable levels of aseptic practices?*
- *Ask the individual responsible for pharmacy services to demonstrate how the following are accomplished to ensure that sterile compounding practices are consistent with USP <797> or equivalent/more stringent standards for the risk level(s) of CSPs being produced for/dispensed to CAH patients:*
 - *Verification of compounding accuracy and sterility.*

- *Environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection;*
- *Personnel training and competency assessment, including but not limited to accuracy/precision in identifying and measuring ingredients; cleansing and garbing; aseptic manipulation skills; environmental quality and disinfection; appropriate work practices within and adjacent to the direct compounding area; verification/calibration of equipment; sterilization; and post-production quality checks.*
- *Review the CAH's procedures for maintaining the quality of CSPs during storage, transport and dispensing. Are CSPs packaged in a manner to protect package integrity and sterility? How are CSP-specific requirements with respect to motion, light exposure, temperature and potentially hazardous contents addressed? How does the CAH ensure that such information is effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable?*
- *Review the pharmacy rules, policies and procedures for determining BUDs (for medications compounded in-house as well as from external sources).*
 - *Can the CAH demonstrate that the policies and procedures are consistent with or more stringent than the applicable USP standards?*
 - *Can it demonstrate that the pharmacy personnel assigned to determining BUDs when a manufacturer's instructions are not available have the expertise and technical support needed to properly conduct the assessments needed to make such determinations in a manner consistent with standards and hospital policies?*
- *Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the CAH and/or to assess how this is done by external source(s) of CSPs. Is there evidence that the BUDs are determined consistent with the CAH's rules, policies and procedures?*
- *If the CAH obtains compounded products from an external source that is not an FDA registered outsourcing facility, can it demonstrate that it systematically evaluates and monitors whether these sources adhere to accepted professional principles for safe compounding?*
- *Does the CAH have a process for following up on adverse drug reactions and errors in medication administration reported by CAH staff in accordance with §485.635(a)(3)(v)? If any have been reported, did the CAH thoroughly assess and analyze them? Has the CAH taken effective preventive action to address identified issues?*
- **Spot-check the labels of individual drug containers to verify that they contain the following minimal information:**

- Each patient’s individual drug container bears his/her full name and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date, *and, when applicable, a BUD.*
- Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date, *and, when applicable, a BUD.*
- 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, expiration date, *and, when applicable, a BUD.*
- *Spot-check* patient-specific and floor stock medications to identify expired, mislabeled or unusable medications, *including medications that are past their BUD.*

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[The policies include the following:]

§485.635(a)(3)(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

Interpretive Guidelines §485.635(a)(3)(v)

CAH staff must report all drug (medication) administration errors and all adverse drug reactions. This required reporting includes two distinct steps in the reporting of drug (medication) administration errors and adverse drug reactions. The first and highest priority reporting relates to the care of the patient, at time of occurrence. The second reporting step is related to the CAH-wide Quality Assurance review as addressed in §485.641(b).

- *Medication administration error:*

The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is “Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.” A medication administration error is one that occurs in the phase of the medication process where the drug actually enters the patient by one of various possible routes, e.g., orally, intravenously, etc.

- *Adverse drug reaction:*

The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as “Any unexpected, unintended, undesired, or excessive response to a drug that:

- 1. Requires discontinuing the drug (therapeutic or diagnostic)*
- 2. Requires changing the drug therapy*
- 3. Requires modifying the dose (except for minor dosage adjustments)*
- 4. Necessitates admission to a hospital*
- 5. Prolongs stay in a health care facility*
- 6. Necessitates supportive treatment*
- 7. Significantly complicates diagnosis*
- 8. Negatively affects prognosis, or*
- 9. Results in temporary or permanent harm, disability, or death.*

Consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs.”

Patient Care

In the case of ADRs or medication administration errors that are not caught before they reach the patient, a “report” must be made to a practitioner responsible for the care of the patient.

For example, if a medication actually is administered to a patient when it should not be, or the wrong dose is administered, or the wrong route of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, then the medication administration error has reached the patient and must be reported to the responsible practitioner.

- *If, on the other hand the wrong dose of a drug is prepared for a patient, but a nurse catches this and does not give that dose to the patient, then a medication administration error has occurred, but the error has not reached the patient, and thus does not need to be reported to the responsible practitioner.*

Not every medication administration error that reaches the patient causes harm or has the potential to cause harm; it depends both on the drug and on the patient’s condition.

In the case of all ADRs and any medication administration error that has harmed or has reached the patient and could potentially cause harm, the report to a practitioner must be made immediately after the staff identify the adverse reaction or (potentially) harmful error, to enable a timely assessment and intervention. The report must be made directly in a manner that confirms a practitioner received the report, for example, via a phone call. If the impact of the medication error that reached a patient is unknown, the error must be reported to a practitioner

immediately. Documentation of the error or reaction, including notification to the practitioner, must be in the patient's medical record.

Medication administration errors that have reached the patient but result in no harm and do not have the potential to cause harm can be reported to a practitioner during usual working hours. For example, if an over-the counter analgesic dose is missed during the night shift, it can be reported first thing in the morning as no further intervention would be required by the practitioner. CAHs should provide clinical staff with expected guidance on how to respond to these situations.

Quality Assurance/Improvement Reporting:

Reduction of medication administration errors and ADRs may be facilitated by effective internal CAH reporting that can be used to assess vulnerabilities in the medication process and implement corrective actions to reduce or prevent reoccurrences. To facilitate reporting, the CAH must educate staff on medication administration errors and ADRs including the criteria for those errors and ADRs that are to be reported for quality assurance/improvement purposes, and how, to whom and when they should be reported.

Reporting for quality assurance/improvement purposes covers all identified medication errors, regardless of whether or not they reach the patient, and those ADRs meeting the criteria specified in the CAH's policies.

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To improve staff willingness to report medication errors and ADR incidents, CAHs are encouraged to adopt a non-punitive approach that focuses on system issues rather than individual health care professionals. A non-punitive approach is likely to encourage reporting by those who otherwise may fear retribution or CAH disciplinary action.

In addition to internal staff reporting, the CAH is expected to take other steps to identify medication administration errors and ADRs. Reliance solely on staff-generated incident reporting fails to identify the majority of adverse drug events. Proactive identification includes observation of medication passes, concurrent and retrospective review of patient's clinical records, implementation of medication usage evaluations for high-alert drugs, and identification of indicator drugs that, when ordered, automatically generate a drug regimen review for a potential adverse drug event.

The CAH must assess the effectiveness of its internal reporting system to determine whether or not it is identifying as many medication errors and ADRs that would be expected for the size and scope of services provided by the CAH. In making such assessments the CAH could refer to established benchmarks or studies on error or ADR rates published in peer-reviewed journals.

For Information Only – Not Required/Not to be Cited

CAHs are encouraged to participate in state-wide and national patient safety organizations for reporting of drug administration errors, ADRs, and drug incompatibilities. National organizations include, but are not limited to, the FDA MedWatch Reporting Program and the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. These organizations, along with other patient safety organizations, collect and analyze data, identify trends, and provide feedback and recommendations to health care organizations to reduce the risk of medication related errors and events.

Survey Procedures §485.635(a)(3)(v)

- *Assess whether the CAH ensures that medication administration errors and ADRs are reported to practitioners in a timely manner.*
 - *Are nursing staff familiar with the concepts of medication errors that do and do not reach the patient, as well as ADRs?*
 - *Ask nursing staff what they would do in the case of a medication administration error that reaches the patient or an adverse drug event.*
 - *Ask nursing staff if they can provide examples of cases where they needed to report an ADR. Is the report to the practitioner documented in the medical record?*
 - *Review records of medication errors and ADRs to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.*
- *Can the CAH demonstrate that it has a system for reporting/identifying ADRs and medication administration errors for quality assurance/improvement purposes?*
 - *Interview CAH staff (nursing, pharmacy and medicine) to ascertain awareness of the CAH's policy on reporting medication administration errors and ADRs for quality improvement purposes*
 - *Does the CAH have evidence of training staff on reporting expectations?*
 - *Does the CAH rely only upon internal staff incident reporting or does it use other methods to identify potential/actual medication errors and ADRs, as well?*

Ask the individual responsible for the QA program to demonstrate how the CAH determines if the number of medication administration errors and ADRs reported is consistent with the size and scope of services provided by the CAH.

- *Review QA activities for medication administration errors and ADRs to determine if, upon analyses of the reports, potential corrective actions are identified and implemented, if appropriate.*

C-0278
(Rev.)

[The policies include the following:]

§485.635(a)(3)(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

Interpretive Guidelines §485.635(a)(3)(vi)

This regulation requires the CAH to have a facility-wide system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel. The National Institute of Allergy and Infectious Diseases (NIAID) defines infectious disease as a disease caused by microbes that can be passed to or among humans by several methods. (<http://www.niaid.nih.gov/topics/microbes/pages/glossary.aspx>)

The Centers for Disease Control and Prevention (CDC) refers on its website to the following definition (from the state of New York) of a communicable disease: “an illness caused by an infectious agent or its toxins that occurs through the direct or indirect transmission of the infectious agent or its products from an infected individual or via an animal, vector or the inanimate environment to a susceptible animal or human host” (<http://www.cdc.gov/tb/programs/laws/menu/definitions.htm>)

A Healthcare-associated infection (HAI) is one that develops in a patient who is cared for in any setting where healthcare is delivered (e.g., acute care hospital, chronic care facility, ambulatory clinic, dialysis center, surgical center, home) and is related to receiving health care (i.e., was not incubating or present at the time healthcare was provided). According to the CDC, healthcare-associated infections, i.e., infections that patients acquire during the course of receiving treatment for other conditions within a healthcare setting, are one of the top ten leading causes of death in the United States. Based on a large sample of U.S. acute care hospitals, a CDC survey found that on any given day, about 1 in 25 hospital patients has at least one healthcare-associated infection. There were an estimated 722,000 HAIs in U.S acute care hospitals in 2011. About 75,000 hospital patients with HAIs died during their hospitalizations. More than half of all HAIs occurred outside of the intensive care unit.

The CAH must provide and maintain a sanitary environment to avoid sources and transmission of infections and communicable diseases. All areas of the CAH must be visibly clean and sanitary. This includes all CAH departments and off-site locations.

The CAH is expected to have a designated individual who is qualified by education and/or experience and who is responsible for the infection control program. This person must have education or experience in the principles and methods for infection prevention and control.

The CAH's program for prevention, control and investigation of infections and communicable diseases must be conducted in accordance with nationally recognized infection control practices or guidelines, as well as applicable regulations of other federal or state agencies. Examples of organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN). The U.S. Occupational Health and Safety Administration (OSHA) also issues federal regulations applicable to infection control practices.

Special Challenges in Infection Control

- ***Multi-Drug Resistant Organisms (MDROs)***

The prevention and control of MDROs is a national priority - one that requires that all healthcare facilities and agencies assume responsibility and participate in community-wide control programs. MDROs are defined as microorganisms – predominantly bacteria – that are resistant to one or more classes of antimicrobial agents. A notable example is methicillin-resistant Staphylococcus aureus (MRSA), an MDRO pathogen which is transmitted within and between healthcare facilities, as well as in the community setting. Options for treating patients with MDRO infections are very limited, resulting in increased mortality, as well as increased length of stay and costs. During the last several decades the prevalence of MDROs in hospitals has increased steadily. CAHs are encouraged to have mechanisms in place for the early identification of patients with targeted MDROs prevalent in their CAH and community, and for the prevention of transmission of such MDROs. When ongoing transmission of targeted MDROs in the CAH is identified, the infection prevention and control program should use this event to identify potential breaches in infection control practice.

- ***Ambulatory Care***

The ambulatory care setting, including emergency departments and outpatient clinics, accounts for a growing number of patient health encounters. Ambulatory care settings present unique challenges for infection control, because patients remain in common areas for prolonged periods waiting to be seen by a healthcare professional or awaiting admission to the CAH, examination or treatment rooms are turned around quickly with limited cleaning, and infectious patients may not be recognized immediately. Furthermore, immuno-compromised patients may receive treatments in rooms among other patients who may be infectious.

The CAH's infection prevention and control program must be designed with these ambulatory care setting challenges in mind. After assessing the likely level of risk in its

various ambulatory care settings, including off-site settings, a CAH might identify particular settings, such as the emergency department, where it would be appropriate to employ measures for screening individuals with potentially communicable diseases during their initial patient encounter, and taking appropriate control measures for those individuals who may present risk for the transmission of infectious agents by the airborne or droplet route. For example, when potentially infectious individuals are identified, prevention measures should include prompt physical separation wherever possible, implementation of respiratory hygiene/cough etiquette protocols, and/or appropriate isolation precautions based on the routes of transmission of the suspected infection.

- ***Communicable Disease Outbreaks***

Community-wide outbreaks of communicable diseases (such as measles, SARS, or influenza) present many of the same issues and require many of the same considerations and strategies as other CAH infectious disease threats. If a communicable disease outbreak occurs, an understanding of the epidemiology, modes of transmission, and clinical course of the disease is essential for responding to and managing the event. Among the infection control issues that may need to be addressed are:

- *Preventing transmission among patients, healthcare personnel, and visitors;*
- *Identifying persons who may be infected and exposed;*
- *Providing treatment or prophylaxis to large numbers of people; and*
- *Logistics issues (staff, medical supplies, resupply, continued operations, and capacity).*

Widespread pandemics present special challenges for CAH staffing, supplies, resupply, etc. CAHs should work with local, State, and Federal public health agencies to identify likely communicable disease threats and develop appropriate preparedness and response strategies.

- ***Bioterrorism***

CAH facilities would confront a set of issues similar to naturally occurring communicable disease threats when dealing with a suspected bioterrorism event. The required response is likely to differ based on whether exposure is a result of a biological release or person-to-person transmission. A variety of sources offer guidance for the management of persons exposed to likely agents of bioterrorism, including Federal agency websites (e.g., <http://www.ahrq.gov/prep>; <http://www.usamriid.army.mil/> ; <http://www.bt.cdc.gov>). Because of the many similarities between man-made and naturally occurring threats, an all-hazards approach to developing emergency response plans is preferred, and CAHs are encouraged to work with their State and local emergency response agencies to develop their plans.

Surveillance & Corrective Action

In order to prevent, control and investigate infections and communicable diseases, the CAH's program must include an active surveillance component that covers both CAH patients and personnel working in the hospital. Surveillance includes infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions.

The CAH must conduct surveillance on a facility-wide basis in order to identify infectious risks or communicable disease problems at any particular location. This does not imply "total hospital surveillance," but it does mean that CAHs must have reliable sampling or other mechanisms in place to permit identifying and monitoring infections and communicable diseases occurring throughout the CAH. The CAH must document its surveillance activities, including the measures selected for monitoring, and collection and analysis methods. Surveillance activities must be conducted in accordance with recognized infection control surveillance practices, such as, for example, those utilized by the CDC's National Healthcare Safety Net (NHSN).

The CAH must develop and implement appropriate infection control interventions to address issues identified through its detection activities, and then monitor the effectiveness of interventions through further data collection and analysis.

Sanitary environment

Prevention of infections includes the proper maintenance of a sanitary environment.

The CAH must provide and maintain a sanitary environment to avoid sources and transmission of infections and communicable diseases. All areas of the CAH must be visibly clean and sanitary. This includes all CAH units and off-site locations. The infection prevention and control program must include appropriate monitoring of housekeeping, maintenance (including repair, renovation and construction activities), and other activities to ensure that the CAH maintains a sanitary environment. Examples of areas to monitor would include: food storage, preparation, serving and dish rooms, refrigerators, ice machines, air handlers, autoclave rooms, venting systems, inpatient rooms, treatment areas, labs, waste handling, surgical areas, supply storage, equipment cleaning, etc. Failure to maintain a clean environment would also be a deficiency related to §485.623(b)(4), which requires the CAH to maintain clean and orderly premises.

Mitigation of Risks

The CAH must have policies and procedures in place to mitigate the risks that contribute to healthcare-associated infections. They must incorporate infection control techniques and standard precautions including, but not limited to:

- Hand Hygiene*
- Respiratory Hygiene/Cough Etiquette*
- Use of Transmission-Based Precautions such as: contact precautions, droplet precautions, and airborne precautions.*

- *Use of personal protective equipment (PPE) for healthcare personnel such as gloves, gowns, masks, and respirators.*
- *Safe work practices to prevent healthcare worker exposure to bloodborne pathogens, such as safety needles and safety engineered sharps devices.*
- *Safe medication preparation and administration practices including, but not limited to:*
 - *Routine preparation of injectable medications takes place in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed;*
 - *Proper hand hygiene before handling medications;*
 - *Always disinfecting a rubber septum with alcohol prior to piercing it;*
 - *Always using aseptic technique when preparing and administering injections;*
 - *Never entering a vial with a used syringe or needle;*
 - *Never administering medications from the same syringe to more than one patient, even if the needle is changed;*
 - *Recognizing that, after a syringe or needle has been used to enter or connect to a patient's IV it is contaminated and must not be used on another patient or to enter a medication vial;*
 - *Never using medications labelled as single-dose or single-use for more than one patient. This includes ampoules, bags, and bottles of intravenous solutions. Exception: It is permissible to use medications that have been **repackaged** from a previously unopened single-dose container if the repackaging has been done by a pharmacy in a manner consistent with USP/NP Chapter <797> standards, and if the repackaged medications have subsequently been stored consistent with USP <797> and the manufacturer's package insert, provided that each repackaged dose is used for a single patient.*
 - *If multi-dose vials are used for more than one patient, they must not be kept or accessed in the immediate patient treatment area. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could then lead to infections in subsequent patients. If a multi-dose vial enters the immediate patient treatment area, it must be dedicated to that patient only and discarded after use.*
 - *Never using bags or bottles of intravenous solution as a common source of supply for more than one patient.*
 - *Wearing a surgical mask when placing a catheter or injecting material into the spinal canal or subdural space.*

- *Never using insulin pens and other medication cartridges and syringes intended for single-patient-use only for more than one person.*
- *Other safe care practices, including, but not limited to:*
 - *Never using the same fingerstick device for more than one person.*
 - *Avoiding sharing blood glucose meters if possible. If they must be shared, the device must be cleaned and disinfected after every use, per manufacturer's instructions. If the manufacturer does not specify how the device should be cleaned and disinfected, it must not be shared.*
 - *Policies to ensure that reusable patient care equipment is cleaned and reprocessed appropriately before use on another patient.*

The CAH must train staff on infection control policies and practices pertinent to the staff's responsibilities and activities. For example, the CAH is expected to provide role-specific education on proper hand hygiene, standard and transmission-based precautions, asepsis, sterilization, disinfection, food sanitation, housekeeping, linen care, medical and infectious waste disposal, injection safety, separation of clean from dirty, as well as other means for limiting the spread of infections.

The CAH is also expected to provide education to patients and their visiting family members/caregivers, when applicable, about precautions to take to prevent infections.

The CAH is expected to monitor compliance with all policies, procedures, protocols, and other infection control program requirements and to conduct program evaluation and revision of the program, when indicated.

Survey Procedures §485.635(a)(3)(vi)

- *Verify that the CAH has designated a qualified individual to be responsible for the infection control program.*
- *Can the responsible individual demonstrate that the CAH's program adheres to nationally recognized practices or guidelines?*
- *Is the environment sanitary throughout the CAH?*
- *Do CAH staff employ standard precautions appropriately?*
- *Do CAH staff employ safe infection control practices for preparing and administering medications?*

- *Does the CAH perform active surveillance to identify infections?*
- *Can the responsible individual demonstrate how staff compliance with infection control program requirements is assessed and what corrective actions are taken?*
- *Can the responsible individual demonstrate that infection control incidents, problems, and trends are analyzed and that corrective actions are taken and further assessed?*
- *Is there evidence of training of staff in infection control practices pertinent to their roles?*

C-0279

(Rev.)

[The policies include the following:]

§485.635(a)(3)(vii) Procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §483.25(i) of this chapter is met with respect to inpatients receiving posthospital SNF care.

Interpretive Guidelines §485.635(a)(3)(vii)

The dietary services must be organized, directed and staffed in such a manner to ensure that the nutritional needs of inpatients are met in accordance with practitioners' orders and recognized dietary practices. The CAH must designate a qualified individual who is responsible for dietary services. The designated individual must be qualified based on education, experience, specialized training, and, if required by State law, licensed, certified, or registered by the State.

If the CAH provides swing-bed services, then it must also comply with the following requirement for resident nutrition:

483.25(i): Nutrition. Based on a resident's comprehensive assessment, the facility must ensure that a resident—

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

(2) Receives a therapeutic diet when there is a nutritional problem.

Each CAH inpatient (including residents) must have their nutritional needs met in a manner that is consistent with recognized dietary practices.

For Information Only – Not Required/Not to be Cited

Although not required by the explicit language of the regulation, CMS recommends that the CAH also ensure it meets the nutritional needs of those patients in observation status whose stay is sufficiently long that they must be fed.

According to the U.S. Department of Agriculture's (USDA) Food and Nutrition Center, the nationally recognized source for recommended dietary intakes allowances is the Institute of Medicine Food and Nutrition Board's Dietary Reference Intakes (DRIs), which are designed to provide recommended nutrient intakes for use in a variety of settings. The DRIs are a set of four reference values:

- Recommended Dietary Allowance (RDA) is the average daily dietary intake of a nutrient that is sufficient to meet the requirement of nearly all (97-98%) healthy persons.*
- Adequate Intake (AI) for a nutrient is similar to the Estimated Safe and Adequate Daily Dietary Intake (ESADDI) and is only established when an RDA cannot be determined. Therefore a nutrient either has an RDA or an AI. The AI is based on observed intakes of the nutrient by a group of healthy persons.*
- Tolerable Upper Intake Level (UL) is the highest daily intake of a nutrient that is likely to pose no risks of toxicity for almost all individuals. As intake above the UL increases, risk increases.*
- Estimated Average Requirement (EAR) is the amount of a nutrient that is estimated to meet the requirement of half of all healthy individuals in the population.*

USDA provides access to an interactive DRI tool and DRI tables at <http://fnic.nal.usda.gov/dietary-guidance/dietary-reference-intakes>

Meeting individual patient nutritional needs may include the use of therapeutic diets. Therapeutic diets refer to a diet ordered as part of the patient's treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium), or to provide mechanically altered food when indicated.

Patients must be assessed for their risk for nutritional deficiencies or need for therapeutic diets and/or other nutritional supplementation. The care plan for patients identified as having specialized nutritional needs must address those needs as well as monitoring of their dietary intake and nutritional status. The methods and frequency of monitoring intake and nutritional status to be used must also be identified in the patient's care plan and could include one or more of the following, as well as other methods:

- *Patient weight (BMI, unintended weight loss or gain)*
- *Intake and output*
- *Lab values*

Examples of patients who may require a comprehensive nutritional assessment include:

- *Patients whose medical condition, surgical intervention, or physical status interferes with their ability to ingest, digest or absorb nutrients;*
- *Patients whose diagnosis or presenting signs/symptoms indicates a risk for malnutrition, (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc.):*
- *Patients whose medical condition can be adversely affected by their nutritional intake and thus require a special diet (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc.).*
- *All patients requiring artificial nutrition by any means (e.g., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);*

All inpatients' diets, including therapeutic diets, must be provided in accordance with orders from a practitioner responsible for the care of the patient.

CAHs may choose, when permitted under State law, to designate qualified dietitians or qualified nutrition professionals as practitioners with diet-ordering privileges. In many cases State law determines what criteria an individual must satisfy in order to be a "qualified dietician;" State law may define the term to mean a "registered dietician" registered with a private organization, the Commission on Dietetic Registration, or State law may impose different or additional requirements. Terms such as "nutritionists," "nutrition professionals," "certified clinical nutritionists," and "certified nutrition specialists" are also used to refer to individuals who are not dietitians, but who may also be qualified under State law to order patient diets. It is the responsibility of the hospital to ensure that individuals are qualified under State law before appointing them to the medical staff or granting them privileges to order diets.

A CAH may provide dietary services under arrangement with a food vendor, but the CAH retains responsibility for ensuring that all dietary services meet the regulatory requirements.

Survey Procedures §485.635(a)(3)(vii)

- *Verify that the individual responsible for dietary services is qualified based on education, experience, specialized training, and, if required by State law, is licensed, certified, or registered by the State.*
- *Ask the responsible individual to demonstrate how the CAH uses DRIs in its menus to meet the nutritional needs of patients.*

- *From the sample of inpatient and swing-bed patient records, identify if patients were assessed using a screening mechanism for the risk of malnutrition and nutritional complications.*
- *Among patients who were assessed as having special nutritional needs , were dietary orders reflecting the assessment written and implemented?*
- *Is/was their dietary intake and nutritional status being monitored, as appropriate? If the CAH has swing bed patients, verify that it has documentation of maintaining acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible;*
- *Verify that all inpatient diets are prescribed by a practitioner(s) responsible for the care of the patient. If the State and the CAH permit dietitians or other nutrition professionals to order diets, has the CAH verified that they meet any requirements for licensure or certification under State law?*

C-0280
(Rev.)

§485.635(b) Standard: Patient Services

(1) General

- (i) The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician’s office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.**

Interpretive Guidelines §485.635(b)(1)(i)

This regulation addresses the minimum level of outpatient services (with the exception of emergency services – see §485.635(b)(4)) which a CAH must provide. Such services must be provided on-site at the CAH, but may be provided either by CAH staff or under an arrangement or contract. At a minimum, the CAH must provide those diagnostic and therapeutic services and supplies which are typically found in an ambulatory healthcare setting where patients first come into contact with the healthcare delivery system. The services required to be provided must, at a minimum, reflect the scope and complexity of services provided in a physician’s office or in a hospital outpatient or emergency department that furnishes low intensity (i.e., less complex) services. Such services include, but are not limited to: taking a patient’s medical history; conducting a physical examination of the patient; specimen collection, assessment of health status, and treatment for a variety of medical conditions. The extent of the CAH’s outpatient services is expected to be sufficient to meet the needs of the patients it services for basic

ambulatory care services. Further, the CAH's outpatient services must be integrated with its inpatient services.

For those outpatient services that fall only within the scope of practice of a physician or non-physician practitioner, in order to demonstrate compliance, a CAH physician or non-physician practitioner must be available to treat patients at the CAH when such outpatient services are provided. This requirement does not mean the CAH must have a practitioner physically present in the CAH 24 hours per day, seven days per week. See the discussion of required emergency services at §485.618(d) concerning required response times for a physician or non-physician practitioner to come to the CAH to provide medical care.

Survey Procedures §485.635(b)(1)(i)

- Does the CAH provide on-site outpatient services that are typical of those provided in a physician office or low intensity hospital outpatient or emergency department, including medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions?
- Determine that the outpatient services are integrated with the appropriate CAH inpatient services in accordance with the needs of the patient care provided.
- Verify that the types and number of qualified personnel are appropriate for the scope and complexity of the outpatient services offered. Review personnel files or contracts to verify current licensure, certifications and training of staff consistent with applicable State laws.
- Verify that equipment, staff and facilities are adequate to provide the outpatient services and are in accordance with acceptable standards of practice.

C-0281

(Rev.)

[\$485.635(b) Standard: Patient Services

(1) General]

(ii) The CAH furnishes acute care inpatient services.

Interpretive Guidelines §485.635(b)(1)(ii)

In accordance with §485.620(b), CAHs are required to have an average annual per acute inpatient length of stay that does not exceed 96 hours. Accordingly, CAHs are expected to provide less complex inpatient services in order to comply with the length of stay requirement. Furthermore, for each Medicare beneficiary, the CAH is required in accordance with Medicare payment law and regulations to have the practitioner who admits the beneficiary as an inpatient

certify that the beneficiary may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH. However, while it may be true that CAHs generally are not expected to handle patients requiring complex, specialized inpatient services, such as those services provided by trauma centers, or cardiac surgery centers, CAHs should be able to handle a range of patient needs requiring inpatient admission. CMS does not believe it is in the best interest of patients for them to routinely be transferred to a more distant hospital if instead their care can be provided locally without compromising quality or the length of stay requirements (78 FR 50749). Accordingly, acute inpatient services must be furnished to patients who present to the CAH for treatment so long as the CAH has an available inpatient bed and the treatment required to appropriately care for the patient is within the scope of services offered by the CAH.

Given the resources of the CAH, the needs of the community it serves, and the variable nature of a CAH's inpatient census, a CAH may not be actively treating inpatients at all times. CAHs may experience significant seasonal variations in the inpatient occupancy rates as well as variations that are a function of the size of the community in which the CAH is located.

A CAH is not required to maintain a minimum average daily census of patients receiving inpatient acute care services or maintain a minimum number of beds that are to be used for inpatient services. However, in determining compliance with this requirement factors to be considered include, but are not limited to, the following:

- What is the volume of emergency services the CAH provides on average quarterly and annually?*
- What is the number of certified inpatient beds in the CAH?*
- Are there dedicated observation beds in the CAH? If so, how many compared to the number of inpatient beds?*
- What is the average acute care occupancy rate for the CAH's inpatient beds quarterly and annually?*
- What is the volume of acute inpatient admissions in the CAH quarterly and annually?*
- What is the volume of patients placed in observation status in the CAH quarterly and annually?*
- What is the percentage of emergency department patients admitted to the CAH as an inpatient versus transferred to a hospital quarterly and annually?*
- What is the range, volume and complexity of outpatient services the CAH provides?*

While there is no specific formula for determining the number of patients a CAH is expected to admit, surveyors must be alert to disproportionate relationships among the CAH's various services. For example, if a CAH has only 4 certified beds and an average of 3 acute care inpatients per month, but has 18 observation beds that have an annual occupancy rate of 85%, has an ED staffed by physicians 24/7 and sees 9,000 ED patients/year, offers extensive and complex outpatient services, such as chemotherapy, advanced diagnostic imaging, sleep lab services, and same day surgery, but transfers to another hospital from the ED almost all patients who need inpatient admission, then these inpatient services would not be reasonably proportional to the overall mix and volume of services offered by the CAH. Based on data published by the Agency for Healthcare Research and Quality (AHRQ), in 2008 approximately

8.3 percent of emergency department (ED) visits in a rural “hospital” resulted in an inpatient admission, compared to 16 percent for non-rural hospital ED visits. Also, a higher percentage of rural ED patients were likely to be discharged – 91.7% compared to 84% for non-rural hospitals. The AHRQ rural hospital data included both hospitals and CAHs, with CAHs accounting for 51 percent of rural EDs.² Other published AHRQ data indicates that, in 2009, 3 percent of patients who lived in a rural area were transferred from the ED where they presented to a hospital, compared to 1.5 percent of all patients nationally who presented to an ED.³

Given that a CAH may offer fewer services than even the average rural hospital and is expected to achieve a 96-hour average length of stay or less, there is no expectation that every CAH is expected to admit 8 percent of its ED patients. This benchmark can, however, provide a useful starting point for assessing compliance.

- Generally, if a CAH admits at least 8 percent of its ED patients annually, it would be considered compliant with the requirement to provide inpatient services and surveyors do not have to investigate further.
- If a CAH admits less than 8 percent of its ED patients annually, this is **not** in and of itself evidence of noncompliance. More investigation is needed to assess compliance by determining whether the volume of activity and number of staff the CAH has for its ED, other outpatient, and inpatient services are reasonably related to each other. There can be great variation among CAHs in their volume and types of activities, despite their relative similarity in size, making a “one size fits all” formula inappropriate. Researchers in one State with 79 CAHs found that they averaged 3,851 ED visits annually, but that visits for individual CAHs ranged from a low of 389, or a little more than one patient per day, to a high of 14,425, or about 40 patients per day. CAHs in this State averaged 19,705 other types of outpatient visits annually, but again the range was very large, from a low of 89 to a high of 86,367 per year. For inpatient admissions the annual average was 836, ranging from a low of 100 to a high of 3,838⁴. Presentation of the data found in this State is not intended to provide benchmarks for CAHs in other States, but rather to emphasize the tremendous range in the volume of activity among CAHs, even within one State.
- A couple of extreme but illustrative examples are presented below to indicate the types of factors to be considered when assessing whether the CAH satisfies the requirement to provide inpatient services:

² Hines, A.L., Frazee, T., and Stocks, C. *Emergency Department Visits in Rural and Non-Rural Community Hospitals*, 2008. HCUP Statistical Brief #116. June 2011. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb116.pdf>

³ Kindermann, D, Mutter, R. and Pines, J.M. *Emergency Department Transfers to Acute Care Facilities*, 2009. HCUP Statistical Brief #155. May 2013. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb155.pdf>

⁴ Moscovice, I. and Casey, M. *Rural-relevant Quality Measures for Critical Access Hospitals*. June 27, 2011 PowerPoint presentation to the Minnesota Rural Health Conference. <http://www.health.state.mn.us/divs/orhpc/conf/2011/presentations/2b.pdf>

- *Example #1: A CAH has a very low volume of ED visits, such as 2 or fewer patients per day on average, discharges over 90% of its annual ED patients, has a total professional health care staff that consists of one physician who spends a limited amount of time on-site, and one nurse practitioner who works days five days per week. In this case it would not be unreasonable for the CAH to admit a patient for acute inpatient services only occasionally and transfer a majority of those ED patients who require inpatient services to a hospital.*
- *Example #2: A CAH has 50 ED visits per day on average, 4 certified inpatient beds, 2 inpatient admissions per month on average (all elective surgery patients who started as outpatient cases), 10 dedicated observation beds and places about 2 ED patients per day in observation; transfers out to a neighboring hospital an average of 15 ED patients per week who require admission, has twenty physicians on staff, is performing an average of three thousand outpatient surgeries per year, provides outpatient chemotherapy, cardiology and advanced diagnostic imaging, and has a total of about 40,000 outpatient visits per year, not counting ED visits. This CAH's services are very skewed toward outpatient services, and the needs of its patient population for inpatient services do not appear to be met by the CAH. The CAH might arguably have the staff to provide a larger volume of inpatient services to many of the ED patients who require admission. The CAH would be expected to demonstrate to the surveyor why it could be reasonable for its inpatient capacity and admissions to be so disproportionately small compared to its outpatient services volume and capabilities, and in view of the needs of its ED patients for inpatient services. The surveyor would also review the medical records of a sample of ED patients transferred out to see if they required services the CAH's professional healthcare staff is not able to provide. (This case might also raise EMTALA issues related to on-call lists and appropriate transfers. See Appendix V)*
- *Example #3: A CAH has 25 ED visits per day, 25 certified beds, 23 of which, on average, are used for swing-bed services and are occupied by nursing home or skilled nursing facility residents. The CAH transfers out to a neighboring hospital an average of eight ED patients per week who require admission, and admits an average of one patient per month for acute inpatient services. The CAH has fifteen physicians on staff, is performing an average of 800 outpatient surgeries per year, provides outpatient chemotherapy, cardiology and advanced diagnostic imaging, and has a total of about 20,000 outpatient visits per year, not counting ED visits. In this situation the CAH's services are skewed towards outpatient and long-term care services and the needs of its patient population for inpatient services do not appear to be met by the CAH. The CAH would be expected to demonstrate to the surveyor why it could be reasonable for its inpatient acute care capacity and admissions to be so disproportionately small compared to its outpatient and long term care services and to the needs of its ED patients for inpatient services. The surveyor would also review the medical records of a sample of ED patients transferred out to see if they required services the CAH's professional healthcare staff is not able to provide. (This case might also raise EMTALA issues related to on-call lists and appropriate transfers. See Appendix V)*

Survey Procedures §485.635(b)(1)(ii)

- *Verify that the CAH is furnishing acute care inpatient services by reviewing data on the number of patients admitted over the prior year.*
- *Determine the percentage of ED visits that result in an admission to the CAH. If fewer than eight percent of ED visits lead to an inpatient admission, review data on transfers of ED patients, overall staffing, the volume and type of outpatient services offered, including observation services, and swing bed services to determine whether there is a reasonably proportionate relationship among the various services the CAH provides.*
- *Review a sample of records of the patients the CAH transferred and determine if the transfers were appropriate based on the services available at the CAH.*

C-0282

(Rev.)

§485.635(b)(2) Laboratory Services

The CAH provides basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include the following:

- (i) Chemical examination of urine by stick or tablet method or both (including urine ketones).
- (ii) Hemoglobin or hematocrit.
- (iii) Blood glucose.
- (iv) Examination of stool specimens for occult blood.
- (v) Pregnancy tests.
- (vi) Primary culturing for transmittal to a certified laboratory.

Interpretive Guidelines §485.635(b)(2)

Laboratory services that must be provided on-site at the CAH's main campus are the tests specified in the regulation, which would be considered the minimum necessary for diagnosis and treatment of a patient:

- Chemical examination of urine by stick or tablet method or both (including urine ketones);

- Hemoglobin or hematocrit;
- Blood glucose;
- Examination of stool specimens for occult blood;
- Pregnancy tests; and
- Primary culturing for transmittal to a certified laboratory.

These services may be provided by CAH staff or under arrangement or agreement *with a laboratory*, or through a combination of CAH staff and a laboratory under arrangement. Laboratory services, whether provided directly by the CAH or under an arrangement with a laboratory contractor, must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter. Compliance with Part 493 is not assessed by CAH surveyors evaluating compliance with the CAH conditions of participation, but surveyors are expected to refer potential issues they may identify to the program responsible for CLIA certification.

Given that the CAH must provide emergency services 24 hours a day, 7 days a week, the CAH must determine which laboratory services are to be immediately available to meet the emergency needs of patients and how the services are to be provided. The emergency laboratory services available should reflect the scope and complexity of the CAH's emergency services operations.

The provision of laboratory services that exceed the minimum tests specified is optional. The scope and complexity of the CAH's laboratory service must be adequate to support the clinical services the CAH offers to patients. Additional laboratory services may be offered directly or through arrangement. The CAH should have a written description of all the laboratory services that it provides, including those delivered on routine and stat basis.

The laboratory must have written policies and procedures for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the CAH must comply with the requirements of the clinical records CoP at §485.638(a)(4)(ii).

Survey Procedures §485.635(b)(2)

- Ask the CAH to identify which laboratory services it offers. Are the required lab services provided at the CAH's main campus?
- Does the CAH have a CLIA certificate or waiver, as applicable, for all laboratory tests performed in CAH facilities?

- Verify that the CAH has a procedure in place for obtaining tests that are needed but unavailable at the CAH laboratory.
- If the CAH refers specimens to another laboratory for testing, does the CAH have documentation that the referral laboratory is CLIA certified for the appropriate tests?
- Has the CAH identified laboratory services that must be available to support the emergency services the CAH provides? Ask the staff who furnish emergency services whether these laboratory services are available whenever they provide emergency services.

C-0283

(Rev.)

§485.635(b)(3) Radiology services. Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards.

Interpretive Guidelines §485.635(b)(3)

Radiologic services encompass many different modalities used for the purpose of medical imaging. Each type of technology gives different information about the area of the body being studied or treated, related to possible disease, injury, or the effectiveness of medical treatment. All the modalities use some form of radiation, such as ionizing radiation (radiography, computed tomography, fluoroscopy), which has enough energy to potentially cause damage to DNA, and other forms of radiation (ultrasound, magnetic resonance imaging) to view the human body in order to diagnose, monitor, or treat medical conditions.

Radiological services furnished by the CAH may be provided by CAH staff or under arrangement. The CAH must maintain and have available diagnostic radiological services to support the services the CAH provides to meet the needs of its patients. These services must be available at all times the CAH provides services, including emergency services. The CAH has the flexibility to choose the types and complexity of radiologic services offered. They may offer only a minimal set of services or a more complex range of services (including nuclear medicine).

All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered should be specified in writing and approved by the governing body (or responsible individual).

Acceptable standards of practice include maintaining compliance with appropriate Federal and State laws, regulations and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations

promoted by nationally recognized professions such as the American Medical Association, Radiological Society of North America, Alliance for Radiation Safety in Pediatric Imaging, American Society of Radiologic Technologists, American College of Cardiology, American College of Neurology, American College of Physicians, American College of Radiology, etc.

Qualified Radiologic Personnel

There *must* be written policies that are developed and approved by the governing body or responsible individual and are consistent with State law, that designate which personnel are qualified to use the radiological equipment *and* administer procedures.

When telemedicine is used to provide teleradiology services, radiologists who interpret radiological tests must satisfy the telemedicine privileging requirements §485.616(c)(3).

In addition to radiologists, there are other types of healthcare personnel who, depending on State law and the scope and complexity of the CAH's radiologic services, may be involved in the delivery of radiologic services in the CAH, including radiologic technologists and medical physicists. Radiologic technologists perform diagnostic imaging examinations and administer radiation therapy treatments. They are educated in anatomy, patient positioning, examination techniques, equipment protocols, radiation safety, radiation protection and basic patient care.

For Information Only – Not Required/Not to be Cited

Well-designed radiologic services include a medical physicist, who, in conjunction with the person responsible for radiologic services, performs or supervises the pertinent procedures necessary to assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result. The responsibilities of the medical physicist include: protection of the patient and others from potentially harmful or excessive radiation; establishment of adequate protocols to ensure accurate patient dosimetry; the measurement and characterization of radiation; the determination of delivered dose; advancement of procedures necessary to ensure image quality; development and direction of quality assurance programs; and assistance to other health care professionals in optimizing the balance between the beneficial and deleterious effects of radiation (www.aapm.org). CAHs are encouraged to involve a medical physicist in the calibration of the imaging equipment and monitoring of radiation dosage exposures.

Safety from Radiation Hazards

The CAH must adopt and implement policies and procedures that ensure safety from radiation hazards for patients and personnel. The CAH must implement and ensure compliance with its established safety standards. The policies *must address* at least the following:

- Adequate radiation shielding for patients, personnel and facilities, which includes:
 - Shielding built into the CAH's physical plant, as appropriate;

- Types of personal protective shielding to be used, under what circumstances, for patients, including high risk patients as identified in radiologic services policies and procedures, and CAH personnel;
- Types of containers to be used for various radioactive materials, if applicable, when stored, in transport, in use, and when disposed;
- Clear signage identifying hazardous radiation areas;
- Labeling of all radioactive materials, including waste, with clear identification of all material(s);
- Transportation of radioactive materials between locations within the CAH;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Periodic testing of equipment for radiation hazards;
- Periodic checking of staff regularly exposed to radiation for the level of radiation exposure, via exposure meters or badge tests;
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.

Radiologic Equipment Maintenance

The CAH must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, and that problems identified are corrected in a timely manner. The CAH must ensure that equipment is inspected *and maintained* in accordance with Federal and State laws and regulations, as applicable, and *the manufacturer's recommendations*. The CAH must have a system in place to correct identified problems. The CAH must have evidence of its inspections and corrective actions.

Radiology Records

The CAH radiology records are to be treated in the same manner as any other part of a medical record. The medical records CoP at §485.638(a)(4)(ii) requires that the CAH maintain reports of physical examinations, diagnostic and laboratory test results, and consultative findings.

Survey Procedures §485.635(b)(3)

- Interview the person responsible for radiologic services.

- Ask what radiologic services the CAH offers at its main campus. At off-site locations ask how the CAH ensures patient needs for radiologic services are met, if applicable.
- Ask how the CAH ensures that radiologic services are provided consistent with acceptable standards of practice.
- Safety:
 - Determine if the radiologic services staff is familiar with the policies and procedures related to safety.
 - Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the CAH.
 - Observe areas where radiologic testing is done and check for safety problems.
 - Verify that hazardous materials are clearly labelled. Review records to verify that they are tracked, handled and stored properly in a safe manner with the requisite containers.
 - Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.
- Equipment maintenance:
 - Review the inspection records to verify that periodic inspections *and maintenance* are conducted *in accordance with the manufacturer's recommendations* .
 - Determine whether any problems identified are properly corrected in a timely manner and the correction is maintained over time.
- Qualified Personnel:
 - Are studies interpreted only by qualified staff approved to do so by the CAH's governing body or responsible individual?
 - Determine which staff are using various pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine if they meet the qualifications for tasks they perform, as established in the CAH's policies and consistent with state law.
 - Ask staff to explain the protocol for the procedures/studies they administer. Ask to see the CAH's written protocols and verify that the staff is adhering to them.

C-0284

(Rev.)

§485.635(b)(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides medical services as a first response to common life-threatening injuries and acute illness.

Interpretive Guidelines §485.635(b)(4)

Emergency services must be provided by the CAH at the CAH campus either by CAH staff or *by individuals providing services* under arrangement or agreement. The individuals providing the services must have the ability to recognize a patient's need for emergency care at all times. The CAH must provide *medically appropriate* initial interventions, treatment and stabilization of any patient who requires emergency services.

Survey Procedures §485.635(b)(4)

The survey procedures for §485.618 apply.

C-0287

(Rev.)

[\$485.635(c)(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—]

(i) Services of doctors of medicine or osteopathy;

§485.635(c)(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Interpretive Guidelines §485.635(c)(1)(i) & §485.635(c)(2)

In accordance with §485.631(a)(1), the CAH is required to have at least one doctor of medicine or osteopathy (MD or DO) on its staff who is responsible for the functions described in §485.631(b). CAHs are free to have additional MDs or DOs on staff, part- or full-time. MDs and DOs who have been credentialed and privileged to provide services on-site at the CAH are part of the CAH's professional healthcare staff, even if they are not at the CAH full-time; they would not be considered to be providing services under an arrangement and would not be covered by these regulatory provisions. These regulations also do not apply to MDs and DOs who provide telemedicine services to the CAH's patients, even when they are provided under arrangement. (See §485.616(c) and §485.635(c)(5) concerning telemedicine requirements.)

Under §485.635(c)(1)(i) & §485.635(c)(2), the CAH must have policies and procedures for referring patients it discharges who need additional specialized MD or DO services not available at the CAH. The policies and procedures must at a minimum identify the services for which the CAH has referral arrangements or agreements, as well as the information to be provided to referred patients. MDs and DOs to whom the CAH refers its patients must participate in Medicare.

The CAH is not required to have referral arrangements in writing, but if it does not, then it must be able to document that patients it has referred to an outside MD or DO have been offered appointments and treatment.

Survey Procedures §485.635(c)(1)(i) & §485.635(c)(2)

- *Verify that the CAH has arrangements with one or more MDs or DOs for referral of discharged CAH patients who need medical services not available at the CAH.*
- *Are the referral arrangements in writing? If not, can the CAH document that patients referred to an outside MD or DO have been offered appointments and treatment?*
- *Does the CAH have policies and procedures addressing referral of discharged patients? Are the CAH's practitioners and staff who handle the discharge of patients familiar with these policies and procedures?*

C-0288

(Rev.)

[§485.635(c)(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—]

(ii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and

§485.635(c)(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

Interpretive Guidelines §485.635(c)(1)(ii) & §485.635(c)(2)

In accordance with §485.635(b)(2), the CAH is required to furnish, either directly by the CAH staff, under arrangement or agreement, or through a combination of CAH staff and a laboratory under arrangement basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). These services must be provided on-site at the CAH and may be provided either by CAH staff or under an arrangement with a laboratory. The CAH is also free to provide

additional laboratory services on-site, beyond the minimum required services. The provision at §485.635(c)(1)(ii) does not apply to laboratory services provided on-site.

Instead, this provision addresses the requirement for the CAH to have an arrangement or agreement, as appropriate, with with a laboratory that can provide additional or specialized clinical laboratory services that are not available at the CAH. The arrangement or agreement may provide either for the CAH to draw the specimens to be examined and send them to the outside laboratory. The CAH is not required to have a written agreement or arrangement, but if it does not, it is expected to be able to document that an outside laboratory to which it sends specimens provides the CAH with test results.

Laboratories that provide additional diagnostic and clinical laboratory services to a CAH *under agreement or arrangement must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter. The CAH is expected to have evidence of the outside laboratory to which it refers patients holding a current CLIA certificate or waiver.*

The CAH must have policies and procedures for additional or specialized laboratory services provided under arrangement or agreement which address at least the following: the specific laboratory services provided under arrangement; and the collection, preservation, transportation, receipt, and reporting of tissue specimen results.

Likewise, although the CAH is expected to provide radiology services in accordance with §485.635(b)(3), it is also expected to have an arrangement or agreement, as appropriate, with other providers or suppliers of diagnostic imaging services, including advanced diagnostic imaging services, such as magnetic resonance imaging, computed tomography, etc. The CAH is not required to have a written agreement or arrangement, but if it does not, it is expected to be able to document that an outside diagnostic imaging facility to which it sends patients provides the CAH with the resulting studies and reports.

Patient diagnostic imaging studies and reports, laboratory results and all other laboratory clinical patient records must be included in the patient's medical record and meet all requirements at §485.638(a)(4)(ii).

Survey Procedures §485.635(c)(1)(ii) & §485.635(c)(2)

- *Verify that the CAH has an agreement or arrangement with an outside laboratory and an outside diagnostic imaging facility for services not provided in the CAH.*
- *Ask the CAH how it ensures that the laboratory with which it has an agreement or arrangement holds the necessary CLIA certification.*

- *If the agreement or arrangement is not in writing, can the CAH document that it is sending specimens to an outside laboratory and patients to an outside diagnostic imaging facility when needed, and that it is receiving test results?*
- *Do policies and procedures address which imaging and lab services are provided under arrangement, as well as, for lab services, collection, preservation, transportation, receipt, and reporting of tissue specimen results?*

C-0289

(Rev.)

[§485.635(c)(1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—]

(iii) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

Interpretive Guidelines §485.635(c)(1)(iii)

If the CAH does not provide all food and other services required to meet the nutritional needs of the CAH's inpatients using CAH staff, then the CAH must provide these services under an agreement or arrangement..

The CAH must assure that dietary services provided under an agreement or arrangement are provided in accordance with the CAH's policies adopted as required by §485.635(a)(3)(vii). Unless the CAH is a grandfathered co-located CAH (see §485.610(e)(1)) that has an arrangement with the co-located facility to provide food services to the CAH's inpatients, it is expected that the CAH's vendor provides dietary services on-site at the CAH in order to meet the needs of the CAH's inpatients. Surveyors assess compliance with the requirements of §485.635(a)(3)(vii) in the same manner, regardless of whether the services are provided by CAH staff or a vendor. In the case of a grandfathered co-located CAH that obtains food services from the co-located facility, surveyors must assess the food service operations in the co-located facility as part of the CAH survey.

Survey Procedures §485.635(c)(1)(iii)

- *Verify that the CAH has an agreement or arrangement with a vendor to provide dietary services to inpatients if the CAH does not use its own staff to provide these services.*

C-0291

(Rev.)

§485.635(c)(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

Interpretive Guidelines §485.635(c)(3)

The CAH must maintain a list of all patient care services furnished by the CAH through arrangements or agreements. The list must be updated each time a contracted service is added or removed. For each service the list must include, at a minimum, the following information:

- *The service(s) being offered;*
- *The individual(s) or entity providing the service(s);*
- *Whether the services are offered on- or off-site;*
- *Whether there is any limit on the volume or frequency of the services provided; and*
- *When the service(s) are available.*

Survey Procedures §485.635(c)(3)

- Review the list of contracted services and verify that *it contains all required information.*
- *Ask the CAH for evidence that the list is updated whenever there are changes.*
- *Ask various CAH staff during the course of the survey whether they work directly for the CAH or some other entity; check that services provided by staff employed by outside entities are on the list of contracted services.*

C-0292

(Rev.)

§485.635(c)(4) The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following:

- (i) **Services furnished in the CAH whether or not they are furnished under arrangements or agreements.**

(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

Interpretive Guidelines §485.635(c)(4)

The person principally responsible for the operation of the CAH, in accordance with §485.627(b)(2), i.e., the CAH's Chief Executive Officer (CEO), is responsible for the operation of all patient care services furnished at the CAH. This includes services provided directly by CAH staff and services provided by the CAH under arrangement or agreement. It includes not only care provided directly to patients, but also services related to patient care, such as environmental cleaning, instrument cleaning and sterilization, laundry, pharmacy services, laboratory services, etc. (This requirement for the CEO to be responsible does not relieve the CAH's governing body of its ultimate responsibility for the CAH's total operation in those CAHs where there are both a governing body and a CEO.)

The CEO must take actions to assure that all services furnished by the CAH through a contractor comply with the applicable requirements of the CAH's CoPs. When assessing compliance of a service provided by a contractor with the CoPs, deficiencies cited under other CoPs warrant a citation of this requirement, because the CEO has failed to assure that the contractor provides services in a manner that allows the CAH to comply with the CoPs.

Survey Procedures §485.635(c)(4)(i)

- *Ask the CAH's CEO to demonstrate how he or she provides oversight of all contracted services related to patient care.*
- *Ask for specific examples of how the CEO assures that services furnished in the CAH comply with the CoPs (e.g. policies and procedures, by-laws, etc.) that the individual responsible for its operations is responsible for all services provided through arrangements or agreements.*

C-0294

(Rev.)

§485.635(d) Standard: Nursing Services

Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

Interpretive Guidelines §485.635(d) & (d)(1)

In order to meet the needs of patients, nursing services must be a well-organized service of the CAH. The CAH designates an individual who is responsible for nursing services, including development of policies and procedures for nursing services. The designated individual is generally expected to be a registered nurse. Various titles may be used for the responsible nurse leader may have (e.g., director of nursing services, nurse executive, chief nursing officer, or nurse manager). The nurse leader is responsible for the overall management and evaluation of nursing care in the CAH, including, but not limited to:

- Development and maintenance of nursing policies and procedures;*
- Supervision of nursing staff, either directly, or, depending on the size of the CAH, indirectly through other nursing managers; and*
- Ongoing review and analysis of the quality of nursing care.*

As required at §485.631(a)(5), the CAH must have a registered nurse, clinical nurse specialist, or licensed practical nurse on duty whenever the CAH has one or more inpatients (including patients in a swing bed receiving long term care services).

The CAH must also ensure that, for outpatient nursing services, appropriate nursing staff are available in accordance with State law and CAH policy.

For both inpatient and outpatient services there must be sufficient numbers of supervisory and non-supervisory nursing personnel with the appropriate education, experience, licensure (as applicable), competence and specialized qualifications to respond to the nursing needs of the patient population of each CAH department or nursing unit. Staffing schedules must be reviewed and revised as necessary to meet patient care needs and to make adjustments for nursing staff absenteeism.

The CAH must have a procedure for assigning and coordinating the nursing care for every CAH patient. A registered nurse must either provide directly, or assign to other staff, the required nursing care for each CAH patient, including patients receiving swing bed services. The RN making the assignment must consider the specialized qualifications and competence of the CAH's available nursing staff in order to meet patients' nursing care needs. Nursing care duties may be assigned to appropriate personnel, such as a licensed practical nurse, nursing assistant or nurse's aide, so long as such assignment is consistent with state law and the individual has the qualifications and competence to perform the assigned tasks.

The CAH must ensure that all CAH nursing staff are adequately trained and oriented, aware of CAH nursing policies and procedures, supervised, and that their clinical activities are evaluated. If temporary outside agency nurses are employed to address temporary nurse staffing needs, determine how are these nurses oriented and supervised. (Note that regular nursing services may be provided under arrangement instead of using CAH employees, but in this case the CAH is responsible for the ongoing training and supervision of these regular nursing staff.)

Survey Procedures §485.635 (d)(1)

- *Determine whether an RN has been designated responsible for nursing services at the CAH.*
- *Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Sources of information to use in the evaluation of the nursing services are: staffing schedules, nursing care plans *for inpatients* credentialing and training files (including contracted staff), and QA activities and reports.*
- *Interview the registered nurse responsible for nursing services and ask the following--*
 - *How are the nursing needs of patients determined? Who makes this determination?*
 - *How are staff assigned to provide nursing care to patients?*
 - *How does the CAH ensure that care provided meets the needs of each patient?*
 - *How are staff trained and oriented? If temporary outside agency nurses are used, how are they oriented and supervised?*
- *Review nursing assignments in one or more inpatient units, the emergency department, and one other outpatient department. Did an RN make the assignments? Was the complexity of patient care needs and the competence and specialized qualifications of the nursing staff taken into consideration?*
- *Review written staffing schedules; do they adhere to the CAH's policies and procedures for staffing levels and types of nursing personnel?*
- *Verify that there is supervision of personnel performance and nursing care for each nursing unit.*
- *If there are temporary agency nurses providing services, interview one or more to determine if they are familiar with the nursing policies and procedures of the unit or department where they are working.*
- *Review personnel files to determine that nursing staff have required licenses and competencies.*

C-0296

(Rev.)

485.635(d)(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

Interpretive Guidelines §485.635(d)(2)

The nursing care of each patient of the CAH must be supervised by a registered nurse or a physician assistant where permitted by State law. Even where permitted under State law, a CAH is not required to have nursing care supervised by a physician assistant. This is simply an option for the CAH.

For inpatients, including patients receiving long term care services in swing beds, evaluation of their nursing care includes evaluating the care for each patient upon admission and, when appropriate, on an ongoing basis in accordance with accepted standards of nursing practice and CAH policy. Evaluation would include assessing the patient's care needs, patient's health status/conditioning, as well as the patient's response to interventions.

Nursing care plans are not developed for outpatients, so the focus of the evaluation would be on adherence to generally acceptable standards of nursing care practice, including requirements at §485.635(d)(3) for medication administration.

Survey Procedures §485.635(d)(2)

- Determine that a registered nurse (or *physician assistant* where *permitted by* State law *and CAH policy*) supervises and evaluates the nursing care for each patient.
- Interview *one or more registered nurses* (or *physician assistants, if applicable*) who supervise and evaluate the nursing care for CAH patients.

C-0297

(Rev.)

485.635(d)(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

Interpretive Guidelines §485.635(d)(3)

As required at §485.635(a)(3)(iv), the CAH must have written policies and procedures for the administration of all drugs and biologicals that adhere to accepted standards of practice and Federal and State laws. In accordance with §485.635(d)(3), all medication administration must be consistent with accepted standards of practice, as well as Federal and State laws. Examples of nationally recognized organizations with expertise in medication administration include, but are not limited to:

- *National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org);*
- *Institute for Healthcare Improvement (<http://www.ihl.org/ihl>) ;*
- *U.S Pharmacopeia (www.usp.org) ;*
- *Institute for Safe Medication Practices, which offers guidelines specifically on timely medication administration, which can be found at: www.ismp.org/Newsletters/acutecare/articles/20110113.asp;*
- *Infusion Nurses Society (<http://www.insl.org>).*

In addition, the Centers for Disease Control and Prevention (CDC) publishes evidenced-based practice guidelines and recommendations on medication preparation and administration practices, designed to reduce the risk of infection associated with these activities.

Who May Administer Medications?

Drugs and biologicals, including intravenous (IV) medications, must be administered by, or under the supervision of, an MD or DO; an RN, or, where permitted by State law, a PA. Other personnel, such as LPN's, may administer medications when permitted by State law and CAH policy, so long as they are supervised by an MD, DO, RN or, where permitted by State law, a PA. The CAH's written policies must delineate the categories of clinical staff authorized to administer medication at the CAH.

Medication Orders

Drugs and biologicals, including intravenous (IV) medications, may only be administered in accordance with orders written and signed by a practitioner who is authorized by CAH policy, and in accordance with State law, to write orders and who is responsible for the care of the patient as specified under §485.631(b)(1)(iii).

Accepted standards of practice

Based on accepted standards of practice for medication administration, the CAH must assure compliance with the following requirements concerning:

- *Minimum content of medication orders;*
- *Policies and procedures for verbal and standing orders;*

- *Self-administration of medications, if the CAH permits this;*
- *Training;*
- *Basic Safe Practices;*
- *Timing of Medication Administration;*
- *Assessment/Monitoring of Patients Receiving Medications;*
- *Intravenous (IV) medications; and*
- *Documentation*

Content of the medication order

In accordance with accepted standards of practice, the minimum elements that must be present in orders for all drugs and biologicals to ensure safe preparation and administration include:

- *Name of patient;*
- *Age and weight of patient, to facilitate dose calculation when applicable. Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the CAH's policies. (Note that dose calculations are based on metric weight (kg, or g for newborns). If a CAH permits practitioners to record weight in either pounds or using metric weight, the opportunity for error increases, since some orders would require conversion while others would not. Accordingly, CAHs must specify a uniform approach to be used by prescribing practitioners. For example, a CAH could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric);*
- *Date and time of the order;*
- *Drug name;*
- *Exact strength or concentration, when applicable;*
- *Dose, frequency, and route;*
- *Dose calculation requirements, when applicable;*
- *Quantity and/or duration, when applicable;*
- *Specific instructions for use, when applicable; and*
- *Name of the prescriber*

Verbal and Standing Orders

Although the regulation requires medication administration be based on a written, signed order, this does not preclude the CAH from using:

- *Verbal orders; or*
- *Standing orders.*

In the case of both verbal and standing orders, a practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact. The CAH must adopt policies and procedures regarding verbal and standing orders. (Note that CAHs that have a distinct part psychiatric and/or rehabilitation unit must follow the hospital CoPs for all services provided in those units, including the hospital requirements for verbal and standing orders.)

For verbal orders, CAH policies must, at a minimum, address the following:

- *Describe situations in which verbal orders may be used, as well as limitations or prohibitions on their use;*
- *Provide a mechanism to establish the identity and authority of the practitioner issuing a verbal order;*
- *List the elements required for inclusion in the verbal order process;*
- *Establish protocols for clear and effective communication and verification of verbal orders. CMS expects nationally accepted read-back verification practice to be implemented for every verbal order..*
- *Identify the categories of clinical staff who are authorized to receive and act upon a verbal order.*
- *Provide for prompt documentation in the medical record of the receipt of a verbal order.*

For standing orders, CAH policies must, at a minimum, address the following:

- *The process by which a standing order is developed; approved; monitored; evaluated and updated when needed;*
- *For each standing order, which staff may initiate it and under what circumstances; (under no circumstances may a CAH use standing orders in a manner that requires any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders); and*
- *The requirements for subsequent authentication by a practitioner responsible for the care of the patient.*

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Verbal Orders

CAHs are encouraged to minimize the use of verbal orders as much as possible and not permit their use merely as a convenience to practitioners. Verbal orders carry a higher risk of miscommunication and error and thus should only be used when necessary. With the increasing use of Electronic Health Records and Computerized Physician Order Entry systems, the need for verbal orders is expected to decline.

Standing Orders

There is no standard definition of a “standing order” in the healthcare community, but the terms “pre-printed standing orders,” “electronic standing orders,” “order sets,” and “protocols for patient orders” are various ways in which the term “standing orders” has been applied. The lack of a standard definition for these terms and their interchangeable and indistinct use by health care facilities professionals may result in confusion

CAHs are encouraged to focus on those situations where their use of “standing orders” permits treatment that is outside the scope of practice of a non-practitioner, such as a nurse, to be initiated by the non-practitioner without a prior specific order from a practitioner responsible for the care of the patient. Such treatment is typically initiated when a patient’s condition meets certain pre-defined clinical criteria. For example, standing orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practical for a nurse to obtain either a written, authenticated order or a verbal order from a practitioner prior to the provision of care.

Appropriate use of standing orders can contribute to patient safety and quality of care by promoting consistency of care, based on objective evidence. Much of the evidence on the effectiveness of standing orders has been narrowly focused on aspects of their use by Rapid Response Teams addressing inpatient emergencies. However, standing orders may also be appropriate in other clinical circumstances, including, but not limited to:

- Protocols for triaging and initiating required screening examinations and stabilizing treatment for emergency department patients presenting with symptoms suggestive of acute asthma, myocardial infarction, stroke, etc. (This does not relieve a CAH of its obligations under the Emergency Medical Treatment and Labor Act (EMTALA) to have qualified medical personnel complete required screening and, when applicable, provide stabilizing treatment in a timely manner.)*
- Post-operative recovery areas.*
- Timely provision of immunizations, such as certain immunizations for newborns, for which there are clearly established and nationally recognized guidelines.*

CAHs are encouraged to address at least the following in their standing orders policies and

procedures:

- *Review and approval of each standing order by a multi-disciplinary team that includes the following individuals or their designees: the MD/DO providing medical direction and the individuals designated responsible for nursing and pharmacy services.*
- *The CAH should be able to document that the standing order is consistent with nationally recognized and evidence-based guidelines. This does not mean that there must be a template standing order available in national guidelines which the CAH copies, but rather that the content of each standing order the CAH uses is consistent with nationally recognized, evidence-based guidelines for providing care.*
- *Clear, specific criteria in the protocol for the order for authorized non-practitioners to initiate the execution of the order, for example, the specific clinical situations, patient conditions, or diagnoses by which initiation of the order would be justified.*
- *Instructions that the clinical staff receive on the conditions and criteria for using standing orders as well as any individual staff responsibilities associated with the initiation and execution of standing orders.*
- *At least annual review of each standing order as well as a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions based on changes in nationally recognized, evidence-based guidelines. Among other things, reviews should consider:*
 - *Whether there have been any preventable adverse patient events resulting from the use of the standing order, and if so, whether changes in the order would reduce the likelihood of future similar adverse events. The review would not be expected to address adverse events that are a likely outcome of the course of patient's disease or injury, even if the order was applied to that patient, unless there is concern that use of the standing order exacerbated the patient's condition; and*
 - *Whether a standing order has been initiated and executed in a manner consistent with the order's protocol, and if not, whether the protocol needs revision and/or staff need more training in the correct procedures.*

Self-Administration of Medications

The CAH may choose to allow practitioners to write orders allowing patients to self-administer CAH-issued drugs and biologicals or drugs the patient has brought from home into the CAH for use during their stay, e.g., an insulin pen for a diabetic patient. If the CAH does permit this, it must develop policies and procedures for self-administration of drugs by patients or their informal caregivers.

Training

Medication administration education and training is typically included in the CAH's orientation or other continuing education programs for nursing staff and other authorized healthcare personnel. Training or continuing education topics regarding medication administration may include but are not limited to the following:

- *Safe handling and preparation of drugs, biologicals, and IV medications;*
- *Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications;*
- *Equipment, devices, special procedures, and/or techniques required for medication administration;*

Policies and procedures must address the required components of the training and if the training provided during CAH orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.

Basic safe practices for medication administration

The CAH's policies and procedures must reflect accepted standards of practice that require the following be confirmed prior to each administration of medication (often referred to as the "five rights" of medication administration practice):

- *Right patient: the patient's identity— acceptable patient identifiers include, but are not limited to: the patient's full name; an identification number assigned by the CAH; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the CAH's policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.*
- *Right medication: the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;*
- *Right dose: the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);*
- *Right route: the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient; and*

- *Right time: the appropriate time, to ensure adherence to the prescribed frequency and time of administration.*

Note: the “5 rights” focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the “5 rights” of medication administration, for example when there has been a prescribing or a dispensing error. CAHs are also expected to comply with requirements for pharmacy services at §485.635(a)(3)(iv), using a systems approach to all components of the medication process.

For Information – Not Required/Not to be Cited

Recent literature identifies up to nine “rights” of medication administration including:*

- Right patient*
- Right drug*
- Right route*
- Right time*
- Right dose*
- Right documentation*
- Right action (appropriate reason)*
- Right form*
- Right response*

However, other sources refer to 8 or 10 “rights, and some of these topics, such as right action, appear to involve prescribing and/or dispensing. Accordingly, there does not (yet) appear to be consensus about expanding beyond the 5 “rights.”

**Reference: Elliott, M. and Lis, Y. (2010). The Nine Rights of Medication Administration: An Overview. British Journal of Nursing, Vol. 19, 5, 300-305.*

CAHs are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly.

Timing of Medication Administration

Appropriate timing of medication administration must take into account the complex nature and variability among medications; the indications for which they are prescribed; the clinical situations in which they are administered; and the needs of the patients receiving them. The chemical properties, mechanism of action, or therapeutic goals of some medications require administration at the exact time prescribed, or within a narrow window of its prescribed

scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However, the therapeutic effect of many other medications is uncompromised by a much broader window of time for administration. Consequently, the application of a uniform required window of time before or after the scheduled time for the administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize nursing care activities appropriately. This could also result in staff work-arounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, CAH policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration. The policies and procedures must address at least the following:

- *Medications **not eligible** for scheduled dosing times;*
- *Medications **eligible for** scheduled dosing times;*
- *Administration of eligible medications outside of their scheduled dosing times and windows; and*
- *Evaluation of medication administration timing policies, including adherence to them.*

Medications or categories of medication not eligible for scheduled dosing times

The policies and procedures must identify medications or categories of medication which are not eligible for scheduled dosing times, either in general or in specific clinical applications. These are medications that require exact or precise timing of administration, based on diagnosis type, treatment requirements, or therapeutic goals. The policies and procedures must reflect consideration of factors including, but not limited to, the pharmacokinetics of the prescribed medication; specific clinical applications; and patient risk factors. Examples of medications that CAHs may choose to identify as not eligible for scheduled dosing times may include, but are not limited to:

- *Stat doses (immediate);*
- *First time or loading doses (initial large dose of a drug given to bring blood, tissue or fluid levels to an effective concentration quickly);*
- *One-time doses; doses specifically timed for procedures;*
- *Time-sequenced doses; doses timed for serum drug levels;*
- *Investigational drugs; or*
- *Drugs prescribed on an as needed basis (PRN doses).*

The policies and procedures must ensure timely administration of such medications. In addition they must specify if the policy for the administration of these medications will be applied throughout the CAH or only for specific CAH units or specific clinical situations or types of diagnoses.

Medications eligible for scheduled dosing times

Medications eligible for scheduled dosing times are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals

(every 1, 2, 3 or more hours), etc. The goal of this scheduling is to achieve and maintain therapeutic blood levels of the prescribed medication over a period of time. Medication administration policies and procedures typically establish standardized dosing times for the administration of all 'scheduled' medications. For example, medications prescribed for BID (twice a day) administration might, under a given CAH's policies and procedures, be scheduled to be administered at 8am and 8pm. Another CAH might choose to schedule BID medications at 7:30 am and 7:30 pm. Use of these standardized times facilitates the medication administration process, e.g., by providing to the CAH's pharmacy that morning doses of all BID drugs must be dispensed and delivered to patient units in time for the scheduled administration. For the nursing staff, the scheduled administration time might prompt prioritization of additional activities that may be required, in the case of particular drugs, such as vital sign assessment or the collection and review of blood work, to ensure safe and timely medication administration.

Policies and procedures for medications eligible for scheduled dosing times must also address: first dose medications, including parameters within which nursing staff are allowed to use their own judgment regarding the timing of the first and subsequent doses, which may fall between scheduled dosing times; retiming of missed or omitted doses; medications that will not follow scheduled dosing times; and patient units that are not subject to following the scheduled dosing times.

Time-critical scheduled medications

Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect. Accordingly, scheduled medications identified under the CAH's policies and procedures as time-critical must be administered within thirty minutes before or after their scheduled dosing time, for a total window of one hour.

It is possible for a given medication to be time-critical for some patients, due to diagnosis, clinical situation, various risk factors, or therapeutic intent, but not time-critical for other patients. Therefore, CAH policies and procedures must address the process for determining whether specific scheduled medications are always time-critical, or only under certain circumstances, and how staff involved in medication administration will know when a scheduled medication is time-critical. Examples of time-critical scheduled medications/medication types may include, but are not limited to:

- *Antibiotics;*
- *Anticoagulants;*
- *Insulin;*
- *Anticonvulsants;*
- *Immunosuppressive agents;*
- *Pain medication (non-IV);*
- *Medications prescribed for administration within a specified period of time of the medication order;*

- Medications that must be administered apart from other medications for optimal therapeutic effect; or
- Medications prescribed more frequently than every 4 hours.

Non-time-critical scheduled medications

Non-time critical scheduled medications are those for which a longer or shorter interval of time since the prior dose does not significantly change the medication's therapeutic effect or otherwise cause harm. For such medications greater flexibility in the timing of their administration is permissible. Specifically:

- Medications prescribed for daily, weekly or monthly administration may be within two hours before or after the scheduled dosing time, for a total window that does not exceed four hours.
- Medications prescribed more frequently than daily but no more frequently than every four hours may be administered within one hour before or after the scheduled dosing time, for a total window that does not exceed two hours.

Missed or late administration of medications

The CAH's policies and procedures must address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time. This includes doses which may have been missed due to the patient being temporarily away from the nursing unit, for example, for tests or procedures; patient refusal; patient inability to take the medication; problems related to medication availability; or other reasons that result in missed or late dose administration. Likewise, policies and procedures must also outline guidelines for the administration and timing of new medications which are initiated between standardized dosing times.

These policies and procedures must identify parameters within which nursing staff are allowed to use their own judgment regarding the rescheduling of missed or late doses and when notification of the practitioner responsible for the care of the patient is required prior doing so. In either case, errors in the administration of medication must be reported internally as required at §485.635(a)(1)(v).

Evaluation of medication administration timing policies

CAHs must periodically evaluate their medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration. Medication errors related to the timing of medication administration must be tracked and analyzed to determine their causes. Based on the results of the evaluations of the policies and the medication administration errors, the CAH must consider whether there is a need to revise the policies and procedures governing medication administration timing.

Assessment/Monitoring of Patients Receiving Medications

Observing the effects medications have on the patient is part of the multi-faceted medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse effects and timely initiation of appropriate corrective action. Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;*
- Physical signs and clinical symptoms relevant to the patient’s medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.*

Certain types of medications – “high alert medications” - are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients

For Information – Not Required/Not to be Cited

The Institute for Safe Medication Practices (ISMP) makes available a list of high alert medications, which it defines as those medications that bear a heightened risk of causing significant patient harm when they are used in error. The current list may be found at: <http://www.ismp.org/Tools/highAlertMedicationLists.asp>

In addition, certain factors place some patients at greater risk for adverse effects of medication. Factors including, but not limited to, age, altered liver and kidney function, a history of sleep apnea, patient weight (obesity may increase apnea or smaller patients may be more sensitive to dose levels of medications), asthma, history of smoking, drug-drug interactions, and first-time medication use may contribute to increased risk.

Consideration of patient risk factors as well as the risks inherent in a medication must be taken into account when determining the type and frequency of monitoring. Further, to enhance continuity of care/safe medication administration, it is essential to communicate all relevant information regarding patients’ medication risk factors and monitoring requirements during hand-offs of the patient to other clinical staff, such as when patients are moved from a nursing for tests, during shift report at change of shift, etc. This would apply to hand-offs involving not only to nursing staff, but also to any other types of staff who administer medications, e.g., respiratory therapists.

Adverse patient reactions, such as anaphylaxis or opioid-induced respiratory depression, require timely and appropriate intervention, per established CAH protocols.

An example of vigilant post-medication administration monitoring in the case of a high-alert medication where patient factors may increase risk would be regularly checking vital signs, oxygen level via pulse oximetry, and sedation levels of a post-surgical patient who is receiving pain medication via a patient controlled analgesia (PCA) pump. Narcotic medications, such as opioids, are often used to control pain but also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. Timely assessment and appropriate monitoring is essential in all parts of the CAH in which opioids are administered, to permit intervention to counteract respiratory depression should it occur. (See also the discussion below for intravenous medications.)

As part of the monitoring process, staff are expected to include the patient's reports of his/her experience of the medication's effects. Further, when monitoring requires awakening the patient in order to assess effects of the medications, the patient and/or the patient's representative must be educated about this aspect of the monitoring process. In addition, CAHs are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

CAH policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the CAH's requirements for the method(s) of communication.

IV Medications & Blood Transfusions

Many of the medications included in the high-alert categories are administered intravenously. CAH policies and procedures for IV medications must address at least the following:

Vascular Access Route

Patients may require a form of vascular access to deliver blood or medications, either venous or arterial, based on the desired treatment plan. Safe administration of blood transfusions and IV medications includes the correct choice of vascular access. IV medications, such as fluids, antibiotics, and chemotherapy, may require specific types of access, such as peripheral or central catheters versus implanted port devices, based on the medication's chemical properties or safety concerns. Hospital policies and procedures must address which medications can be given intravenously via what type of access.

Other Patient Safety Practices

In addition to the basic safe practices that apply to all medication administration, there are additional safe practices specific to IV medication administration that require consideration, including but not limited to, the following:

- *Tracing invasive lines and tubes prior to administration to ensure the medication is to be administered via the proper route (for example, peripheral catheter versus epidural catheter connections);*
- *Avoiding forcing connections when the equipment offers clear resistance;*
- *Verifying proper programming of infusion devices (concentrations, flow rate, dose rate).*

Monitoring patients receiving IV medications

To the extent that IV medications have a more rapid effect on the body, it is important that staff administering medications via IV understand each medication and its monitoring requirements. Policies and procedures for IV medication administration must address appropriate IV medication monitoring requirements, including assessment of patients for risk factors that would influence the type and frequency of monitoring.

For example: a 50 year old patient with a history of renal failure is receiving IV vancomycin to treat a wound infection. The CAH policy for IV antibiotics, including vancomycin, requires the patient's kidney function to be monitored daily with blood draws. Based on review of the lab results, a practitioner responsible for the care of the patient would be expected to determine on a timely basis whether or not the antibiotic dose needs to be adjusted to protect kidney function or prevent drug toxicity while achieving the desired therapeutic effects. Staff administering the medication would be expected to review the lab results as well, and to raise with a practitioner responsible for the care of the patient any concerns they might have about whether an adjustment in the medication is needed.

CAH policies and procedures related to monitoring patients receiving IV medications are expected to address, but are not limited to, the following:

- ***Monitoring for Fluid & Electrolyte Balance***

Whenever IV medications and blood transfusions are administered, the patient may become at risk for fluid and electrolyte imbalance. Policies and procedures must address monitoring and treatment for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications.

- **Monitoring Patients Receiving High-alert Medications, Including IV Opioids**

Policies and procedures related to IV medication administration must address those medications the CAH has identified as high-alert medications and the monitoring requirements for patients receiving such drugs intravenously.

At a minimum, if the CAH provides surgical services, it is expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients

Opioids are a class of medication used frequently to treat pain. The sedating effects of opioids make it difficult at times to properly assess the patient's level of sedation. It can be erroneously assumed that patients are asleep when they are actually exhibiting progressive symptoms of respiratory compromise - somnolence, decreased respiratory rate, and decrease in oxygen levels. These symptoms, if unrecognized, can progress to respiratory depression and even death.

In addition to those patient characteristics that affect risk of adverse effects from medication discussed above, other factors placing patients receiving IV opioids at higher risk for oversedation and respiratory depression include, but are not limited to⁵:

- *Snoring or history of sleep apnea*
- *No recent opioid use or first-time use of IV opioids*
- *Increased opioid dose requirement or opioid habituation*
- *Longer length of time receiving general anesthesia during surgery*
- *Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other central nervous system depressants*
- *Preexisting pulmonary or cardiac disease*
- *Thoracic or other surgical incisions that may impair breathing*

Of particular concern are patients receiving IV opioids post-operatively. The effects of IV opioids in post-operative patients must be monitored vigilantly via serial assessments of pain, respiratory status, and sedation levels.

CAHs that provide surgical services must have policies and procedures related to the use of high-alert medications, including IV opioids for post-operative patients. Policies and procedures must address, at a minimum, the process for patient risk assessment, including who conducts the assessments, and, based on the results of the assessment, monitoring frequency and duration, what is to be monitored, and monitoring methods. The policies and procedures must also address whether and

⁵ Jarzyna D., Junquist C., Pasero C., et al. American Society for Pain Management Nursing - Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression. *Pain Management Nursing*, Vol 12, No. 3 (September), 2011: pp 118-145

under what circumstances practitioners prescribing IV opioids are allowed to establish protocols for IV opioid administration and monitoring that differ from the CAH's policies and procedures.

The frequency of the serial assessments and duration of the monitoring timeframe for post-operative patients receiving IV opioids must be determined based on at least the following considerations:

- *Patient risk for adverse events;*
- *Opioid dosing frequency and IV delivery method. (push or patient-controlled analgesia (PCA));*
- *Duration of IV opioid therapy.*

Regardless of the above factors, at a minimum monitoring must include the following:

- *Vital signs (blood pressure, temperature, pulse, respiratory rate)*
- *Pain level;*
- *Respiratory status;*
- *Sedation level; sedation levels are important indicators for the clinical effects of opioids. Sedation is a useful assessment parameter to observe the effects of opioids since sedation typically precedes respiratory depression⁶. See the blue box below for information on sedation assessment methods.*

For Information – Not Required/Not to be Cited

In addition to assessing risk for respiratory depression, the Institute for Safe Medication Practices recommends hospitals use a standard sedation scale when assessing patients receiving PCA. Scales such as the Richmond Agitation Sedation Scale, Pasero, Ramsey, or Glasgow Coma Scale are useful in assessing sedation.

Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

In addition to vigilant nursing assessment at appropriate intervals, CAHs may choose to use technology to support effective monitoring of patients' respiratory rate and oxygen levels.

⁶ *Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013*

For additional information regarding recommendations of expert organizations on post-operative opioid monitoring, including technology-supported monitoring, see blue boxes below. The practices described in the blue boxes below are not required under the regulations.

The assessment and monitoring process must be explained to the patient and/or the patient's representative, to communicate the rationale for vigilant monitoring, including that it might be necessary to awaken the patient in order to assess effects of the medications. In addition, CAHs are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

<i>For Information – Not Required/Not to be Cited Institute for Safe Medication Practices Guidelines for PCA Monitoring</i>						
<i>Assessment of Opioid Tolerance</i>	<i>Vital Signs</i>	<i>Pain</i>	<i>Sedation</i>	<i>Respiratory</i>		
				<i>Rate</i>	<i>Quality</i>	<i>SPO₂* &/or ETCO₂**</i>
<i>Baseline Assessment before PCA</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>
<i>PCA Initiation or Change in Drug/Syringe Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>
<i>PCA Dose Change or Bolus Q 1 hour x 4 hours Then Q 2 hours</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>
<i>Adverse Event or Patient Deterioration (e.g., adverse change in sedation score) Q 15 minutes x 1 hour Q 1 hour x 4 hours Then Q 2 hours</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>
<i>Hand-offs/Shift Change</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>	<i>X</i>
<i>Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to happen...Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013 ISMP adapted these recommendations from the San Diego Patient Safety Council</i>						
<i>* SPO₂: Saturation of peripheral oxygen via pulse oximetry</i>						
<i>** ETCO₂: End-tidal carbon dioxide via capnography</i>						

For Information – Not Required/Not to be Cited

Anesthesia Patient Safety Foundation

- *APSF calls for every patient receiving postoperative opioid analgesics to be managed based on the following clinical considerations*:*
 - *Individualize the dose and infusion rate of opioid while considering the unique aspects of each patient's history and physical status.*
 - *Make continuous monitoring of oxygenation (pulse oximetry) the routine rather than the exception.*
 - *Assess the need for supplemental oxygen, especially if pulse oximetry or intermittent nurse assessment are the only methods of identifying progressive hypoventilation.*
 - *When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.*

*APSF also has issued a video on opioid induced ventilatory impairment:
http://apsf.org/resources_video4.php*

**Stoelting, RK., Weinger MB. Dangers of postoperative opioids: Is there a Cure? APSF Newsletter 2009;24:2.*

For Information – Not Required/Not to be Cited

PSMF recommends all patients receiving IV opioids have continuous measure-through motion and low perfusion pulse oximetry, and that patients on supplemental oxygen also have continuous respiration rate monitoring. It also calls for the monitoring system to be linked with a notification system to clinical staff who can respond immediately. It calls for an escalation protocol so that if a staff person does not acknowledge the alert in 60 seconds a second person will be notified.

The Patient Safety Movement Foundation - Actionable Patient Safety Solution (APSS) #1: Failure to Rescue: Post-Operative Respiratory Depression. January 13, 2013

Adverse patient reactions to IV medications require timely and appropriate intervention, per established protocols.

IV Blood Administration Procedures

According to the U.S. Department of Health and Human Services, 13,785,000 units of whole blood and red blood cells were transfused in the United States in 2011⁷. The collection, testing, preparation, and storage of blood and blood components are regulated by the Food and Drug Administration. Blood transfusions can be life-saving. However, they are not without risk of harm to patients. Transfusion reactions and/or errors can be fatal.

In addition to the safe practices and other safety considerations that apply to all IV medication administration, policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to:

- *Confirming the following prior to each blood transfusion:*
 - *the patient's identity*
 - *verification of the right blood product for the right patient*

The standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation.

- *Requirements for patient monitoring, including frequency and documentation of monitoring*
- *How to identify, treat, and report any adverse reactions the patient may experience during or related to transfusion.*

Documentation

Note that documentation of medication administration is addressed in the Medical Records CoP at §485.638(a)(4)(iii). This regulation requires that the record contain: "All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment..." Documentation is expected to occur after actual administration of the drugs or biologicals to the patient; advance documentation is not only inappropriate, but may result in medication errors. Proper documentation of medication administration actions taken and their outcomes is essential for planning and delivering future care of the patient. See

⁷ *The 2011 National Blood Collection and Utilization Survey Report. Retrieved September 27, 2013 from <http://www.hhs.gov/ash/bloodsafety/2011-nbcus.pdf>*

the guidance for the various parts of §485.638 concerning documentation in the medical record. Deficiencies in documentation would be cited under the Clinical Records regulation.

Survey Procedures §485.635(d)(3)

- *Ask the person responsible for nursing services what type of personnel administer drugs and biologicals, including IVs. Are they practicing within their permitted scope?*
- *If anyone other than an MD/DO, RN or PA administers drugs or biologicals, are they supervised by an RN or, if permitted under State law and CAH policy, a PA?.*
- *Verify that nursing staff administering drugs have completed training consistent with CAH training policy.*
- *Review a sample of medication orders and determine if they contain the required elements:*
 - *Determine if orders are legible, timed, dated and authenticated with a signature by the practitioner or practitioners responsible for the care of the patient.*
 - *Was the administration of the medication consistent with the order, i.e., the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the hospital's policies and procedures? Check that the practitioner's order was still in force at the time the drug was administered.*
- *Ask nursing staff if the CAH permits verbal orders and, if so, what the policy is for a verbal order. If staff are unaware of any policy, or if their description of a policy suggests it is incomplete or inconsistent with accepted standards of practice, ask to see the written policy.*
- *Ask nursing staff whether they initiate medications in accordance with standing orders. Are they familiar with the hospital's policies and procedures for using standing orders? Are they following the policies and procedures? Ask to see the protocol for a standing order used by nursing staff, and ask nursing staff to explain how their practice conforms to the protocol.*
 - *Determine whether all standing orders which were initiated by a nurse were authenticated by an authorized practitioner.*
- *Ask nursing staff if the CAH permits patient self-administration of medications.*
 - *If yes, does the CAH have policies and procedures addressing this?*

- *Is there an order from a practitioner responsible for the care of the patient permitting self-administration of medications, either issued by the CAH or brought from home?*
- *Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed.*
 - *Is the patient's identity confirmed prior to medication administration?*
 - *Are procedures to assure the correct medication, dose, and route followed?*
 - *Are drugs administered in accordance with the hospital's established policies and procedures for timely medication administration?*
 - *Does the nurse remain with the patient until medication is taken, unless they are permitted to self-administer?*
- *Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?*
- *Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?*
 - *Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?*
- *Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.*
 - *Are they able to identify time-critical and non-time-critical scheduled medications? Medications not eligible for scheduled dosing times?*
 - *Are they able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies?*
- *Interview nursing staff who administer IV medications and blood transfusions. Are staff knowledgeable with respect to:*
 - *Venipuncture techniques;*
 - *Safe medication administration practices, including general practices applying to all types of medications and practices concerning IV tubing and infusion pumps;*
 - *Maintaining fluid and electrolyte balance;*

- *Patient assessment for risk related to IV medications and appropriate monitoring;*
- *Early detection and intervention for IV opioid-induced respiratory depression in post-operative patients;*
- *With respect to blood transfusions:*
 - *Blood components;*
 - *Process for verification of the right blood product for the right patient; and*
 - *Transfusion reactions: identification, treatment, and reporting requirements.*
- *If able, observe blood transfusion and IV medication administration to assess staff adherence to accepted standards of practice.*
 - *Were safe medication administration practices used?*
 - *Was the transfused patient correctly identified and matched to the correct blood product prior to administration?*
 - *Was the appropriate access used for IV medications?*
 - *Were appropriate steps taken with regard to IV tubing and infusion pumps?*
 - *Are patients being monitored post-infusion for adverse reactions?*
- *If staff appear to not be following accepted standards of practice for patient risk assessment related to IV medications, particularly opioids, and appropriate monitoring of patients receiving IV medications and/or blood transfusions, review policies and procedures for IV medication administration and blood transfusion to determine if they address safe practices considerations.*

C-0298
(Rev.)

485.635(d)(4) A nursing care plan must be developed and kept current for each inpatient.

Interpretive Guidelines §485.635(d)(4)

There must be a nursing care plan for every CAH inpatient. Nursing care planning starts upon admission. It includes planning the patient's care while in the CAH as well as planning for transfer to a hospital, to a post-acute care facility or for discharge. A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis). The assessment considers the patient's treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. The plan develops appropriate nursing interventions in response to the identified nursing care needs. One resource for information about nursing care plans is The American Nurses Association <http://www.nursingworld.org/EspecialtyforYou/StudentNurses/Thenursingprocess.aspx>.

The nursing care plan is kept current by ongoing assessments of the patient's needs and of the patient's response to interventions, and updating or revising the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's clinical record and must comply with the clinical records requirements at §485.638.

CAHs have the flexibility of developing the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. This method may serve to promote communication among disciplines and reinforce an integrated, multi-faceted approach to a patient's care, resulting in better patient outcomes. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote the collaboration between members of the patient's health care team.

Survey Procedures §485.635(d)(4)

Select a *representative* sample of nursing care plans *based on the number of inpatient records reviewed*.

- Are the *care* plans created as soon as possible after admission for each patient?
- Are the care plans based on the nurse's assessment of the individual patient?
- *Is there evidence that the care plans are reviewed on an ongoing basis?*
- *Is there evidence that the nursing care plan is revised as needed and is there documentation of nursing reassessment?*
- Verify that there is evidence that the nursing care plans *have been* implemented.

C-0299 **(Rev.)**

§485.635(e) Standard: Rehabilitation Therapy Services

Physical therapy, occupational therapy, and speech-language therapy pathology services furnished at the CAH, if provided, are provided by staff qualified under State law, and consistent with the requirements for therapy services in §409.17 of this subpart.

Interpretive Guidelines §485.635(e)

Rehabilitation services are optional CAH services. If a CAH provides any rehabilitative services to its patients, either directly or under arrangement or agreement, either inpatient or outpatient, the services must be provided by staff qualified under State law, and consistent with the requirements for therapy services in §409.17. Rehabilitation services services can be initiated only upon the order of a practitioner responsible for the care of the patient. Physical therapy, occupational therapy, or speech-language pathology must be furnished in accordance with the

regulation at 42 CFR 409.17, which specifies the following rehabilitation services plan of care requirements:

- *Establishment of the plan: “The plan must be established before treatment begins by one of the following: (1) A physician. (2) A nurse practitioner, a clinical nurse specialist or a physician assistant. (3) The physical therapist furnishing the physical therapy services. (4) A speech-language pathologist furnishing the speech-language pathology services. (5) An occupational therapist furnishing the occupational therapy services.”*
- *Content of the plan: “The plan: (1) Prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and (2) Indicates the diagnosis and anticipated goals.”*
- *Changes in the plan: “Any changes in the plan are implemented in accordance with the provider’s policies and procedures.”*

Also in accordance with 42 CFR 409.17, rehabilitation services must be provided by qualified physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists who meet the personnel qualifications defined in 42 CFR 484.4. CAHs must have policies and procedures consistent with State law.

Rehabilitation services must be provided according to national standards of practice as established by professional organizations such as, but not limited to, the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association.

Survey Procedures §485.635(e)

If the CAH provides rehabilitation services:

- *Review clinical records of patients who received rehabilitation services. Determine whether the required care plan was developed and implemented.*
- *Review employee personnel files to verify the rehabilitation service providers (i.e., physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists) have the necessary education, experience, training, and documented competencies to provide rehabilitation services.*
- *Ask the CAH what national standards of rehabilitation practice provide the basis for its rehabilitation services. Is there supporting documentation?*

Attachment 6



U.S. Food and Drug Administration

Protecting and Promoting *Your Health*

Compounded Drugs Stored in Becton-Dickinson (BD) 3 ml and 5 ml Syringes: FDA Warning - Do Not Use

[Posted 08/18/2015]

AUDIENCE: Pharmacy, Compounding, Nursing, Risk Manager

ISSUE: FDA is alerting health care professionals not to administer to patients compounded or repackaged drugs that have been stored in 3 milliliter (ml) and 5ml syringes manufactured by Becton-Dickinson (BD) unless there is no suitable alternative available. Preliminary information indicates that drugs stored in these syringes may lose potency over a period of time due to a possible interaction with the rubber stopper in the syringe. If you have been using products packaged in these syringes, be aware that using a substitute product may require a dosage adjustment in case the patient has been receiving a subpotent product, or adverse consequences could occur.

BD's 10ml, 20ml and 30ml syringes may also contain the same rubber stopper. The company is alerting their customers not to use these syringes as a closed container system for compounded and repackaged drugs.

BACKGROUND: FDA has cleared these syringes as medical devices for general purpose fluid aspiration and injection only. These syringes were not cleared for use as a closed container storage system for drug products, and the suitability of these syringes for that purpose has not been established. This issue may extend to other general use syringes made by other manufacturers that were not cleared for the purpose of closed-container storage usage. FDA has received several reports of compounded and repackaged drugs, such as fentanyl, morphine, methadone and atropine, losing potency when stored in BD 3ml and 5ml general purpose syringes. It is possible that this chemical reaction may affect other compounded and repackaged drugs stored in syringes not FDA cleared for closed-container storage.

RECOMMENDATION: Hospital and pharmacy staff should check supply stocks and remove drug products that were filled by pharmacies or outsourcing facilities and stored in general purpose BD 3ml and 5ml syringes. These syringes are marked with the BD logo at the base of the syringe. At this time, FDA does not have information on how long drugs can be stored in these syringes before degrading. There is no information to suggest that there is a problem with potency or drug degradation when medication is administered promptly after the syringes are filled.

This warning does not extend to products approved by FDA for marketing as pre-filled syringes, because as part of the approval process, FDA has determined that these products have been shown to maintain stability in the syringe container through the expiration date on the product.

The FDA is continuing to investigate this issue and will provide more information when it is available.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[08/18/2015 - Warning - [FDA](#)]



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Acute Care ISMP Medication Safety Alert!

Educating the Healthcare Community About Safe Medication Practices

Special ALERT

Loss of drug potency

Some hospital pharmacists have been in touch with us recently to report potency issues with certain medications prepared in advance in 3 mL or 5 mL BD syringes. One of the medications is fentaNYL citrate injection diluted to 10 mcg per mL for pediatric use, which was prepared in a hospital pharmacy. One hospital sent 3 syringes of diluted fentaNYL 10 mcg/mL to an outside laboratory for testing. At 48 hours, the potency had declined to 67% on average, and by day 6, the potency was at 55%. Another hospital tested syringes of fentaNYL 5 mcg/mL in 3 mL syringes and found a range of potencies between 10% and 70%. Retesting at two other laboratories showed similar results. A third hospital reported inadequate patient analgesia, also with diluted fentaNYL.

We spoke with a BD representative, who confirmed that an issue exists. The issue may be related to black plunger rod stoppers from a secondary supplier that affect "pH sensitive" medications such as fentaNYL citrate, methadone hydrochloride, and possibly a few others. BD continues to investigate the matter and is planning to send a letter shortly to pharmacy directors to provide more details. Potency problems have **not** been identified with BD 1 mL, 10 mL, and larger syringe sizes, and no problems have been reported with other manufacturers' syringes.

According to BD, the loss of potency is also time dependent. At 24 hours, fentaNYL remains between 90 to 100% potent, but by 48 hours, some deterioration may already be underway, as noted above. Patient safety could be compromised if subpotent opioid doses cause a dose elevation that is followed by administration of a fully potent opioid at the higher dose via a syringe that does not have this issue.

Until further information is available from BD and the problem is resolved, hospitals using BD 3 mL and 5 mL syringes should prepare medication syringes as close to the time of administration as possible. One of the hospitals that identified the problem is providing a 1 mL dose of fentaNYL 10 mcg per mL in a 2 mL vial for now.

Resources

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200 Lakeside Drive, Suite 200, Horsham, PA 19044, Phone: (215) 947-7797, Fax: (215) 914-1492

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CANTRELL DRUG COMPANY

Pharmaceutical Outsourcing Specialists

August 21, 2015

Re: BD 3 mL and BD 5 mL Syringes For Compounded Sterile Products

Dear Valued Client,

Voluntary Recall:

Cantrell Drug Company is initiating a voluntarily recall of fentaNYL citrate injections packaged in certain lots of BD 3 mL and 5 mL plastic syringes. This recall only affects a small number of clients and Cantrell will notify each affected client directly. The reason for the recall is potential adsorption of fentaNYL citrate to a reported modified component in specific lots of BD syringes. Cantrell Drug Company was notified of specific modified lot numbers on August 20th, 2015. BD Medical Affairs has assured us that the 10 mL, 30 mL and 50 mL syringes are not affected by this issue. Details of this recall will be sent to any client hospital today that has received affected fentaNYL citrate product.

Cantrell lots of fentaNYL citrate identified using the modified BD component are: 5425, 5977, 6234, 6977, 5784, 6208, 6851, 6943, 5737, 5960, 6324, 5695, 144735, 147647, 147858, 143734, 150125, 145906, 148525, 151142, 146567, 150370, 140306, 144607, 148292, and 150610.

Quarantine Action:

Except for fentaNYL citrate, Cantrell is not recalling other medications packaged in the modified BD syringe lot numbers. However, in the abundance of caution, we ask client hospitals to quarantine all medications in the affected BD 3 mL and 5 mL syringes until further notice. Specific product names and lot numbers are found in the attachment to this letter. Cantrell has begun testing retention samples with a FDA registered third party analytical laboratory working through the weekend to test and analyze stability data of other products packaged in the BD modified syringe lot numbers. Upon data receipt from testing identified above, results will be reviewed and clients will be notified of the status of the quarantine. We expect results of testing early next week.

Background:

On August 4th Cantrell Drug Company (Cantrell) became aware of an Institute for Safe Medication Practices (ISMP) Safety Alert stating that some hospital pharmacists have recently reported potency issues with certain compounded medications prepared in advance in 3 mL or 5 mL BD syringes and one other hospital reported inadequate analgesia. Analytical results reported to those hospitals ranged from 10% to 70%.



CANTRELL DRUG COMPANY

Pharmaceutical Outsourcing Specialists

This ISMP Safety Alert prompted Cantrell to immediately launch a stability review of all our products, especially for fentaNYL citrate, compounded using BD 3 mL and 5 mL syringes. As you are probably aware, fentaNYL citrate has the potential for adsorption to certain containers and tubing (adsorption is the adhesion of atoms, ions, or molecules to a surface). Furthermore, fentaNYL citrate concentrations are manufactured in extremely low concentrations (i.e. microgram concentrations), so small amounts of adsorption to a container's materials may cause significant reductions in the amount of available fentaNYL citrate. Our stability studies did not see precipitous drops in concentration experienced by those in the ISMP Safety Alert, nor have we received any reports from our clients of a lack of therapeutic effect. Testing of fentaNYL citrate retained samples in 3 mL and 5 mL BD syringes that had reached their beyond-use-date (BUD) were tested and found to be well within specifications.

On August 18th the FDA issued a MedWatch Safety Alert for Human Medical Products alerting healthcare professionals that compounded drugs stored in Becton-Dickinson (BD) 3 mL and 5 mL syringes should not be used. We became aware that only certain lot numbers of these syringes were the potential cause of the noted instability. On August 19th we spoke directly with BD Medical Affairs personnel asking for those specific lot numbers. On August 20th we received the requested lot numbers from BD and immediately compiled a list of Cantrell products that were compounded using those lot numbers. In the interim, we proactively compounded and packaged new lots of fentaNYL citrate in multiple BD syringes. The results, when analyzed against BD lot numbers in question, revealed out-of-specification results for fentaNYL citrate packaged in the BD syringe lot numbers with modifications. Importantly, non-modified lot numbers of BD syringes resulted in expected concentrations of fentaNYL citrate.

Cantrell shares your concern over the potential impact on the supply of necessary medications to your patients and is taking aggressive actions to ensure that product you receive from Cantrell meets the highest of quality standards.

Please refer to our website for immediate publishing of information regarding the matter.

Sincerely,

Raymond C Anderson, PhD
Vice-President of Quality Assurance and Regulatory Affairs



CANTRELL DRUG COMPANY

Pharmaceutical Outsourcing Specialists

Quarantine List of Cantrell Drug Company Products and Lot Numbers Packaged in BD 3 mL & 5 mL Modified Syringes

ATROPINE SULFATE 0.4 MG/ML INJECTION SOLUTION 1 ML SYRINGE
144757
145585
148324
148574
149690
151665
ATROPINE SULFATE 0.4 MG/ML INJECTION SOLUTION 2 ML SYRINGE
144873
145900
147037
148163
149198
151454
151962
BETAMETHASONE SODIUM PHOSPHATE 6_MG/ML INJECTION SOLUTION (PH 8.5) 1 ML SYRINGE
146504
147968
149181
149980
151497
151861
DEXAMETHASONE SODIUM PHOSPHATE 24 MG/ML INJECTION SOLUTION 1ML_SYRINGE
147497
149668
EPHEDRINE SULFATE 10 MG/ML IN 0.9%_SODIUM CHLORIDE 5 ML SYRINGE
144129
144891
EPHEDRINE SULFATE 50 MG/ML IN 0.9%_SODIUM CHLORIDE 1 ML SYRINGE
149266
150655
150740
151508
GLYCOPYRROLATE 0.2 MG/ML INJECTION SOLUTION 1 ML SYRINGE
5794
6100
6336
6461
6698
6861



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Quarantine List of Cantrell Drug Company Products and Lot Numbers Packaged in BD 3 mL & 5 mL Modified Syringes

GLYCOPYRROLATE 0.2 MG/ML INJECTION SOLUTION 2 ML SYRINGE
5882
6172
6401
6660
HEPARIN SODIUM 0.5 USP UNITS/ML IN 0.45% SODIUM CHLORIDE 2 ML IN A 3 ML BD SYRINGE
5804
6146
HYDROMORPHONE HCL 0.5 MG/ML IN 0.9% SODIUM CHLORIDE 1 ML SYRINGE
6192
6558
KETAMINE HCL 50 MG/ML INJECTION SOLUTION 1 ML SYRINGE
144537
145910
146487
147062
149162
149495
149881
150840
LIDOCAINE HCL 1% BUFFERED WITH SODIUM_BICARBONATE INJECTION
145259
146142
147251
148248
149643
150033
150947
151087
MIDAZOLAM HCL 0.1 MG/ML IN 5%_DEXTROSE 2.5_ML_SYRINGE
147016
149167
MIDAZOLAM HCL 0.5 MG/ML IN 0.9% SODIUM CHLORIDE 1 ML SYRINGE
5940
6090
6218
6877
MIDAZOLAM HCL 1 MG/ML IN 0.9% SODIUM CHLORIDE 2 ML SYRINGE
6178
6529



CANTRELL DRUG COMPANY

Pharmaceutical Outsourcing Specialists

Quarantine List of Cantrell Drug Company Products and Lot Numbers

Packaged in BD 3 mL & 5 mL Modified Syringes

MORPHINE SULFATE 0.5 MG/ML IN 0.9%_SODIUM_CHLORIDE 1 ML SYRINGE	
	143692
	147713
	151504
MORPHINE SULFATE 1 MG/ML IN 0.9% SODIUM CHLORIDE 1 ML SYRINGE	
	6184
ONDANSETRON HCL 2 MG/ML INJECTION SOLUTION 2 ML SYRINGE	
	147926
PHENYLEPHRINE HCL 1.5% IN BALANCED SALT SOLUTION	
	148802
PHENYLEPHRINE HCL 1.5% WITH LIDOCAINE HCL 1% IN BALANCED SALT SOLUTION 1 ML SYRINGE	
	147654
	149175
	150845
PHENYLEPHRINE HCL 1_MG/ML IN 0.9%_SODIUM_CHLORIDE 1 ML SYRINGE	
	145377
	147125
	150471
PHENYLEPHRINE HCL 100_MCG/ML IN 0.9%_SODIUM_CHLORIDE 1 ML SYRINGE	
	144230
	148580
PHENYLEPHRINE HCL 2.5% IN BALANCED_SALT_SOLUTION	
	148211
	150506
SUCCINYLCHOLINE CHLORIDE_20_MG/ML INJECTION SOLUTION 5 ML	
	144693

Attachment 7

Contains Nonbinding Recommendations

Draft — Not for Implementation

#230

Guidance for Industry Compounding Animal Drugs from Bulk Drug Substances

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Eric Nelson (CVM) at 240-402-5642, or by e-mail at eric.nelson@fda.hhs.gov.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine (CVM)**

May 2015

Contains Nonbinding Recommendations

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Contains Nonbinding Recommendations

Draft — Not for Implementation

Guidance for Industry¹ **Compounding Animal Drugs from Bulk Drug Substances**

This draft guidance, when finalized, represents the Food and Drug Administration's (FDA or Agency) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this draft guidance using the contact information on the title page of this guidance.

I. INTRODUCTION AND SCOPE

This draft guidance sets forth the Food and Drug Administration's ("FDA") policy regarding compounding animal drugs from bulk drug substances² by state-licensed pharmacies, licensed veterinarians, and facilities that register with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b). This guidance reflects FDA's current thinking regarding compounding animal drugs from bulk drug substances and describes the conditions under which FDA generally does not intend to take action for violations of the following sections of the FD&C Act: section 512 (21 U.S.C. 360b), section 501(a)(5) (21 U.S.C. 351(a)(5)), section 502(f)(1) (21 U.S.C. 352 (f)(1)), and, where specified, section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)), when a state-licensed pharmacy, licensed veterinarian, or an outsourcing facility³ compounds animal drugs from bulk drug substances.

This draft guidance only addresses the compounding of animal drugs from bulk drug substances. It does not apply to the compounding of animal drugs from approved new animal or new human drugs. Such compounding can be conducted in accordance with the provisions of section 512(a)(4) and (5) of the FD&C Act (21 U.S.C. 360b(a)(4) and (5)) and 21 CFR part 530. In addition, this draft guidance does not address the compounding of drugs intended for use in

¹ This draft guidance has been prepared by the Center for Veterinary Medicine (CVM) in consultation with the Center for Drug Evaluation and Research (CDER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

² FDA regulations define "bulk drug substance" as "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances." 21 CFR 207.3(a)(4). "Active ingredient" is defined as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." 21 CFR 210.3(b)(7). Any component other than an active ingredient is an "inactive ingredient." See 21 CFR 210.3(b)(8). Inactive ingredients used in compounded drug products commonly include flavorings, dyes, diluents, or other excipients.

³ "Outsourcing facility" refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the FD&C Act. See draft guidance for industry *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm434171.pdf>.

Contains Nonbinding Recommendations

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humans, which is addressed in other guidances.⁴ Further, the draft guidance does not address new animal drugs for investigational use. See 21 CFR part 511.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Regulatory Framework

To be legally marketed, new animal drugs must be approved under section 512 of the FD&C Act, conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc), or included on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species under section 572 of the FD&C Act (21 U.S.C. 360ccc-1). The FD&C Act does not generally distinguish between compounding and other methods of animal drug manufacturing. Animal drugs that are not approved or indexed are considered "unsafe" under section 512(a)(1) of the FD&C and adulterated under section 501(a)(5) of the FD&C Act.

Although sections 503A (21 U.S.C. 353a) and 503B of the FD&C Act provide certain statutory exemptions for compounded human drugs, these sections do not provide exemptions for drugs compounded for animal use. The compounding of an animal drug from bulk drug substances results in a new animal drug that must comply with the FD&C Act's approval/indexing requirements.⁵ Further, all animal drugs are required to, among other things, be made in accordance with current good manufacturing practice (cGMP) requirements (section 501(a)(2)(B)) of the FD&C Act and 21 CFR parts 210 and 211) and have adequate directions for use (section 502(f)(1) of the FD&C Act).

Sections 512(a)(4) and (5) of the FD&C Act provide a limited exemption from certain requirements for compounded animal drugs made from already approved animal or human drugs. Such use is considered an extralabel use and the FD&C Act provides an exemption from the approval requirements and requirements of section 502(f) of the FD&C Act for extralabel uses that meet the conditions set out in the statute and FDA regulations at 21 CFR part 530. Among other things, these regulations specify that nothing in the regulations should be construed as permitting compounding animal drugs from bulk drug substances.

In 1996, FDA announced the availability of a CPG (section 608.400) entitled, "Compounding of Drugs for Use in Animals" (61 FR 34849, July 3, 1996), to provide guidance to FDA's field and headquarters staff with regard to the compounding of animal drugs by veterinarians and pharmacists. An updated CPG was made available on July 14, 2003 (68 FR 41591). This draft guidance supersedes that CPG, which has now been withdrawn.

⁴ <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm>.

⁵ See *Medical Center Pharmacy v. Mukasey*, 536 F.3d 383, 394 (5th Cir. 2008).

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B. Compounding Animal Drugs

Numerous drugs are approved or indexed for use in animals. However, there are many different species of animals with different diseases and conditions for which there are no approved or indexed animal drugs. In some cases, approved human drugs can be used to treat an animal under the extralabel use provisions of the FD&C Act and FDA regulations (sections 512(a)(4) and (a)(5) of FD&C Act and 21 CFR part 530). For example, various chemotherapeutic drugs approved for humans are used to treat cancer in dogs and cats. FDA recognizes that there are circumstances where there is no drug available to treat a particular animal with a particular condition, because either no drug is approved for a specific animal species or no drug is available under the extralabel drug use provisions. In those limited circumstances, an animal drug compounded from bulk drug substances may be an appropriate treatment option.

However, FDA is concerned about the use of animal drugs compounded from bulk drug substances, especially when approved alternatives exist that can be used as labeled or in an extralabel manner consistent with the requirements of FDA's extralabel provisions. Compounded drugs have not undergone premarket FDA review of safety, effectiveness, or manufacturing quality. The unrestricted compounding of animal drugs from bulk drug substances has the potential to compromise food safety, place animals or humans at undue risk from unsafe or ineffective treatment, and undermine the incentives to develop and submit new animal drug applications to FDA containing data and information to demonstrate that the product is safe, effective, properly manufactured, and accurately labeled.

III. POLICY

As discussed above, animal drugs are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act. Generally, FDA does not intend to take action under sections 512(a), 501(a)(5), 502(f)(1) and 501(a)(2)(B) of the FD&C Act if a state-licensed pharmacy or a licensed veterinarian compounds animal drugs from bulk drug substances in accordance with the conditions described below, and the drug is not otherwise adulterated or misbranded. In addition, FDA generally does not intend to take action under sections 512(a), 501(a)(5), and 502(f)(1) of the FD&C Act if an outsourcing facility compounds animal drugs in accordance with all of the applicable conditions described below, and the drug is not otherwise adulterated or misbranded.

FDA's decision not to take enforcement action depends on its ability to evaluate whether the compounding of animal drugs is in accordance with the conditions below. Therefore, entities compounding animal drugs should keep adequate records to demonstrate that they are compounding such drugs in accordance with all of the applicable conditions described below.

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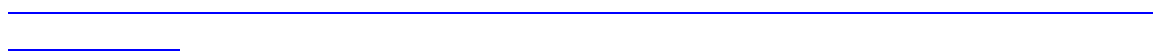
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The conditions referred to above are as follows:

- A. If the animal drug is compounded in a state-licensed pharmacy:
1. The drug is compounded by or under the direct supervision of a licensed pharmacist.
 2. The drug is dispensed after the receipt of a valid prescription from a veterinarian for an individually identified animal patient that comes directly from the prescribing veterinarian or from the patient's owner or caretaker to the compounding pharmacy. A drug may be compounded in advance of receipt of a prescription in a quantity that does not exceed the amount of drug product that the state-licensed pharmacy compounded pursuant to patient-specific prescriptions based on a history of receipt of such patient-specific prescriptions for that drug product over any consecutive 14-day period within the previous 6 months.
 3. The drug is not intended for use in food-producing animals, and the prescription or documentation accompanying the prescription for the drug contains the statement "This patient is not a food-producing animal." For purposes of this draft guidance, all cattle, swine, chicken, turkey, sheep, goats, and non-ornamental fish are always considered to be food-producing animals regardless of whether the specific animal or food from the specific animal is intended to be introduced into the human or animal food chain (e.g., pet pot-bellied pigs and pet chicks are always considered to be food-producing animals). In addition, for purposes of this draft guidance, any other animal designated on the prescription or in documentation accompanying the prescription by the veterinarian as a food-producing animal, regardless of species, is considered to be a food-producing animal (e.g., rabbits, captive elk, captive deer).
 4. If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug:
 - a. there is a change between the compounded drug and the comparable FDA-approved animal or human drug made for an individually identified animal patient that produces a clinical difference for that individually identified animal patient, as determined by the veterinarian prescribing the compounded drug for his/her patient under his/her care, and
 - b. the prescription or documentation accompanying the prescription contains a statement that the change between the compounded drug and the FDA-approved drug would produce a clinical difference for the individually identified animal patient. For example, the veterinarian could state that, "Compounded drug X would produce a clinical difference for the individually identified animal patient because the approved drug is too large a dose for the animal and cannot be divided or diluted into the small dose required."
 5. If there is an FDA-approved animal or human drug with the same active ingredient(s), the pharmacy determines that the compounded drug cannot be made from the FDA-approved drug(s), and documents that determination.

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⁶ Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations* can be found in the combined *United States Pharmacopeia and National Formulary (USP-NF)*, available at <http://www.usp.org>.

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2. The drug is not intended for use in food-producing animals as defined in section III.A.3 of this guidance.
 3. If the drug contains a bulk drug substance that is a component of any marketed FDA-approved animal or human drug, there is a change between the compounded drug and the comparable FDA-approved animal or human drug made for an individually identified animal patient that produces a clinical difference for that individually identified animal patient, as determined by the veterinarian prescribing the compounded drug for his/her patient under his/her care.
 4. There are no FDA-approved animal or human drugs that can be used as labeled or in an extralabel manner under sections 512(a)(4) and (5) of the FD&C Act and 21 CFR part 530 to appropriately treat the disease, symptom, or condition for which the drug is being prescribed.
 5. The drug is compounded in accordance with USP—NF Chapters <795> and <797> (e.g., a sterile drug is compounded in an area with air quality that meets or exceeds ISO Class 5 standards (see USP—NF Chapter <797>, Table 1)).
 6. Any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis.
 7. The drug is not sold or transferred by the veterinarian compounding the drug. For purposes of this condition, a sale or transfer does not include administration of a compounded drug by the veterinarian to a patient under his or her care, or the dispensing of an animal drug compounded by the veterinarian to the owner or caretaker of an animal under his or her care.
 8. Within 15 days of becoming aware of any product defect or serious adverse event associated with animal drugs the veterinarian compounded from bulk drug substances, he or she reports it to FDA on Form FDA 1932a. Form FDA 1932a can be downloaded at <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/animaldrugforms/ucm048817.pdf>.
 9. The label of any compounded drug indicates the species of the intended animal patient, the name of the animal patient and the name of the owner or caretaker of the animal patient.
- C. If the animal drug is compounded by an outsourcing facility:
1. The drugs are compounded only from bulk drug substances appearing on Appendix A of this draft guidance.
 2. The drug is compounded by or under the direct supervision of a licensed pharmacist.

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3. The drug is not intended for use in food-producing animals, as defined in Section III.A.3 of this guidance, and the prescription or order, or documentation accompanying the prescription or order, for the drug contains the statement, “This drug will not be dispensed for or administered to food-producing animals.”
4. The drug is compounded in accordance with cGMP requirements.⁷
5. Any bulk drug substance used is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360) (including a foreign establishment that is registered under section 360(i)) and is accompanied by a valid certificate of analysis.
6. The drug is not sold or transferred by an entity other than the outsourcing facility that compounded such drug. For purposes of this condition, a sale or transfer does not include administration of a compounded drug by a veterinarian to a patient under his or her care.
7. Within 15 days of becoming aware of any product defect or serious adverse event associated with animal drugs it compounded from bulk drug substances, the outsourcing facility reports it to FDA, on Form FDA1932a. Form FDA 1932a can be downloaded at <http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/animaldrugforms/ucm048817.pdf>.
8. All drugs compounded for animals by an outsourcing facility are included on the report required by section 503B of the FD&C Act to be submitted to the Food and Drug Administration each June and December identifying the drugs made by the outsourcing facility during the previous 6-month period, and providing the active ingredient(s); source of the active ingredient(s); NDC number of the source ingredient(s), if available; strength of the active ingredient(s) per unit; the dosage form and route of administration; the package description; the number of individual units produced; and the NDC number of the final product, if assigned.⁸ The outsourcing facility should identify which reported drugs were intended for animal use.
9. The veterinarian’s prescription or order states that the drug is intended to treat the species and condition(s) for which the substance is listed in Appendix A.

⁷ FDA intends to determine whether this condition is met by evaluating whether the facility complies with FDA regulations applicable to cGMPs for compounding of human drugs by outsourcing facilities. *See, e.g.*, draft guidance for industry, *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* (July 2014), at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf>

⁸ FDA has issued a draft guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (November 2014), which prescribes how human drug compounding facilities are to submit drug product reports to FDA. Available at <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM424303.pdf>. Although this guidance addresses reporting of compounded human drug products, outsourcing facilities should follow the same procedure to electronically report the animal drug products they compounded.

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10. The label of the drug includes the following:
- a. Active ingredient(s).
 - b. Dosage form, strength, and flavoring, if any.
 - c. Directions for use, as provided by the veterinarian prescribing or ordering the drug.
 - d. Quantity or volume, whichever is appropriate.
 - e. The statement “Not for resale.”
 - f. The statement “For use only in [fill in species and any associated condition or limitation listed in Appendix A].”
 - g. The statement “Compounded by [name of outsourcing facility].”
 - h. Lot or batch number of drug.
 - i. Special storage and handling instructions.
 - j. Date the drug was compounded.
 - k. Beyond use date (BUD) of the drug.
 - l. Name of veterinarian prescribing or ordering the drug.
 - m. The address and phone number of the outsourcing facility that compounded the drug.
 - n. Inactive ingredients.
 - o. The statement “Adverse events associated with this compounded drug should be reported to FDA on a Form FDA 1932a.”
 - p. If the drug is compounded pursuant to a patient specific prescription, the species of the animal patient, name of the animal patient, and name of the owner or caretaker of the animal patient.

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APPENDIX A⁹

LIST OF BULK DRUG SUBSTANCES THAT MAY BE USED BY AN OUTSOURCING FACILITY TO COMPOUND DRUGS FOR USE IN ANIMALS

This Appendix, when finalized, will contain a list of bulk drug substances that may be used by facilities registered under section 503B as outsourcing facilities to compound animal drugs pursuant to a prescription from a veterinarian for an individually identified animal patient or pursuant to an order from a licensed veterinarian for veterinarian office use, and in accordance with any specified limitations or conditions.

This list will be developed with public input; the process for nominating bulk drug substances for this list is described in the Federal Register notice soliciting nominations for such bulk drug substances. FDA intends to limit the bulk drug substances in this Appendix to address situations where all of the following criteria are met:

- there is no marketed approved, conditionally approved, or index listed animal drug that can be used as labeled to treat the condition;
- there is no marketed approved animal or human drug that could be used under section 512(a)(4) or (a)(5) and 21 CFR Part 530 (addressing extralabel use of approved animal and human drugs) to treat the condition;
- the drug cannot be compounded from an approved animal or human drug;
- immediate treatment with the compounded drug is necessary to avoid animal suffering or death; and
- FDA has not identified a significant safety concern specific to the use of the bulk drug substance to compound animal drugs (under the listed conditions and limitations).

FDA intends to review the nominated bulk drug substances on a rolling basis and to periodically update this Appendix.

LIST:

⁹ To submit nominations for this list, refer to the Federal Register notice entitled, “List of Bulk Drug Substances That May be Used by an Outsourcing Facility to Compound Drugs for Use in Animals,” published May 19, 2015. After the period for nominations closes, you may petition FDA under 21 CFR 10.30 to add or remove specific listings.