

PHARMACY SERVICES / MEDICATION USE

STANDARD / ELEMENT	EXPLANATION	SCORING PROCEDURE	SCORE
<p>25.01.02 Supervision of Pharmacy Activities. <i>In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice consistent with Federal and State law.</i></p> <p>§482.25(b)(1)</p>	<p>All pharmaceutical services involving compounding, packaging, or dispensing of drugs and biologicals must be conducted by or under the supervision of a registered pharmacist and performed consistent with State and Federal laws.</p> <p>The hospital must adopt and implement written policies and procedures to ensure all medications are prepared by authorized personnel.</p> <p>COMPOUNDED PREPARATIONS</p> <p>Hospitals use many medications that need to be reconstituted, mixed or which otherwise may be considered “compounded” preparations. Some may be compounded in the hospital pharmacy and/or the hospital may obtain some or all from external sources. The external sources could include:</p> <ul style="list-style-type: none"> • Manufacturers, • Registered outsourcing facilities, and/or • Compounding pharmacies. <p>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 devastating or even lethal consequences for the patients who receive them.</p> <p>USE OF REGISTERED OUTSOURCING FACILITIES</p>	<p><u>OBSERVATION, INTERVIEW AND DOCUMENT REVIEW</u></p> <p>1. Determine that only pharmacists or pharmacist supervised personnel compound, package and dispense drugs or biologicals in accordance with State and federal laws and regulations and as accepted standards of practice by:</p> <ul style="list-style-type: none"> • Interviewing pharmacy and hospital staff to determine who prepares and dispenses drugs and biologicals; • Observing on site preparation and dispensing operations (if applicable); • Inspecting drug storage areas. <p>2. Can the hospital 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>?</p> <ul style="list-style-type: none"> • Can the pharmacy director provide evidence 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 	<p><input type="checkbox"/> 1 = Compliant <input type="checkbox"/> 2 = Not Compliant</p> <p>This standard is not met as evidenced by:</p>

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	<p>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.”</p> <p>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, per section 503B:</p> <ul style="list-style-type: none"> • 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 	<p>described in USP <795> and <797>?</p> <ul style="list-style-type: none"> • If the hospital obtains compounded products from external compounding sources, are the external source(s) registered with the FDA as outsourcing facilities? If not, can the hospital demonstrate that it systematically evaluates and monitors whether the outside compounding pharmacy adheres to accepted standards for safe compounding? For example, does the contract include provisions ensuring that the hospital has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements, and can the hospital document that it obtains and reviews such data? <p>3. Can the pharmacy director 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?</p> <p>4. If any CSPs are produced in the hospital:</p> <ul style="list-style-type: none"> • 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. 	

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	<ul style="list-style-type: none"> • Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound. <p>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,</p> <p><i>“[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.”</i></p> <p>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/ucm37864</p>	<p>Interview pharmacy personnel assigned to carry out this function within the hospital and/or to assess how this is done by external source(s) of CSPs.</p> <ul style="list-style-type: none"> • Is there evidence that the BUDs are determined consistent with the hospital’s policies and procedures? • Interview staff who engage in sterile and non-sterile compounding. Are they knowledgeable about applicable levels of aseptic practices? • Ask the pharmacy director 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 hospital patients: <ul style="list-style-type: none"> • 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 	

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	<p>5.htm</p> <ul style="list-style-type: none"> Note that these registered outsourcing facilities are also popularly referred to as “503B pharmacies.” <p>USE OF COMPOUNDING PHARMACIES</p> <p>Compounding pharmacies, not registered as an outsourcing facility with the FDA, are popularly referred to as “503A pharmacies” and generally are subject to oversight only by their State pharmacy board.</p> <p>If a hospital obtains compounded medications from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the hospital 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.</p> <p>For example, does the contract with the vendor include provisions:</p> <ul style="list-style-type: none"> Ensuring that the hospital has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements, and can the hospital document that it obtains and reviews such data? Requiring the vendor to meet the requirements 	<p>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.</p> <p>5. Review the hospital’s procedures for maintaining the quality of CSPs during storage, transport and dispensing.</p> <ul style="list-style-type: none"> 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 hospital ensure that such information is effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable? <p>6. Can the hospital document that it is systematically monitoring and tracking adherence to all of the quality assurance and personnel training and competency standards described above?</p>	

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of Section 503A of the FDCA concerning pharmacy compounding of human drug products?

*For Information –
Not Required/Not to be Cited*

*ASHP Research and Education FoundationTM
“Outsourcing Sterile Products Preparation:
Contractor Assessment Tool”*

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

- Have any problems or risks been identified? If so, did the hospital take effective action to protect patients, if relevant, and to effectively remedy the problem/risk?

MEDICATIONS COMPOUNDED BY THE HOSPITAL’S PHARMACY

Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when there is a need for emergency or immediate patient administration of a compounded sterile preparation). In addition, all compounding of medications used or dispensed by the hospital must be performed consistent with standards of practice equivalent to or more stringent than those described

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	<p>in the compounding-related chapters in the United States Pharmacopeia and the National Formulary (USP) published by the U.S. Pharmacopeial Convention, which are recognized as authoritative guidance regarding minimum standards of safe practice applicable to both sterile and non-sterile compounding.</p> <p>DEFINITION 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:</p> <ul style="list-style-type: none"> • 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 		

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- 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.

MINIMUM STANDARDS OF PRACTICE

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.

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	<p>“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:</p> <ul style="list-style-type: none"> • Baths and soaks for live organs and tissues; • Injections [and infusions]; • Irrigations for wounds and body cavities; • Ophthalmic drops and ointments; • Tissue implants.” <p>PHYSICAL LAYOUT AND STRUCTURE</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • 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 		

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	<p>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.</p> <ul style="list-style-type: none"> • 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. <p>GOAL 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.</p> <p>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.”</p>		

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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 hospital (or its vendor) is able to meet (low-risk level, medium-risk level and high-risk level are discussed here; see §482.23(c) 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.

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	<ul style="list-style-type: none"> • 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. <p>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:</p> <ul style="list-style-type: none"> • 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. 		

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	<ul style="list-style-type: none"> • 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 		

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	<p>packaging, storage and transportation conditions for CSPs.</p> <ul style="list-style-type: none"> • 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. <div style="border: 1px solid black; padding: 10px; margin-top: 20px;"> <p style="text-align: center;">For information – Not Required / Not to be Cited</p> <p>USP<797> Appendices I and III-V contain summaries and assessment tools that hospitals may find helpful. However, there is no requirement to use specific forms or materials as long as the hospital and/or its external sources of CSPs are implementing plans, procedures, testing and documentation consistent with applicable standards for safe compounding.</p> <p>These USP<797> materials are referenced here only as examples:</p> <ul style="list-style-type: none"> • “Appendix I: Principal Competences, 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 </div>		

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| <p>of Compounding Personnel”</p> <ul style="list-style-type: none"> • “Appendix IV: “Sample Form for assessing Aseptic Technique and Related Practices of Compounding Personnel” • “Appendix V: “Sample Form for Assessing Cleaning and Disinfection Procedures” |
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PACKAGING AND LABELING OF MEDICATIONS

Safe medication use includes proper packaging and labeling to reduce the risk of error.

For individual drug containers:

- Each floor stock drug container is expected to be labeled 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 beyond-use date (BUD).
- It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-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

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labeled 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 labeled 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 hospitals are expected to comply with these requirements, surveyors conducting a Medicare survey do not assess compliance with other Federal laws.

DISPENSING OF MEDICATIONS

Medications must be dispensed in a manner that is safe and meets the needs of the patient.

1. Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of patients.
2. Medications are dispensed in a timely manner.

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The hospital must have a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly.

3. Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit dose that have been repackaged by the pharmacy.
4. The hospital consistently uses the same dose packing system, or, if a different system is used, provides education about the use of the dose packaging system.
5. All concerns, issues or questions are clarified with the individual prescriber before dispensing; **and**
6. **Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.**

AVAILABILITY OF MEDICATIONS

Medications must be 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**

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pharmacy, night cabinets, contracted services after hours via telepharmacy contracting, on-call pharmacists, etc.

- 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.

<p>For Information Only Not Required/Not to be Cited</p> <p>When utilizing automated dispensing cabinets (ADCs), the Institute for Safe Medication Practices recommendations include the following:</p> <p>http://www.ismp.org/Newsletters/acutecare/articles/20090212.asp</p> <p style="text-align: center;">And</p> <p>http://www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf</p> <p>Security processes are established to ensure adequate control of medications outside of the pharmacy and to reduce the potential for medication diversion from ADCs.</p>

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- 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 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 bin that is maintained by pharmacy, not to an individual pocket or bin within the ADC.