Objective: Since the prospect of an unannounced CMS survey could occur at anytime, advanced vigilant planning and preparation needs to take place. This tool can be used to prepare you for surveys.

Instructions: Complete the checklist.

Use: Review the responses to ascertain if your hospital is ready for a CMS unannounced survey in the area of Pharmaceutical Services. If the response to several of these items is no, you could run the risk of not being prepared when the survey team arrives.

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§482.25 Condition of Participation: Pharmaceutical Services

- Must provide pharmaceutical services that meet the needs of its patients. **A-Tag 0489 (Revised 11/20/15 per Transmittal 151)**
- Services must include a pharmacy that is directed by a pharmacist, or, when appropriate, a drug storage area that is competently supervised. **A-Tag 0489 (Revised 11/20/15 per Transmittal 151)**
- Medical staff is responsible for developing pharmaceutical policies and procedures that minimize the potential for medication errors. **A-Tag 0489 (Revised 11/20/15 per Transmittal 151)**
- Must have pharmaceutical services that meet the needs of the patients...:
  - Procuring, storing, compounding, repackaging, and dispensing all medications, biologicals, chemicals and medication related devices within the hospital. **A-Tag 0490 (Revised 11/20/15 per Transmittal 151)**
- Provide medication-related information to care professionals and as well as direct provision of medication-related care. **A-Tag 0490 (Revised 11/20/15 per Transmittal 151)**

- Scope and complexity of pharmaceutical services available must be consistent with volume and type of patients the hospital serves. **A-Tag 0490 (Revised 11/20/15 per Transmittal 151)**

- Except in unusual circumstances, expected to make available in a timely manner the volume and types of medications typically needed. **A-Tag 0490 (Revised 11/20/15 per Transmittal 151)**

- ...The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service. **A-Tag 0491**

- The hospital...must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision.... **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**

### §482.25(a) Standard: Pharmacy Management and Administration

- The pharmacy or drug storage area is administered in accordance with accepted professional principles. **A-Tag 0491**

- Must ensure safe timely and appropriate procurement, storage, preparation, dispensing, use, tracking and control, and disposal of medications and medication-related devices throughout the hospital, for both inpatient and outpatient services. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**

- Hospitals with only a drug storage area must only use drugs that are pre-packaged and need no further preparation beyond that required at the point of care. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**

- Hospital must develop, implement and periodically review and revise policies and procedures governing provision of pharmaceutical services. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**

- Policies and procedures must reflect accepted professional pharmacy principles, and pharmacy director must be able to identify the source(s) used when developing and adopting the policies and procedures. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**

- There must be a process to train staff on the applicable policies and procedures and to monitor their adherence. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**

- Policies and procedures must be designed to prevent, identify and minimize drug errors and are expected to address:
  - High-alert medications. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- Investigational medications. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- Adherence to professional standards of practice for all compounding, packaging dispensing and drug disposal activities **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- Standardizing medication-related devices and equipment where feasible. I.E. limit the types of general-purpose infusion pumps to one or two. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- Availability of up-to-date medication information and pharmacy expertise on-call when pharmacy does not operate 24-hours per day. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- Standardization of prescribing and communication practices **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- The prohibition to write "resume previous orders" **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- Availability of patient-specific information to all individuals involved in the provision of pharmaceutical care. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- When weight-based dosing for pediatric populations is required **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- A voluntary, non-punitive reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions) **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- Monitoring drug alerts and/or recalls. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**
- Must be integrated into hospital-wide QAPI program and, important to flag new types of mistakes and continually improve and refine policies and procedures as a result of analyses of errors and adverse events. **A-Tag 0491 (Revised 11/20/15 per Transmittal 151)**

§482.25(a)(1) Standard: Pharmacy Management and Administration

- A full-time, part-time, or consulting pharmacist is responsible for developing, supervising, and coordinating all the activities of the pharmacy services. **A-Tag 0492**
- Director must have documented training or expertise in hospital pharmacy practice and management. **A-Tag 0492 (Revised 11/20/15 per Transmittal 151)**
- Hospital must have written criteria for the qualifications of the pharmacy director in accordance with the scope of services provided. **A-Tag 0492 (Revised 11/20/15 per Transmittal 151)**
- If the hospital does not have a full-time pharmacist, it must be able to provide evidence of how a part-time or consulting pharmacist is
able to perform all functions relating to developing, supervising and coordinating all pharmacy services activities. A-Tag 0492 (Revised 11/20/15 per Transmittal 151)

- If the hospital has a drug storage area in lieu of a pharmacy, the day-to-day operations of pharmaceutical services must be under the supervision of an individual who, if not a pharmacist, nevertheless has documented competency to oversee compliance with all the pharmaceutical services regulatory requirements (e.g., security, access to locked areas, etc.). A-Tag 0492 (Revised 11/20/15 per Transmittal 151)

- The hospital must establish in writing the qualifications of the drug storage area supervisor. A-Tag 0492 (Revised 11/20/15 per Transmittal 151)

- The job description or the written agreement for the responsibilities of the pharmacist director should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services, including active leadership of those committees responsible for establishing medication-related policies and procedures. A-Tag 0492 (Revised 11/20/15 per Transmittal 151)

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§482.25(a)(2) Standard: Pharmacy Management and Administration

- The pharmaceutical service has an adequate number of personnel to ensure quality pharmaceutical services, including emergency services. A-Tag 0493

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§482.25(a)(3) Standard: Pharmacy Management and Administration

- The pharmaceutical service keeps current and accurate records of the receipt and disposition of all scheduled drugs. A-Tag 0494

- The hospital has policies and procedures that describe a system to keep current and accurate records of the receipt and disposition of all scheduled drugs. This system is capable of doing the following:
  - Provide information on controlled substances in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs; A-Tag 0494
  - Track 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; A-Tag 0494
  - Readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion. A-Tag 0494

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§482.25(a)(2) Standard: Pharmacy Management and Administration
The pharmaceutical services staff is sufficient in number and training to provide quality services, including 24-hour, 7-day emergency coverage or, alternately, there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff. A-Tag 0493

There are sufficient pharmacy personnel to meet the needs of the patient population being served to ensure the following: A-Tag 0493
- Accurate and timely medication delivery. A-Tag 0493
- Accurate and safe medication administration. A-Tag 0493
- Appropriate clinical services. A-Tag 0493
- Participation in continuous quality improvement programs. A-Tag 0493

§482.25(b) Standard: Delivery of Services (Revised 11/20/15 per Transmittal 151)

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.

Must have a process in place for medication orders to be received in the pharmacy and dispensed in a safe and timely manner. A-Tag 0500 (Revised 11/20/15 per Transmittal 151)

Safe dispensing of medications must be in accordance with accepted standards of practice and includes, but is not limited to, the following. A-Tag 0500 (Revised 11/20/15 per Transmittal 151)
- Implementing systems such as dose limits, pre-printed orders, special labeling, or double checks to minimize adverse drug events, especially for high alert medications. A-Tag 0500 (Revised 11/20/15 per Transmittal 151)
- Reviewing all medication orders (except in emergency situations) for appropriateness by a pharmacist before the first dose is dispensed. A process is established for resolving questions with the prescribing practitioner and the discussion and outcome are documented in the patient's medical record or pharmacy copy of the prescriber's order. A-Tag 0500 (Revised 11/20/15 per Transmittal 151)

This review should include:
- Therapeutic appropriateness of a patient's medication regime A-Tag 0500 (Revised 11/20/15 per Transmittal 151)
- Therapeutic duplication in the patient's medication regimen A-Tag 0500 (Revised 11/20/15 per Transmittal 151)
- Appropriateness of the drug, dose, frequency, and route of administration A-Tag 0500 (Revised 11/20/15 per Transmittal 151)
- Real or potential medication-medication, medication-food,
medication-laboratory test and medication-disease interactions \textbf{A-Tag 0500} (Revised 11/20/15 per \textbf{Transmittal 151})

- Real or potential allergies or sensitivities \textbf{A-Tag 0500} (Revised 11/20/15 per \textbf{Transmittal 151})

- Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons. \textbf{A-Tag 0500}

- Policies and procedures that address the use of medications brought into the hospital by patients or their families when self-administration of medications is permitted by hospital policy. \textbf{A-Tag 0500} (Revised 11/20/15 per \textbf{Transmittal 151})

- Having a system in place to reconcile medications that are not administered (e.g., left in the patient's medication drawer) when the pharmacy inventories patient medications or restocks patient medications. \textbf{A-Tag 0500} (Revised 11/20/15 per \textbf{Transmittal 151})

- Having a system in place for monitoring the effects of medication therapies for cases specified per hospital policy. \textbf{A-Tag 0500} (Revised 11/20/15 per \textbf{Transmittal 151})

\section*{§482.25(b)(1) Standard: Delivery of Services}

- All pharmaceutical services involving compounding, packaging, or dispensing of drugs and biologicals, must be conducted by or under the supervision of a pharmacist and performed consistent with State and Federal laws. \textbf{A-Tag 0501} (Revised 11/20/15 per \textbf{Transmittal 151})

- The hospital must adopt and implement written policies and procedures to ensure all medications are prepared by authorized personnel. \textbf{A-Tag 0501} (Revised 11/20/15 per \textbf{Transmittal 151})

- \textbf{Use of Registered Outsourcing Facilities}
  - Must comply with the FDA's Current Good Manufacturing Practice (CGMP) requirements \textbf{A-Tag 0501} (Revised 11/20/15 per \textbf{Transmittal 151})
  - Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound. \textbf{A-Tag 0501} (Revised 11/20/15 per \textbf{Transmittal 151})

- \textbf{Use of Compounding Pharmacies}
  - 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. \textbf{A-Tag 0501} (Revised 11/20/15 per \textbf{Transmittal 151})

- \textbf{Use of 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). **A-Tag 0501 (Revised 11/20/15 per Transmittal 151)**

- 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 in the compounding-related chapters in the United States Pharmacopeia and the National Formulary (USP) USP Chapter <795>. **A-Tag 0501 (Revised 11/20/15 per Transmittal 151)**

- All compounded dosage forms that must be sterile when they are administered to patients. **A-Tag 0501 (Revised 11/20/15 per Transmittal 151)**

  This includes but is 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 and
  - Tissue implants

- All sterile compounding practices are consistent with USP <797>, which specifies differing standards for the physical layout and structure of the locations in which compounding takes place. **A-Tag 0501 (Revised 11/20/15 per Transmittal 151)**

- All processes, precautions and quality assurance practices as described in USP<797> are implemented during the preparation, transport and storage of CSPs including:
  - Implementation and maintenance of proper procedures and quality assurance checks **A-Tag 0501 (Revised 11/20/15 per Transmittal 151)**
  - 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 **A-Tag 0501 (Revised 11/20/15 per Transmittal 151)**
  - Methods for sterilization, depyrogenation and for verifying compounding accuracy and sterility; **A-Tag 0501 (Revised 11/20/15 per Transmittal 151)**
  - Personnel training and 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 **A-Tag 0501 (Revised 11/20/15 per Transmittal 151)**
  - 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. **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*

- Use of standard operating procedures to protect the quality of the environment in which CSPs are prepared **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*
- Quality control related to ingredients, devices and equipment used in relation to CSPs **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*
- Quality checks to be performed before CSPs are dispensed or administered; **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*
- Issues related to beyond-use dating and packaging, storage and transportation conditions for CSPs **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*
- Protecting dispensed and distributed CSPs **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*
- Patient education issues; **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*
- Monitoring for and reporting adverse patient events related to CSPs; **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*
- Requirements for a formal quality assurance program to be maintained by providers of CSPs. **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*

**Packaging and Labeling of Medications**

- Safe medication use includes proper packaging and labeling to reduce the risk of error. Each floor stock drug container is must be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date. **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*
- The BUD for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-punctured) does not exceed 28 days unless otherwise specified by the manufacturer. **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*
- Each patient's individual drug container is labeled with the patient's full name and quantity of the drug dispensed. **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*
- If the unit dose system is utilized, each single unit dose package labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD. **A-Tag 0501** *(Revised 11/20/15 per Transmittal 151)*

**Dispensing of Medications (Revised 11/20/15 per Transmittal 151)**

- The hospital dispenses medications in a safe manner and meets the needs of patients. A-Tag 501. The following are
examples of methods to safely dispense medications:

- Quantities of medications are dispensed that minimize diversion and potential adverse events while meeting the needs of the patient. A-Tag 0501
- Medications are dispensed in a timely manner. The hospital has a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly. A-Tag 0501
- 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. A-Tag 0501
- The hospital consistently uses the same dose packaging system or, if a different system is used, provides education about the use of the dose packaging system. A-Tag 0501
- All concerns, issues, or questions are clarified with the individual prescriber before dispensing. A-Tag 0501

- Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons. A-Tag 0501 (Revised 11/20/15 per Transmittal 151)
- Medications must be available for administration to patients when needed, including when the pharmacy is not open. A-Tag 0501 (Revised 11/20/15 per Transmittal 151)
- Policies and procedures must address who can access medications during after-hours. A-Tag 0501 (Revised 11/20/15 per Transmittal 151)

§482.25(b)(2) Standard: Delivery of Services

- (i) All drugs and biologicals must be kept in a secure area, and locked when appropriate. A-Tag 0502 (Revised 11/20/15 per Transmittal 151)
- (i) The medication storage areas are periodically inspected by pharmacy staff to ensure proper storage. A-Tag 0502 (Revised 11/20/15 per Transmittal 151)
- (i) If patient self-administration of drugs and biologicals is permitted, policies and procedures are implemented and effective. A-Tag 0502 (Revised 11/20/15 per Transmittal 151)
- (iii) Only authorized personnel can access locked areas. A-Tag 0504

§482.25(b)(3) Standard: Delivery of Services

- Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use. A-Tag 0505 (Revised
Drugs that are the subject of a manufacturer's recall are not available for patient use. A-Tag 0505 (Revised 11/20/15 per Transmittal 151)

The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a "beyond-use date" (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) A-Tag 0505 (Revised 11/20/15 per Transmittal 151)

For individual drug containers, each floor stock container includes:
- A label with the name and strength of the drug, lot and control number of equivalent, and expiration date A-Tag 0505 (Revised 11/20/15 per Transmittal 151)
- Appropriate accessory and cautionary statements A-Tag 0505 (Revised 11/20/15 per Transmittal 151)
- The expiration date and/or, if applicable, a BUD. A-Tag 0505 (Revised 11/20/15 per Transmittal 151)

Each patient's individual drug container bears his/her full name and strength and quantity of the drug dispensed. A-Tag 0505 (Revised 11/20/15 per Transmittal 151)

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/or, if applicable, a BUD. A-Tag 0505 (Revised 11/20/15 per Transmittal 151)

§482.25(b)(4) Standard: Delivery of Services

- When a pharmacist is not available, only authorized personnel can remove drugs and biologicals from the pharmacy or storage area. A-Tag 0506
- The hospital has a system in place to accurately document the removal of medications (type and quantity) from either the pharmacy or the after-hours supply. A-Tag 0506
- The pharmacist reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile. A-Tag 0506
- The pharmacist routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital. A-Tag 0506

§482.25(b)(5) Standard: Delivery of Services

- The hospital automatically stops drugs and biologicals not specifically prescribed as to time or number of doses after a reasonable time that is predetermined by the medical staff.
• Hospitals with an electronic health record (EHR) system may have time and dose parameters automatically built into computerized provider order entry (CPOE) screens. These may be part of the hospital's plan for addressing automatic stop orders. **A-Tag 0507 (Revised 11/20/15 per Transmittal 151)**

§482.25(b)(6) Standard: Delivery of Services

• The hospital ensures immediate reporting of drug administration errors, adverse drug reactions, and incompatibilities to the attending physician and, if appropriate, to the hospital-wide wide quality assessment and performance improvement (QAPI) program where medical errors and adverse patient events are measured, analyzed and tracked. **A-Tag 0508**

§482.25(b)(7) Standard: Delivery of Services

• The hospital ensures abuses and losses of controlled substances are reported to the individual responsible for the pharmaceutical service and to the chief executive officer, as appropriate, in accordance with applicable Federal and State laws. **A-Tag 0509**
• A spot-check of drug use and other inventory records confirms drugs are properly accounted for. **A-Tag 0509**

§482.25(b)(8) Standard: Delivery of Services

• Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff. **A-Tag 0510 (Revised 11/20/15 per Transmittal 151)**
• The pharmacy must be a resource to healthcare practitioners and personnel for medication related information. Information must be available concerning drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration to professional staff. **A-Tag 0510 (Revised 11/20/15 per Transmittal 151)**
• Pharmacy service remains responsible for the provision of accurate, up-to-date information to meet the needs of the hospital's practitioners, nursing staff and patients. **A-Tag 0510 (Revised 11/20/15 per Transmittal 151)**
• Must have immediately available sufficient up-to-date reference material on drug therapy, whether in electronic or hard copy format. A pharmacist also should be readily available by telephone or other means to respond to questions from practitioners and nursing personnel. **A-Tag 0510 (Revised 11/20/15 per Transmittal 151)**

§482.25(b)(9)

• The medical staff has established a formulary system that lists
drugs that are available to assure quality pharmaceuticals at reasonable costs. **A-Tag 0511**

### Related CoP Checklists:

- [Checklist for CoP: Nursing Services](#)
- [Checklist for CoP: QAPI](#)
- [Checklist for CoP: Compliance with Federal, State, and Local Laws](#)
- [Checklist for CoP: Medical Staff](#)
- [Checklist for CoP: Patient's Rights (Excluding Restraints)](#)
- [Checklist for CoP: Patient's Rights (Restraints)](#)