1. **PURPOSE**

The facility recognizes that this drugs and biologicals policy (“Policy”) assists in ensuring that drugs and biologicals are managed in a manner that is safe and appropriate. The purpose of this policy is:

1. To establish written rules regarding the storage, handling, dispensing, administration, and disposing of drugs and biologicals, in accordance with accepted professional principles of pharmacy and medication administration practices including compliance with federal and state law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations.
2. To maintain medication integrity, promote the availability of medications when needed, minimize the risk of medication diversion, and reduce potential dispensing errors.
3. To establish responsibility for the implementation of this Policy and leadership’s commitment to the policy.
4. To fulfill Critical Access Hospital conditions of participation in the Medicare program and Joint Commission accreditation standards.
5. **POLICY / SCOPE**
6. The facility is responsible for ensuring that this Policy and its associated systems are in place and operate so as to provide quality health care in a safe environment, as well as for designating the Responsible Individual who is tasked with implementing this Policy.
7. The Policy Advisers shall be responsible for development and review of this Policy.
8. The Responsible Individual shall be responsible for the overall implementation of this Policy and the facility’s pharmacy services, including development of the pharmacy services rules, which include the requirements in this Policy.
9. The standards captured in the Program shall apply to specifically to the Pharmacy Department, and all departments, all clinical and nonclinical staff, independent contractors, medical staff members, and any other person who works in the facility that stores, handles, dispenses, administers, stocks, or otherwise interacts with drugs and biologicals.
10. **DEFINITIONS**

***“Authorized Personnel”*** include nurses, physicians, or other individuals who in accordance with State and Federal law and facility policy have authorized access to the drugs and biologicals.

***“Handling”*** includes (1) reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug’s manufacturer; and (2) compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either facility staff or a contracted pharmacy service.

***“High-alert medications”*** are those medications that bear a heightened risk of causing significant patient harm and/or sentinel events when they are used in error and, as a result, require special safeguards to reduce the risk of errors. Examples of high-alert medications include opioids, insulin, anticoagulants, and neuromuscular blocking agents. Lists of high-alert medications are available from organizations such as the Institute for Safe Medication Practices (ISMP) and referenced in Section VII below for reference..

***“Hazardous drugs and medications”*** are those in which studies in animals or humans indicate that exposure to them has a potential for causing cancer, developmental or reproductive toxicity, genotoxicity, or harm to organs. An example of a hazardous drug is one that contains antineoplastic agents or other ingredients that cause the aforementioned risks. Lists of hazardous drugs are available from the National Institute for Occupational Safety and Health (NIOSH) and referenced in Section VII below for reference.

***“Outside Compounders”*** means a facility at one geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outside compounder, and complies with all of the requirements of section 503B of the Federal Food, Drug, and Cosmetic Act (“FDCA”), including the FDA’s Current Good Manufacturing Practice requirements, inspections, and other conditions. Outside Compounders may also be referred to in regulations as Outsourcing Facilities or 503B Pharmacies.

1. ***“Policy Advisers”*** means the members of the facility’s professional healthcare staff, including one or more physicians and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff, who help develop this Policy
2. ***“Responsible Individual”*** means the person who has overall responsibility for the facility’s pharmacy services, including development of this Policy. Unless a different person or title is expressly listed, the Responsible Individual shall be responsible ensuring that the facility requirements set forth in this Policy are executed and met.
3. **PROCEDURES**
4. Facility Responsibilities. The facility, through its governing body or individual, will:
   1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
   2. Ensure that written rules, plans, or policies for the storage, handling, dispensation, and administration of drugs and biologicals are developed and maintained.
   3. Obtain the advice of members of its professional healthcare staff, including one or more physicians and one or more physician assistants, nurse practitioners, or clinical nurse specialists in developing and adopting this Policy.
   4. Designate a Responsible Individual and exercise oversight over the Responsible Individual to the extent necessary to ensure that he or she is fulfilling the responsibilities set forth in this Policy.
      1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols for designating and appointing the Responsible Individual]
   5. Ensure drugs and biologicals are managed in a manner that is safe and appropriate.
   6. Ensure that its pharmacy system provides all drugs and biologicals prescribed by its practitioners in a timely manner for administration to its patients.
   7. Ensure that its staff is aware of and understands this Policy, specifically its controlled substance policies.
      1. [PLACEHOLDER – If relevant to implementation of this responsibility, provide any organization-specific education/training policies]
   8. Evaluates the effectiveness of its medication management system and this Policy by:
      1. Collecting, analyzing, and comparing data on performance of the system and this Policy;
      2. Reviewing the literature for technologies and best practices;
      3. Acting on opportunities for improvement when identified within the system and tracking those actions;
      4. Taking additional action when planned improvements are not achieved or sustained.
5. Responsible Individual’s Responsibilities. The Responsible Individual will:
   1. Be qualified through education, training, experience, or certification as follows:
      1. [PLACEHOLDER – include any qualifications, education, training, experience, or certification that your organization shall require for the Responsible Individual.]
   2. Develop and implement the requirements in this Policy based on sources of nationally recognized, accepted professional principles of pharmacy practice and create rules, policies, and procedures for the facility’s pharmacy services necessary to implement these requirements.
   3. Maintain the expertise to conduct effective quality oversight regarding external sources of compounded medications and other compounding policies, practices, and quality assurance within the facility.
   4. Ensure compliance with State law requirements governing who may perform pharmacy services and the supervision of pharmacy staff.
   5. Ensure that pharmacy practices adhere to accepted, nationally recognized professional principles and maintain documentation of the sources of accepted professional pharmacy practices it relies on in developing and implementing rules, policies, and procedures.
6. Responsibilities of the Policy Advisers. At least one active physician and at least one active advanced practice provider will:
   1. Assist and advise regarding the development of this Policy.
   2. Review the developed policy at least every other year.
   3. [PLACEHOLDER – include any education, training, experience, or certification that your organization shall require for these advisers]
   4. [PLACEHOLDER – Populate with any organization-specific selection, appointment, or election procedures applicable]
7. Holistic Planning Related to Maintenance and Use of Drugs and Biologicals
   1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
   2. The facility coordinates the following planning efforts across multiple services and disciplines to ensure the safety and quality of medication management.
   3. *Access to Patient Information*
      1. The facility ensures that each licensed independent practitioner and staff member who participates in a patient’s medication management has access to the following information about the patient:
         1. Age
         2. Sex
         3. Diagnoses
         4. Allergies
         5. Sensitivities
         6. Current medications
         7. Height and weight (when necessary)
         8. Pregnancy and lactation information (when necessary)
         9. Laboratory results (when necessary)
   4. *High-Alert and Hazardous Medications*
      1. The facility develops and maintains a list of High-Alert medications and Hazardous medications, including sample medications, based on the facility’s utilization patterns, internal data about medication errors and sentinel events, and safety issues published in professional literature.
      2. The facility develops and follows a process to manage High-Alert and Hazardous medications, including sample medications.
      3. As needed, the facility will ensure that appropriate information to avoid medication errors or adverse events is incorporated into the Adverse Drug Reactions and Drug Administration Errors Policy.
   5. *Look-Alike and Sound-Alike Medications*
      1. The facility develops and maintains a list of look-alike and sound-alike medications, including sample medications, that are stored, dispensed, or administered within the facility. The facility reviews the look-alike and sound-alike list annually.
      2. The facility takes actions to prevent errors involving the interchange of medications, including sample medications, that look-alike or sound-alike.
      3. As needed, the facility will ensure that appropriate information to avoid medication errors or adverse events is incorporated into the Adverse Drug Reactions and Drug Administration Errors Policy.
   6. *Selection and Procurement of Medications*
      1. For rehabilitation and psychiatric distinct part units, medical staff members, licensed independent practitioners, pharmacists, and staff develop written criteria for determining which medications, including sample medications, are available for dispensing or administering to patients.
      2. The facility develops and follows a process to select, approve, and procure medications, including sample medications, for inclusion in its formulary. The process shall include evaluation of at least the following criteria:
         1. Indications for use
         2. Effectiveness
         3. Drug interactions
         4. Potential for errors and abuses
         5. Adverse drug events
         6. Sentinel event advisories
         7. Other risks
         8. Costs
      3. The facility maintains a formulary, which includes medication strength and dosage. The formulary is readily available to all clinical and non-clinical staff and licensed independent practitioners involved in medication management.
         1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols regarding where formulary available to all personnel.]
      4. The facility standardizes and limits the number of drug concentrations available to meet patient care needs.
      5. Medications designated as available for dispensing or administration on the formulary are reviewed at least annually based on emerging safety and efficacy information.
      6. The facility addresses all medications, including sample medications, and investigational medications in the storage, dispensing, labeling, and distribution standards in this Policy. Standards specific to these medications may additionally include review, approval, supervision and monitoring, where applicable.
   7. *Shortages and Substitutions*
      1. The facility follows a process to communicate medication shortages and outages to licensed independent practitioners and staff who participate in medication management.
      2. The facility follows written medication substitution protocols to be used in the event of a medication shortage or outage.
      3. The facility follows a process to communicate the medication substitution protocols for shortages or outages to licensed independent practitioners and staff who participate in medication management.
   8. *Medications Procured Outside the Hospital or Self-Administered*
      1. The facility safely controls medications brought into the facility by patients and their families.
      2. The facility clearly indicates when patients or their families may bring medications into the facility, when those medications may be administered, who may administer the medications, the training and supervision required for administration or self-administration, and documentation required.
      3. Before use or administration of medication brought by a patient or family member, the facility will identify the medication and visually evaluate the medication’s integrity.
   9. *Medication Orders*
      1. Only appropriately licensed health care practitioners are permitted to order medications or approve protocols for the administration of certain medications.
      2. The facility undertakes actions to ensure that medication orders are clear and accurate throughout oral or written communication and/or transcription.
      3. [PLACEHOLDER – if applicable, include organization-specific processes and protocols. These should include differentiation between different types of orders (PRN, standing, titrating, taper, range, signed and held, compounded drugs, devices, investigational medications, etc.).]
      4. Facility medication order sheets are updated as indicated by current evidence and practice, and include the following information:
         1. Medication name
         2. Medication dose,
         3. Medication route
         4. Medication frequency
         5. Indications for use (when required)
         6. Precautions for Look-Alike and Sound-Alike medications
         7. Actions when medication orders are unclear
         8. Elements required for medication titration orders.
         9. [PLACEHOLDER – if applicable, include organization-specific processes and protocols. These should include objective clinical criteria which are then included in Section VII below for reference and should be tailored to the populations treated by the facility. For example, if the CAH treats a significant number of pediatric patients, include information about weight-based dosing, if applicable.]
      5. A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the facility and all concerns, issues, or questions are clarified with the individual prescriber before dispensing.
      6. All medication orders are reviewed for the following information:
         1. Patient allergies or potential sensitivities
         2. Existing or potential interactions between the medication ordered and food and medications the patient is currently taking
         3. The appropriateness of the medication, dose, frequency, and route of administration
         4. Current or potential impact as indicated by laboratory values
         5. Therapeutic duplication
         6. Other contraindications
      7. When an on-site pharmacy is not open 24 hours a day, 7 days, a week, a health care professional determined to be qualified, review the medication order in the pharmacist’s absence. The pharmacist will conduct retrospective review of all medication orders reviewed when the pharmacist is absent.
8. Storage and proper environmental conditions.
   1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
   2. Medication storage is designed to assist in maintaining medication integrity, promoting the availability of medications when needed, minimizing the risk of diversion, and reducing dispensing errors.
   3. The facility will ensure appropriate storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.
      1. Where provided, the facility will follow all manufacturers’ FDA-approved labeled conditions for storage of drugs including environmental conditions such as temperature, humidity, and exposure to light.
      2. The facility will exercise caution in dispensing or using any drug or biological that is not labeled to indicate proper storage conditions or that may have been stored under inadequate conditions.
      3. The facility removes all expired, damaged, or contaminated medications and stores them separately from medications available for administration.
   4. Compounded sterile medications (“CSPs”) will be packaged in a manner to protect package integrity and sterility.
      1. The facility will address CSP-specific requirements and have procedures for maintaining the quality of CSPs during storage, transport, and dispensing, specifically with respect to motion, light exposure, temperature, and potentially hazardous contents, and will ensure that such information is effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable.
      2. [PLACEHOLDER – Include any organization-specific procedures or processes used to implement this Section]
   5. Emergency services medications
      1. The facility leaders, medical staff members, and licensed independent practitioners decide which emergency medications and associated supplies will be readily accessible in patient care areas.
      2. Medication used in treating emergency cases are readily available for treating emergency cases.
      3. The items available will include the following:
         1. Analgesics;
         2. Local anesthetics;
         3. Antibiotics;
         4. Anticonvulsants;
         5. Antidotes and emetics;
         6. Serums and toxoids;
         7. Antiarrythmics;
         8. Cardiac glycosides;
         9. Antihypertensives;
         10. Diuretics;
         11. electrolytes and replacement solutions (but concentrated electrolytes are present only when patient safety necessitates their immediate use); and
         12. Any other drugs and biologicals commonly used in life-saving procedures.
      4. Used or expired emergency medications or supplies are replaced or restocked as soon as possible to ensure maintenance of a full stock.
   6. The facility periodically inspects all medication storage areas for compliance with the requirements of this Policy.
9. Security of drugs and biologicals:
   1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
   2. Facility policies and procedures are consistent with State and Federal law in addressing who is authorized access to the pharmacy or drug storage area.
   3. Drugs and biologicals are stored in a secure manner to prevent unmonitored access by unauthorized individuals.
      1. Areas restricted to authorized personnel only are considered “secure areas.”
      2. For the storage of non-controlled drugs and biologicals, the facility is permitted flexibility when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion, such that areas in which staff are actively providing care to patients or preparing to receive patients are considered “secure areas.”
      3. Both controlled and non-controlled substances are locked up when a patient care area is not staffed or patient care is not being provided.
      4. Drugs and biologicals are not stored in areas that are readily accessible to unauthorized persons.
   4. Medication carts, anesthesia carts, epidural carts, and other non-automated medication carts containing drugs or biologicals will be secured when not in use.
      1. Authorized Personnel will be close by and directly monitoring carts containing drugs and biologicals that are in use and unlocked as these persons are responsible for the security of the drugs and biologicals in the cart. Authorized Personnel will further be aware of other people’s activities near the cart.
      2. [PLACEHOLDER – The facility’s is 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. Please provide those policies and procedures here or reference where providers may find the relevant information]
   5. Previously dispensed but unused, expired, or returned medications in the critical access hospital will be accounted for, controlled, and disposed of in order to keep patients safe and prevent diversion.
   6. The facility develops and follows written rules, plans, or policies addressing who controls medication between receipt by an individual health care provider and administration of the medication, including safe storage, handling, wasting, security, disposition, and return to storage.
10. Handling drugs and biologicals*:*
    1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
    2. The facility is responsible for ensuring proper Handling of drugs and biologicals whether furnishing the services via facility staff or a contractor.
    3. Except in emergencies or when not feasible, only the pharmacy department or a qualified contracted pharmacy shall perform reconstituting, mixing, admixing, or compounding associated with Handling.
11. Dispensing drugs and biologicals*:*
    1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
    2. The facility will comply with applicable State law that governs the qualifications, certification, or licensure of staff who dispense drugs and biologicals.
    3. The facility will maintain sufficient numbers and types of personnel to provide accurate and timely medication delivery.
    4. Medications will be dispensed in a timely manner.
    5. Medications are dispensed in a manner to avoid diversion and for accurate recordkeeping.
    6. Medications are dispensed in the most ready-to-administer forms commercially available and, if feasible, in unit doses that have been repackaged by the pharmacy or licensed repackager.
    7. Pharmacy staff will clarify any concerns, issues, or questions about the medication order with the prescribing practitioner or another practitioner responsible for the care of the patient before dispensing.
    8. The facility will 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.
       1. 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 tele-pharmacy contracting, on-call pharmacists, etc.
    9. The facility utilizes a unit dose system, individual prescription, floor stock system or a combination of these systems, properly stored, which should be used as follows:
       1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
    10. Only the following Authorized Personnel can access medications afterhours:
        1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
    11. When the pharmacy is closed or non-operational, staff shall follow the following process to provide medications to patients:
        1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
        2. Only the following non-pharmacist health care professionals are permitted to obtain medications after the pharmacy closes:
           1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
        3. The facility maintains a list of approved medications that will be available when the pharmacy is closed
        4. The facility stores and secures the medications approved for use outside of the pharmacy and in accordance with the storage and safety standards in this Policy.
        5. Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system such as bar coding) are in place to prevent medication retrieval errors.
        6. The facility arranges for a qualified pharmacist to be available either on-call or at another location (for example, at another organization that has 24-hour pharmacy service) to answer questions or provide medications beyond those accessible to non-pharmacy staff.
    12. The facility has adopted the following processes, which should be implemented as follows:
        1. A do-not-use abbreviation list in accordance with 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) ;
        2. A high alert drug list in accordance with the Institute for Safe Medication Practices (https://www.ismp.org/tools/institutionalhighAlert.asp);
        3. For specific high alert medications designated by the facility, two health professionals independently check doses in accordance with guidance from the Institute for Safe Medication Practices concerning appropriate use of double-checks (http://www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=51);
        4. Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;
        5. 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;
        6. The facility 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
        7. Floor stocks of medications should be limited to medications for emergency use and routinely used safe items (e.g. mouthwash, antiseptic solutions) in accordance with guidance from The American Society of Health-System Pharmacists (ASHP)
        8. When utilizing automated dispensing cabinets (ADCs), include the following the Institute for Safe Medication Practices recommendations regarding security processes to ensure adequate control of medications outside of the pharmacy and to reduce the potential for medication diversion from ADCs: (See: http://www.ismp.org/Newsletters/acutecare/articles/20090212.asp and http://www.ismp.org/Tools/guidelines/ADC\_Guidelines\_Final.pdf ).
        9. Utilize biometric user identification or, at a minimum, change user passwords quarterly.
        10. 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.
        11. Limiting the availability of overrides to the ADC system.
        12. Limiting access to drugs based on the patients profile so to decrease medication selection errors.
        13. Store each medication and strength in an individual lidded ADC compartment that opens only when the specific medication is selected.
        14. 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.
        15. 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.
12. Administration of drugs and biologicals to patients*:*
    1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
    2. Staff who administer drugs and biologicals are appropriately certified, qualified, and licensed and adhere to accepted standards of practice for medication administration.
    3. Before administration, the individual administering the medication does the following:
       1. Verifies that the medication selected matches the medication order and product label
       2. Visually inspects the medication for particulates, discoloration, or other loss of integrity
       3. Verifies that the medication has not expired
       4. Verifies that no contraindications exist
       5. Verifies that the medication is being administered at the proper time, in the prescribed dose, and by the correct route
       6. Discusses any unresolved concerns about the medication with the patient’s licensed independent practitioner, prescriber (if different from the licensed independent practitioner), and/or staff involved with the patient's care, treatment, and services
       7. Informs the patient or family about any potential clinically significant adverse drug reactions or other concerns regarding administration of medication.
       8. If the medication is a radioactive pharmaceutical for diagnostic purposes, staff verifies that the dose to be administered is within 20%of the prescribed dose, or, if the dose is prescribed as a range, staff verify that the dose to be administered is within the prescribed range.
    4. All drugs, biologicals, and intravenous medications are 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.
       1. To minimize treatment delays and patient backup, emergency departments are permitted to let qualified staff administer medications ordered by a licensed independent practitioner. The practitioner s not required to remain at the patient’s bedside during administration, but will be available to provide immediate intervention if the patient experiences an adverse drug event.
       2. In the radiology department, licensed independent practitioner will provide direct supervision of a patient during and after IV contrast media is administered to ensure the practitioner’s timely intervention in the event of a patient emergency.
13. Recordkeeping for the receipt and disposition of all scheduled drugs*:*
    1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
    2. Staff will timely and accurately track the receipt and disposition of all scheduled drugs used within the facility in the facility’s recordkeeping system to ensure that drug use and inventory records properly account for all drugs
       1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this requirement. Specifically, address any unique processes related to the facility’s EMR or staff requirements for documentation]
    3. The facility’s recordkeeping system for scheduled drugs shall ensure:
       1. Locked storage of scheduled drugs when not in use.
       2. Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.
       3. Movement tracking 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.
       4. Provision of documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs
       5. Any discrepancies in count are reconciled promptly. The facility 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.
14. Ensuring that outdated, mislabeled, or otherwise unusable drugs are not used or available for patient care*:*
    1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
    2. The facility has pharmacy labeling, inspection, and inventory management systems that ensure that outdated, mislabeled, or otherwise unusable drugs and biologicals, including drugs that are discontinued or the subject of a manufacturer’s recall, are not available for patient use. The facility notifies staff, prescribers, and patients or recalls or discontinuations.
    3. 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.
    4. 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.
    5. 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 should take 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.
    6. The BUD should be based on information provided by the manufacturer, whenever such information is available. When complete BUD information is not available from the manufacturer, the facility will implement and maintain policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD (for both medications compounded in-house and from external sources) that are consistent with or more stringent than applicable nationally accepted standards.
       1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this requirement. ]
    7. Pharmacy personnel assigned to determining BUDs when a manufacturer’s instructions are unavailable will have the expertise and technical support needed to properly conduct the assessments needed to make such determinations in a manner consistent with standards and facility policies.
       1. [PLACEHOLDER – include any qualifications, education, training, experience, or certification that your organization shall require for the pharmacy personnel responsible for these determinations.]
    8. For individual drug containers:
       1. Each floor stock drug container will be labeled with the:
          1. Name
          2. strength of the drug,
          3. lot and control number equivalent,
          4. amount,
          5. expiration,
          6. date prepared, and
          7. the diluent for all compounded intravenous admixtures and parenteral nutrition formulas.
       2. Appropriate accessory and cautionary statements will be included as well as the expiration date and/or, if applicable, a BUD.
       3. Where applicable, each patient’s individual drug container is expected to be labeled with the patient’s full name and strength and quantity of the drug dispensed.
    9. If the facility uses the unit dose system, each single unit dose package will be labeled with the name and strength of the drug, lot and control number equivalent, expiration date, and/or, if applicable, a BUD.
15. Compounding*:*
    1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this Section.]
    2. Compounding will be performed consistent with accepted professional principles applicable to both sterile and non-sterile compounding to protect against physical, chemical, or microbial contamination and unintended variations in strength.
    3. Staff engaging in sterile and non-sterile compounding should be knowledgeable about applicable levels of aseptic practices.
       1. [PLACEHOLDER – include any qualifications, education, training, experience, or certification that your organization shall require for the pharmacy personnel responsible for these activities.]
    4. Staff visually inspect preparations for particulates, discoloration, or other loss of integrity.
    5. The facility uses a laminar airflow hood or other ISO Class 5 environment in the pharmacy for preparing intravenous(IV) admixture or any sterile product that will not be used within 24 hours.
    6. The facility pharmacy shall ensure that all sterile and non-sterile compounded preparations dispensed and/or administered to the facility’s patients are being compounded consistent with accepted professional standards to ensure safety.
    7. Only pharmacists or other personnel authorized in accordance with State and Federal law may compound, label, and dispense drugs or biologicals, regardless of whether the services are provided by facility staff or under arrangement.
       1. [PLACEHOLDER – include any qualifications, education, training, experience, or certification that your organization shall require for the individuals responsible for these activities.]
    8. The facility will ensure that its standard operating procedures for compounding, if performed in-house, and for quality oversight of compounding, regardless of source, are consistent with accepted professional principles and quality assurance practices.
       1. The Responsible Individual shall identify and document the risk level(s) of the compounded sterile medications (“CSPs”) being produced in-house and/or obtained from external sources.
       2. The Responsible Individual shall ensure that sterile compounding practices are consistent with standards for the risk level(s) of CSPs being produced for/dispensed to facility patients, including:
          1. Verifying compounding accuracy and sterility;
          2. Ensuring environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection;
          3. Ensuring 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.
16. Use of Outside Compounders*:*
    1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this requirement. ]
    2. Compounding may take place in the facility’s pharmacy on-site and/or the facility may obtain some or all of its compounded medications from external sources in accordance with this Policy.
       1. If the facility uses compounded medications from external sources, the facility may consider using a registered Outside Compounder published on the FDA’s posted list of Registered Human Drug Compounding Outsourcing Facilities.
       2. The facility may also use a the ASHP Research and Education Foundation “Outsourcing Sterile Products Preparation: Contractor Assessment Tool” for assessing vendors that provide compounded sterile preparations. The tool is available at <http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx>
    3. If the facility obtains compounded products from an external source that is not an FDA registered Outside Compounder or a manufacturer, the facility will ensure that the external source adheres to accepted professional principles for safe compounding.
    4. Contracts with external sources that are not FDA registered Outside Compounders or manufacturers shall require the external source to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products.
17. Assessing adverse drug reactions and medication administration errors*:*
    1. [PLACEHOLDER – if applicable, include organization-specific processes and protocols related to this requirement. ]
    2. Staff shall identify, respond to, and report adverse drug reactions and medication administration errors in accordance with the Adverse Drug Reaction and Medication Errors Policy.
    3. Pharmacy services shall assess all such reports to determine if problems or errors in pharmacy services caused or contributed to the adverse reaction or medication administration error in accordance with the Adverse Drug Reaction and Medication Errors Policy.
18. **CROSS-REFERENCED POLICIES**

Related Drugs and Biologicals Policies: [Include specific drugs and biologicals policies, *if not addressed in separate documents* captured in **Section VI. RELATED DOCUMENTS AND FORMS** below. ]

Adverse Drug Reactions and Drug Administration Errors Policy: [PLACEHOLDER: Policy # - Reference your organization’s Adverse Drug Reactions and Drug Administration Errors Policy to account for the overlap existing amongst the two policies regarding the role of Pharmacy Services.]

Antimicrobial and Antibiotic Stewardship Policy: [PLACEHOLDER: Policy # - Reference your organization’s Antimicrobial and Antibiotic Stewardship Policy to account for the overlap existing amongst the two policies.]

Pharmacy Services Policies and Procedures: [PLACEHOLDER: Policy # – If applicable to your organization, cross-reference or incorporate any relevant policies, procedures, or requirements that address or overlap with standards in alignment with this policy.]

Nursing Services Policies and Procedures: [PLACEHOLDER: Policy # – If applicable to your organization, cross-reference any relevant policies, procedures, or requirements that address or overlap with standards in alignment with this policy.]

Physical Plant and Environment Program: [PLACEHOLDER: Policy # - If applicable, reference your organization’s housekeeping and preventive maintenance programs which should include procedures to ensure drugs and biologicals are appropriately stored.]

Emergency Services Policies and Procedures: [PLACEHOLDER: Policy # - If applicable to your organization, cross-reference any relevant policies, procedures, or requirements that address or overlap with emergency medication storage and stocking standards in alignment with this policy.]

Clinical Research Policies: [PLACEHOLDER: Policy # - If applicable to your organization, cross-reference any relevant policies, procedures, or requirements related to investigational medications.]

1. **RELATED DOCUMENTATION AND FORMS**

Related Drugs and Biologicals Documents: [Include specific drugs and biologicals documentation, standards or forms *if not addressed in separate policies* captured in **Section V. CROSS-REFERENCED POLICIES** above. Include at least the following documents:

1. Formulary
2. Hazardous Drugs List
3. High-Alert Drugs List
4. Sound-Alike and Look-Alike Drugs List]
5. **SOURCES**
6. 42 C.F.R. § 485.618(b)(1)
7. 42 C.F.R. § 485.623(b)(2)
8. 42 C.F.R. §§ 485.635(a)(3)(iv); (d)(3) (2019)
9. The [State Operations Manual, Appendix W](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_w_cah.pdf) includes Survey Procedures and Interpretive Guidelines for this condition of participation, which are encompassed in this policy. In future reviews, update with any new procedures and guidelines.
10. The Joint Commission, Critical Access Hospital – Medication Management Chapter, MM.07.01.01 *et seq.*
11. If applicable, manufacturers’ guidelines defining the facility’s approach to medication storage.
12. [PLACEHOLDER – Include any clinical guidelines or best practice documents used to populate the clinical information above. *For example, consider incorporation of standards and guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations including:* [U.S. Pharmacopeia](http://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](http://www.nccmerp.org), [the Institute for Healthcare Improvement](http://www.ihi.org/ihi), or [the Infusion Nurses Society](http://www.ins1.org). A list of high-alert medications, is available at <https://www.ismp.org/recommendations>. A list of hazardous drugs is available at <https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf>. A list of look-alike/sound-alike medication name pairs is the Institute for Safe Medication Practice, available at <https://www.ismp.org/recommendations/confused-drug-names-list>.]