

**Standards of Practice
2004
Montana Pharmacy Association**

These standards are intended to improve the quality of the practice of pharmacy and the delivery of pharmaceutical care in Montana. They have been developed by the Montana Pharmacy Association and undergo annual review and updating.

D) Initial Evaluation

A) Obtain and utilize patient history data as appropriate for level of care provided

- 1) Pharmacists perform medication histories (including prescription, OTC and Herbal/Alternatives products) on all new patients.
- 2) Minimum data required for all levels of care
 - 2.1 Condition being treated
 - 2.2 Allergy information
 - 2.3 Age
 - 2.4 Current disease states
 - 2.5 If pediatric, weight and date of birth
 - 2.6 Pregnancy/lactation status
- 3) Minimum data required for higher levels of care
 - 3.1 Have access to and utilize relevant patient information consistent with the level of care being provided by the pharmacist.
 - 3.1.1 Renal and hepatic status
 - 3.1.2 Nutritional status
 - 3.1.3 Blood chemistry panel
 - 3.1.4 Complete blood count
 - 3.1.5 Serum drug levels
 - 3.1.6 Physical assessment of patient
- 4) All patient data is maintained in a confidential information system for storage and rapid retrieval of patient information records.
 - 4.1 The pharmacy maintains a computerized prescription profile for each individual patient that shall be used during the prescription dispensing process, patient counseling, and patient assessment.

B) Prescription/Medication Order

- 1) A prescription/medication order should be legible and contain the following:
 - 1.1 The date the order was written;
 - 1.2 The patient's name, address and birth date;
 - 1.3 The indication for which the medication was prescribed;
 - 1.4 Medication name and strength;
 - 1.5 Medication dose;
 - 1.6 Medication route;
 - 1.7 Patient instructions;
 - 1.8 Quantity to dispense;
 - 1.9 Refills available;
 - 1.10 Prescriber signature and information. If the signature is not legible the prescriber should legibly print their name;
 - 1.11 If appropriate, it should contain the time the order was written, the time the medication is to be given, the duration of therapy, and specific dosage form to be dispensed;
 - 1.12 For pediatric patients, it should include the patient weight, calculated dose and mg/kg.

- 2) A pharmacist reviews all prescriptions/medication orders prior to drug administration to a patient

- 3) All verbal or telephone orders should be read back to the prescriber to ensure accuracy.
 - 3.1 When a prescription/medication order is transmitted by a verbal or telephone order, the name and title of the person who issued the order and the name of the pharmacist who transcribed the order should be present.
 - 3.2 For telephone orders left on voice mail or answering machines, the prescriber should be directed to repeat the order at least once and give one verifying piece of information to confirm the patient's identity (e.g. birthday).
 - 3.3 The prescriber should be directed to mention the drug's indication when giving verbal orders to help avoid misinterpretation.
 - 3.4 Prescribers should speak directly with pharmacy staff rather than having prescriptions phoned in by support staff. If this is not possible, the prescription should be faxed to the pharmacy after it is called in by support staff, or the patient should take the original prescription to the pharmacy when picking up the medication. If the latter approach is used, it needs to be clearly indicated on the document that the prescription is a duplicate and for informational purposes only. The

name and phone number of the pharmacy where the verbal order was phoned in should also be indicated.

3.5 Verbal or telephone orders for cancer chemotherapy are not acceptable.

C) Medication Verification/Selection

- 1) The pharmacist ensures that the medication is appropriate for the patient, verifying that it is the right drug, route, dose, duration, and directions.
- 2) The pharmacist resolves all medication problems/questions directly with the prescriber in a time frame and manner which meets the patient's needs and documents these patient care interventions
- 3) The pharmacist utilizes a pharmacy computer system to compare all new medication orders/prescriptions with the patient's current medication profile to detect dosage problems, potential contraindications, drug-drug interactions, drug-disease interactions, drug-laboratory interactions, and therapeutic duplication before dispensing. The pharmacy computer system should also:
 - 3.1 Provide the ability to set sensitivity of drug-drug interaction warning flags to minimize non-clinically relevant warnings;
 - 3.2 Automatically conduct dose range checks and warn practitioners about potential underdoses and overdoses;
 - 3.3 Have a required field for patient allergies such that prescription orders cannot be entered unless the patient's allergies have been properly coded and entered;
 - 3.4 Alert staff of new drugs entered for which there is no screening information;
 - 3.5 Provide special alerts to remind practitioners about problematic drugs such as high risk medications and look-alike/sound-alike drug names, packaging, and labeling;
 - 3.6 Have adequate backup and recovery systems.

D) Establish/Document goals of therapy

- 1) If not implicit, the pharmacist establishes and documents the pharmacotherapeutic goals so as to be able to adequately assess the attainment of these goals upon subsequent patient evaluation.

II) Medication Preparation, Dispensing, and Patient Counseling

A) Medication Preparation/Dispensing

- 1) Medications must be prepared in a clean and uncluttered area appropriate for the type of medication being handled.

- 2) Sufficient equipment necessary to carry out the activities of the pharmacy shall be available. The equipment shall be maintained in good operating condition. Procedures for routine cleaning, maintenance, and calibration shall be documented and routinely performed.
- 3) An ongoing quality assurance process is utilized to detect and correct any issues related to the content and quality of prepared products.
- 4) All medications are properly labeled in accordance with state and federal law, including samples.
- 5) A standard routine is used to enter, fill, and check prescriptions
 - 5.1 The pharmacist ensures legibility of the prescription and contacts the prescriber for clarification on all ambiguous or questionable orders (e.g. take as directed, unclear abbreviations, etc).
 - 5.2 The pharmacist double checks all dose, height, weight, and any other applicable calculations and if necessary verifies them with an appropriate reference or protocol.
 - 5.3 A “double check” system is in place for anyone who enters, fills and checks the prescription.
 - 5.4 Pharmacy personnel look at the written prescription when filling and checking the prescription.
 - 5.5 Pharmacy personnel work with one drug product at a time and affix the label to the patient’s prescription container before working on the next prescription. No prescription containers are left unlabeled.
 - 5.6 If possible, “multiple sets of eyes” are engaged in the dispensing process (e.g. one person enters the prescription into the pharmacy computer system, another person fills the prescription, and another pharmacist checks the final product.)
 - 5.7 The pharmacist provides or oversees the final review and verification for accuracy of the completed prescription order prior to dispensing. Documentation of this verification is maintained as part of the prescription record.
 - 5.8 The pharmacy follows a standard process to ensure that the medications are actually given to the correct patient (e.g. patient’s complete name, address, and phone number are verified prior to giving them the medication).
- 6) The medication is provided to the patient in a timely manner consistent with the patient’s condition.
- 7) Proper measuring devices are dispensed or recommended (e.g. oral syringe) with all liquid medications.

- 8) Patients are notified of last refills or prescription expiration so as to allow adequate time for the patient to contact the prescriber.

8.1 Pharmacists should utilize all avenues available to ensure that patients have access to a limited supply of their medications in order to provide continuous therapy when situations arise which may limit the patient's ongoing drug therapy (such as emergency trips, lost drug supply, etc.).

B) Non-Sterile Compounding

- 1) Pharmacists who engage in drug compounding are competent and proficient in the art of compounding and maintain proficiency through training. Pharmacists engaged in compounding comply with good manufacturing practices and all applicable state and federal laws and regulations related to the compounding and/or manufacturing of drug products.
- 2) Accountability for the ongoing quality control program is the responsibility of the compounding pharmacist.
- 3) Pharmacies who engage in compounding have an adequate area for the orderly compounding of prescriptions, including the placement of equipment and materials. The area used for compounding is maintained in a clean and sanitary condition. Equipment used in compounding is of appropriate design, appropriate capacity, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in compounding is of suitable composition so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. Automatic, mechanical, electronic, or other equipment used in compounding is routinely inspected, calibrated, and checked according to the manufacturer's recommendations to ensure proper performance. Equipment and utensils used in compounding are cleaned, sanitized, and stored appropriately to prevent contamination.
- 4) Written procedures for the compounding of drug products shall be followed to ensure the safety, identity, strength, quality, and purity of the finished product. These written procedures include a listing of the bulk drug substances and components, their amounts in weight or volume, the order of bulk drug substance or component addition, and a description of the compounding processes. All equipment and utensils as necessary shall be listed.
- 5) Bulk substances and components used in compounding shall meet all USP standards. If no USP monograph exists for a substance used in compounding, it must be a component of an FDA approved food or drug or must appear on a list of bulk drug substances developed by the FDA. In addition, the substance must be manufactured at an FDA registered establishment and be accompanied by a valid

certificate of analysis. All bulk substances must be stored appropriately according to required guidelines for the product.

6) Bulk drug substances and components used in the compounding of drug products are accurately weighed or measured as appropriate. These operations are verified and documented at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures.

7) A production record is maintained for each drug product compounded, both that prepared for an individual patient or prepared in bulk. This record contains the production date, list of ingredients and quantities of each ingredient used, amount made, initials of each person involved in each of the compounding steps, initials of the pharmacist verifying each of the compounding steps, and the prescription number. Bulk products that are compounded in advance and used to fill prescriptions based upon prior prescribing patterns are assigned a unique internal control number. When some of the bulk product is dispensed, this internal control number is documented in the prescription record.

8) To ensure the reasonable uniformity and integrity of compounded drug products, tests or examinations are conducted where appropriate on the product being compounded to monitor the output and to validate the performance of the compounding processes. Control procedures include, when applicable, capsule weight variation, adequacy of mixing to ensure uniformity and homogeneity, and clarity or pH of solutions.

9) When applicable, the compounded product shall be labeled with an expiration date based upon published data. When such data is unavailable, expiration dating shall be based upon professional judgment or appropriate testing.

10) For each batch of drug product compounded, labels are affixed that contain the drug product name or formula, dosage form, strength, quantity per container, internal control or prescription number, and expiration date.

C) Sterile Compounding

1) All injectable, ophthalmic, otic or inhaled products are prepared in a sterile environment in accordance with USP Chapter 797, Pharmaceutical Compounding: Sterile Preparations, where applicable.

D) Counseling/Patient Education

- 1) The pharmacist is readily accessible and identifiable to patients and health care providers in a timely manner consistent with the needs of the patient.
- 2) The pharmacist performs and documents patient counseling appropriate for the patient's current needs.

- 3) Prior to counseling the pharmacist assesses the patient's baseline understanding related to the following: What did the prescriber tell you the medication is for? How did the prescriber tell you to take the medication? What did the prescriber tell you to expect?
 - 3.1 Counseling appropriate for the needs of the patient should then cover the following points related to the above questions:
 - 3.1.1 What the medication is for
 - 3.1.1.1 Name of the medication
 - 3.1.1.2 Purpose of the medication
 - 3.1.1.3 Dosage form
 - 3.1.2 How to take the medication
 - 3.1.2.1 Dosing schedule
 - 3.1.2.2 Duration of therapy
 - 3.1.2.3 Special directions
 - 3.1.2.4 Storage recommendations
 - 3.1.2.5 Missed dose information
 - 3.1.2.6 Refill information
 - 3.1.3 What to expect from the medication
 - 3.1.3.1 Expected outcomes
 - 3.1.3.2 Precautions
 - 3.1.3.3 Common possible side effects
 - 3.1.3.4 Possible interactions
 - 3.1.3.5 Techniques for self monitoring
 - 3.2 If the patient is present, show the medication to the patient during dispensing whenever possible. Ensure that the color, shape, and size of the medication are consistent with what the patient has received in the past. If the medication is not consistent, confirm the identity with the patient prior to dispensing.
 - 3.3 The pharmacy keeps reference material or has other procedures in place to facilitate counseling to non-English speaking patients, individuals with disabilities, or other populations with special needs.
 - 3.4 The patient should be informed how they can contact a pharmacist should later questions arise.
- 4) The pharmacist assesses understanding of the education provided and delivers additional counseling if necessary to ensure the patient and/or caregiver has an adequate understanding of the drug regimen.
- 5) The pharmacist always provides written drug information commensurate with the language and cognitive level of the patient and/or caregiver. This written information reinforces the information already covered in verbal counseling. Written information never supplants the need for verbal counseling.
- 6) Pharmacists educate and inform patients about general principles or strategies they can do to help prevent medication errors and adverse drug reactions.

III) Medication Administration

A) Pharmacists administer medications in a safe and consistent manner which includes the following:

- 1) Accurate identification of the patient
- 2) Final verification of the right drug, route, dose, duration, directions and time.
- 3) Shows the medication to the patient, if appropriate.
- 4) If applicable, ensure adequate training has been completed to safely operate infusion pumps and other drug delivery devices.

IV) Monitoring/Assessment of Drug Therapy

A) The pharmacist regularly communicates with the patient and/or caregivers and prescribers in order to perform the following:

- 1) Assess patient adherence with the prescribed regimen at every patient encounter. When the pharmacist notices that a patient is not adhering to his or her prescribed regimen, the pharmacist discusses the situation with the patient and, if necessary, notifies the patient's prescriber.
- 2) Assess the achievement of therapeutic goals of drug therapy.
 - 2.1 Assess toxicity and efficacy of the prescribed regimen and document at appropriate intervals (e.g. blood pressure, cholesterol level, liver enzymes, symptoms, etc.)
 - 2.2 If the therapeutic goals have not been met, the pharmacist collaborates with the patient and prescriber to modify or change the regimen in order to attain the desired therapeutic goals.
- 3) Re-assess the patient's understanding of drug therapy and provide additional patient teaching as necessary.
- 4) On a regular basis, the pharmacist reviews the patient's profile, assessing potential drug-related problems and discusses the problems with the prescriber if necessary. The following are reviewed where appropriate depending upon the needs of the patient:
 - 4.1 Untreated indications
 - 4.2 Medication use without an indication
 - 4.3 Contraindications
 - 4.4 Improper drug selection
 - 4.5 Overdose/sub-therapeutic dose
 - 4.6 Therapeutic duplication
 - 4.7 Potential drug interactions
 - 4.8 Weight changes
 - 4.9 Appropriate duration of therapy

V) Purchasing/Inventory Management

A) Pharmacists implement and oversee an inventory control system that assures drug availability and safety.

- 1) Dangerous products, concentrated solutions, and look-alike sound-alike products are stored in a manner to minimize possible mix-ups.
- 2) If drugs with more pronounced error potential must be purchased, safety enhancement strategies are initiated prior to the use of the product (e.g. separate from existing stock, use a differentiating label, etc.)
- 3) A routine expiration date checking system is implemented for all drug products.
- 4) Medication supplies are rotated during restocking to minimize product expiration.
- 5) All pharmaceutical products are stored in a manner consistent with the original manufacturer's labeling requirements and the United States Pharmacopeia standards.
- 6) A system is implemented which ensures that appropriate storage conditions exist for all drugs at all times (e.g. refrigerated storage conditions during power outages).
- 7) Appropriate security measures and systems in accordance with state and federal laws and regulations are in place in the pharmacy.

B) Pharmacists take a proactive approach to identify potential drug shortages.

- 1) Pharmacists manage existing supplies of medications in short supply to ensure their most rational use.
- 2) Pharmacists work with patients and prescribers to identify alternative therapeutic options for drugs that are unavailable.

VI) Systems of Care

A) Quality Assurance/Patient Safety

- 1) The pharmacy shall have a quality assurance program designed to ensure the accuracy and quality of the medications dispensed and the pharmaceutical care services offered. There are written policies and procedures which describe the review and verification of key steps in the medication use process.
- 2) A medication error performance improvement process exists which establishes a formalized mechanism for reporting and analyzing medication errors and near misses in an effort to implement system or process improvements to increase medication safety.

- 2.1 Employees are encouraged to report medication errors and near misses and are allowed to suggest potential improvements to the medication use system.
- 2.2 Systems are in place to review trends in reported medication errors and preventable adverse drug events.
- 2.3 A non-punitive system exists so that fear of retribution is not a barrier to medication error reporting. Error prevention strategies should target the system, not individual practitioners.
- 2.4 Training and education is regularly provided on the medication use process and medication error reporting system. An emphasis on medication use safety practices is included in didactic and experiential training of pharmacy staff.
- 2.5 Practitioners involved in a serious or potentially serious medication error help perform root cause analyses to identify the system failures that contributed to the error and redesign the process or underlying system failures to minimize potential for similar errors.
- 2.6 Potential problem-prone aspects of the medication use process are prospectively evaluated to help prevent errors before they occur.

B) Work Environment

- 1) There is adequate work and product storage space to adequately support the volume and activities of the pharmacy.
- 2) Fatigue-reducing environmental conditions are implemented in all areas where medications are ordered, dispensed, and administered (e.g. lighting, temperature, noise-level, ergonomic fixtures).
- 3) Distractions are minimized in all areas where medications are ordered, dispensed, and administered

C) Pharmacy Resources

- 1) As technology advances, any readily available technology that can improve patient safety should be utilized throughout the medication use process (e.g. bar coding, computerized physician order entry, robotics, etc).
- 2) Pharmacists maintain or have ready access to adequate reference material and professional literature. Pharmacists keep abreast of and utilize in their practice the most contemporary evidence-based principles available related to rational drug therapy.

D) Pharmacy Personnel

- 1) A pharmacy shall have adequate organization, management, and staff necessary to comply with all applicable state and federal laws and regulations.
- 2) The pharmacy has sufficient personnel to support the volume and the activities of the pharmacy.

- 3) Double-shifts are minimized and adequate breaks are provided for all pharmacy personnel.
- 4) All pharmacy personnel have the appropriate education, experience, training, and licensure requirement to perform their duties and responsibilities. All pharmacy personnel are initially assessed for competency related to the job functions they are required to perform as part of their job. Ongoing assessment and training are provided and documented to ensure ongoing competency.

E) Patient Confidentiality

- 1) Confidentiality in accordance with all HIPAA standards is always maintained in every step of the medication use process. However, pharmacists have an obligation to always act in the best interest of the patient's safety and welfare if issues arise where not communicating the information to appropriate individuals could cause direct harm to the patient and/or others.
- 2) Computerized patient identifiable information shall be maintained and managed in such a manner as to protect patient confidentiality and so as to restrict access to only those pharmacy personnel that require this information for performance of their duties.
- 3) Confidential patient counseling areas are available.

F) Standards of Practice For Specific Systems of Care

- 1) The Montana Pharmacy Association believes that these Standards of Practice must be updated and refined continuously in order to reflect the dynamic nature of this profession. Accordingly, the Association will continue its work in 2003 and beyond, with especial attention to the following:

Standards of Practice for Long Term Care
Standards of Practice for Institutional Care
Standards of Practice for Home Infusion
Standards of Practice for Pharmacy Technicians