Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 34 BOARD OF PHARMACY

10.34.35 Infusion Pharmacy Services in an Alternate Site Care Environment

Authority: Health Occupations Article, §12-205, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) “Alternate site care environment” means the location where the patient is receiving infusion therapy other than an inpatient hospital setting.

(2) “Compounding worksheet” means a document or electronic record which:

(a) Specifies instructions for a specific compounded parenteral medication;

(b) Documents the manufacturer’s:

(i) Ingredients;

(ii) Lot numbers; and

(iii) Expiration dates; and

(c) Includes a copy of the prescription label.

(3) Delegated Pharmacy Act.

(a) "Delegated pharmacy act" means an activity that constitutes the practice of pharmacy delegated by a licensed pharmacist under Health Occupations Article, Title 12, Subtitle 6B, Annotated Code of Maryland, and this chapter.

(b) "Delegated pharmacy act" does not include:

(i) An act within the parameters of a Drug Therapy Management contract as provided under Health Occupations Article, Title 12, Subtitle 6A, Annotated Code of Maryland;

(ii) The administration of an influenza vaccination in accordance with Health Occupations Article, §12-508, Annotated Code of Maryland, or Health Occupations Article, Title 12, Annotated Code of Maryland;

(iii) The delegation of a pharmacy act by a pharmacy technician, pharmacy student, or pharmacy technician trainee;

(iv) A pharmacy activity performed by a pharmacy student in accordance with Health Occupations Article, §12-301(b), Annotated Code of Maryland;

(v) A pharmacy activity performed by an applicant for a license to practice pharmacy, if the applicant does not perform delegated pharmacy acts for more than 10 months; or

(vi) The performance of other functions prohibited in regulations adopted by the Board.

(4) “End of therapy” means the conclusion of parenteral infusion therapy as ordered by the prescriber.

(5) “Infusion nurse” means a registered nurse providing infusion therapy as defined in COMAR 10.27.20.02B in an alternate site environment.

(6) “Infusion pharmacy” means a pharmacy that provides pharmaceutical care to patients receiving parenteral therapy in an alternate site care environment.

(7) “Licensed authorized prescriber of record” means an individual with the authority to prescribe and monitor a patient’s parenteral infusion therapy for the duration of the patient’s infusion therapy.

(8) “Parenteral infusion access device” means, but is not limited to, intravenous, subcutaneous, intrathecal, epidural, or peripheral nerve catheter device through which parenteral medications may be administered.

(9) “Patient care plan” means an individualized care plan that reflects the patient’s parenteral infusion therapy pharmaceutical monitoring plan aimed at optimizing the outcome of therapy while minimizing untoward effects from the medication.

(10) “Patient triage form” means a written or electronic tool used by a clinician or by a registered pharmacy technician when communicating with a patient, a patient’s caregiver, or an infusion nurse to document the patient’s current status, including but not limited to, the patient’s response to therapy, medication changes or adverse reactions, and pain level.

(11) "Permit holder" means a person, corporation, or other legal entity authorized by the Board to establish and operate a pharmacy.

(12) "Pharmacy technician" means an individual who is registered with the Board to perform delegated pharmacy acts.

(13) “Pharmacist” means an individual who is licensed to practice pharmacy.

(14) “Supervision” means the on-site provision of management, direction, oversight and review of tasks assigned to personnel.

.02 Permit Holder Responsibilities.

The permit holder shall:

A. Develop and maintain a policy and procedure manual which establishes the pharmacy’s policies and standard operating procedures related to the provision of infusion therapy services;

B. Ensure that an annual review of the policy and procedure manual is performed by a qualified clinician or clinicians to assure that the policies and procedures meet the current standards of practice and regulatory requirements;

C. Ensure that there is a process to verify the name, address, and contact information of the licensed authorized prescriber of record before initiation of therapy;

D. Establish and maintain a training program which includes, but is not limited to, the requirements set forth in Regulation .07 of this chapter;

E. If the infusion pharmacy is performing sterile compounding, ensure compliance with COMAR 10.34.19;

F. If the infusion pharmacy outsources sterile compounding to another pharmacy, confirm that the secondary pharmacy is appropriately licensed and in compliance with COMAR 10.34.04 and COMAR 10.34.19;

G. Assign a supervising pharmacist to provide oversight of the facility and operations as specified in Regulation .03 of this chapter;

H. Ensure adequate supervision to unlicensed personnel;

I. Limit access to the infusion pharmacy area to authorized personnel;

J. Secure the facility and patient records in compliance with federal and State laws and regulations; and

K. Develop and implement a written performance improvement program as set forth in Regulation .08 of this chapter.

.03 Supervising Pharmacist Responsibilities.

The supervising pharmacist or the supervising pharmacist's designee shall ensure compliance with:

A. State and federal regulations;

B. Infusion pharmacy practice standards:

(1) As set forth in this chapter; and

(2) As established by nationally recognized professional organizations and accrediting bodies as appropriate;

C. The infusion pharmacy's policies and procedures manual;

D. An established training program; and

E. An established performance improvement program.

.04 Supervising Pharmacist Responsibilities.

A. A pharmacist in an infusion pharmacy shall adhere to the policies and procedures set forth in Regulation .06 of this chapter.

B. A pharmacist shall:

(1) Provide infusion therapy services in accordance with:

(a) Orders issued by a licensed authorized prescriber of record; and

(b) Where applicable, protocols issued by a licensed authorized prescriber of record.

(2) Perform and document initial and ongoing assessments of the appropriateness of infusion therapy using the following information:

(a) Patient demographics including:

(i) Name;

(ii) Address;

(iii) Telephone number;

(iv) Gender; and

(v) Date of birth;

(b) Emergency contact information;

(c) Diagnoses, including:

(i) Diagnosis being treated; and

(ii) Concurrent conditions, including pregnancy and lactation status if applicable;

(d) Medical history;

(e) Allergies;

(f) If applicable, height;

(g) Weight;

(h) Parenteral medication orders, including length of therapy;

(i) Parenteral infusion access device:

(i) Location;

(ii) Type; and

(iii) If available, date of placement;

(j) Ongoing medication profile review and reconciliation at end of therapy;

(k) First dose status;

(l) Caregiver information including, but not limited to:

(i) Name;

(ii) Address;

(iii) Phone number; and

(iv) Relationship to patient;

(m) If applicable, contact information for other agencies or individuals involved in the patient's home care;

(n) Documented applicable medical and social factors and functional limitations which may affect infusion therapy including but not limited to:

(i) Language;

(ii) Sight;

(iii) Hearing;

(iv) History of IV drug abuse;

(v) History of drug or alcohol abuse; or

(vi) Other physical or mental limitations; and

(o) If applicable to therapy, baseline labs;

(3) Create a patient care plan specific to the patient's:

(a) Diagnosis;

(b) Prescribed therapy; and

(c) Concurrent conditions;

(4) When compounding sterile preparations, comply with COMAR 10.34.19;

(5) If sterile compounding is outsourced, comply with COMAR 10.34.04;

(6) As applicable, retrieve and assess lab values and other monitoring parameters;

(7) Document in the patient chart:

(a) New prescription orders;

(b) Changes in prescription orders;

(c) Information obtained from the patient or caregiver; and

(d) Other necessary information obtained from the:

(i) Patient;

(ii) Caregiver;

(iii) Infusion nurse;

(iv) Licensed authorized prescriber of record; or

(v) Other sources relevant to patient care;

(8) Verify prescription label accuracy;

(9) Communicate as appropriate, throughout the patient's therapy with the:

(a) Licensed authorized prescriber of record or agent of the licensed authorized prescriber of record;

(b) Patient's infusion nurse;

(c) Patient; and

(d) Caregiver; and

(10) Review therapy-specific considerations such as pain and nutrition status.

.05 Support Personnel.

A. Pharmacy Technicians.

(1) A pharmacist working in an infusion pharmacy may delegate pharmacy acts to a pharmacy technician in accordance with COMAR 10.34.34.

(2) A pharmacy technician working in an infusion pharmacy may not perform delegated pharmacy acts as set forth in COMAR 10.34.34.03.

(3) A pharmacy technician working in an infusion pharmacy shall:

(a) Communicate immediately to the pharmacist reported changes in:

(i) Patient condition;

(ii) Patient medication list; and

(iii) Allergies; and

(b) Obtain pharmacist approval before processing refills.

(4) A pharmacy technician working in an infusion pharmacy may not:

(a) Except as provided in COMAR 10.34.34, accept or transcribe a new or change verbal order from an licensed authorized prescriber of record or the licensed authorized prescriber of record's agent;

(b) Perform the clinical assessment of a patient;

(c) Communicate clinical matters except as required in §A(3)(a) of this regulations;

(d) Provide therapy-related direction to a patient or caregiver; and

(e) Create a patient care plan specific to a patient's therapy.

B. Unlicensed Personnel.

(1) Unlicensed personnel working in an infusion pharmacy under the supervision of a pharmacist may perform operational support which the unlicensed personnel have been trained to adequately perform in accordance with COMAR 10.34.21.

(2) Unlicensed personnel shall be appropriately trained to perform the following tasks, as applicable, including but not limited to:

(a) Schedule delivery dates based on;

(i) Patient supply needs;

(ii) Patient or caregiver availability; and

(iii) If applicable, geographic delivery zones;

(b) Create delivery tickets;

(c) Communicate with the infusion nurse or pharmacist concerning supply needs and problems; and

(d) Clean, test, and maintain patient-use equipment.

(3) Unlicensed personnel working in an infusion pharmacy shall refer clinical questions or concerns reported by patients or caregivers immediately to the pharmacist.

(4) Unlicensed personnel may not perform delegated pharmacy acts.

.06 Minimum Requirements for Policies and Procedures.

The policies and procedures shall:

A. Be congruent with State regulations and standards of care from accrediting bodies and professional organizations; and

B. Address:

(1) Personnel:

(a) Training and Orientation;

(b) Duties; and

(c) Qualifications;

(2) Security of the facility;

(3) Standards of patient care;

(4) Infection control;

(5) Initial and ongoing home safety assessments;

(6) The provision of patient or caregiver education including, but not limited to:

(a) Drug and therapy administration-specific information and precautions;

(b) Reporting adverse drug reactions;

(c) Reporting side effects;

(d) Infusion pharmacy contact information;

(e) Emergency measures related to:

(i) Changes in patient condition requiring medical intervention; and

(ii) Events which may delay or prevent delivery of pharmaceuticals or nursing care; and

(f) Equipment use and safety.

(7) Patient care operations, including but not limited to:

(a) If applicable, pharmacist checking procedures related to order entry and compounding accuracy;

(b) Therapy-specific monitoring parameters for:

(i) Laboratory testing;

(ii) Appropriate frequency of testing; and

(iii) Patient follow-up; and

(c) Pump, or other patient-use equipment, between-patient cleaning, testing, and preventive maintenance, which include specific:

(i) Procedures and documentation of cleaning, testing and preventive maintenance for patient equipment according to manufacturer's guidelines; and

(ii) Frequencies for all equipment maintenance activities;

(8) Delivery arrangements;

(9) Patient confidentiality and the Health Insurance Portability and Accountability Act, 45 CFR Parts 160 and 164; and

(10) Availability of a pharmacist on call after-hours to respond to:

(a) Pharmacy related patient or caregiver inquiries; and

(b) Medication or supply needs.

.07 Training Requirements.

A. Personnel shall be trained in the following areas where appropriate:

(1) Patient rights and responsibilities;

(2) Patient safety;

(3) Performance improvement program;

(4) Universal precautions which are incorporated by reference in COMAR 10.06.01.01-1;

(5) Warehouse and equipment orientation;

(6) Waste management;

(7) Handling hazardous substances;

(8) Policies and procedures;

(9) Recognizing signs of patient abuse and neglect;

(10) Recognizing signs of IV drug abuse;

(11) Customer service and cultural sensitivity training;

(12) Emergency policies and procedures which support the continuum of patient care during natural or manmade disasters; and

(13) Patient confidentiality and the Health Insurance Portability and Accountability Act, 45 CFR Parts 160 and 164.

B. A pharmacist shall be trained and evaluated in the following areas, including but not limited to:

(1) Clinical management of therapies and disease states managed by the infusion pharmacy services, including but not limited to:

(a) Specific dosing and monitoring protocols;

(b) Care planning;

(c) Lab value ranges; and

(d) Side effects;

(2) Pump use and programming;

(3) Parenteral infusion access devices and therapy-specific appropriateness by device;

(4) Supplies by therapy and device;

(5) Accurate set-up of compounding worksheet instructions;

(6) Pharmacist functions on computer systems;

(7) Documentation;

(8) If performing sterile compounding, COMAR 10.34.19;

(9) Medication storage;

(10) IV compatibility and stability;

(11) Calculations to ensure:

(a) IV dose appropriateness; and

(b) Compounding accuracy, if applicable; and

(12) On-call requirements and procedures for handling after-hours care.

C. A pharmacy technician obtaining clinical information shall be trained and evaluated in the following areas, including but not limited to:

(1) Pharmacy technician functions on computer systems;

(2) Parenteral infusion access devices

(3) Supplies specific to therapy and device

(4) Storage and shipping protocols;

(5) Pharmaceutical calculations for IV compounding, if applicable;

(6) Patient triage forms — therapy-specific training and communication with the pharmacist as specified in Regulation .05A(3)(a) of this chapter; and

(7) Documentation of:

(a) Communication with patients or caregiver; and

(b) Delivery scheduling.

D. Unlicensed personnel shall be trained and evaluated in the following areas as applicable:

(1) Insurance pre-authorization;

(2) Billing;

(3) Delivery procedures;

(4) Supplies;

(5) Picking and packing of supplies;

(6) Drug storage;

(7) Shipping protocols; and

(8) Cleaning, testing, and maintenance of patient-use equipment according to manufacturers' specifications.

.08 Performance Improvement Program.

A. The performance improvement program shall consist of:

(1) A committee which:

(a) Consists of representation of personnel and varied areas of job responsibility; and

(b) Is responsible for analysis of data, reporting trends and corrective actions; and

(c) Meets at least quarterly;

(2) Quality assurance and performance improvement monitoring parameters;

(3) Documentation requirements for:

(a) Established monitoring parameters;

(b) Trend analyses; and

(c) Retention of committee meeting minutes for 3 years;

(4) Documentation of tracking, trending, analyzing, resolving, and developing corrective action plans as appropriate for:

(a) Medication errors;

(b) Adverse drug reactions; and

(c) Equipment malfunctions;

(5) Reporting of adverse events to regulatory and standard-setting bodies as applicable to State and federal regulations;

(6) Documentation and resolution of patient care issues involving:

(a) Incorrect equipment, supplies, or medications;

(b) Delays in delivery of care;

(c) Missed doses;

(d) Patient infections;

(e) Failures in after-hours care; and

(f) Patient, caregiver, or health care provider complaints;

(7) Documentation of patient outcomes;

(8) Recall management;

(9) Patient compliance monitoring; and

(10) Staff training and competency compliance.

B. The permit holder shall review the performance improvement program at a minimum of every 3 years.

.09 Discontinuation of Infusion Therapy.

A. If not addressed in the initial order, the infusion pharmacy shall verify an end of therapy order.

B. The infusion pharmacist shall:

(1) Communicate with the licensed authorized prescriber of record or agent of the prescriber of record to verify:

(a) An end of therapy order, if not addressed in the initial order; and

(b) Parenteral infusion access device disposition, including orders for removal or line maintenance; and

(2) Forward the most current medication list to:

(a) The licensed authorized prescriber of record; and

(b) To the patient or caregiver.

C. If appropriate, the infusion pharmacy shall arrange with the patient or caregiver for pick-up of medical equipment.

.10 Reference Materials.

A. An infusion pharmacy shall maintain an adequate reference library to enable it to prepare and dispense infusion therapy properly.

B. In addition to the requirements of COMAR 10.34.07.03, an infusion pharmacy's reference library shall include:

(1) Material Safety Data Sheets (MSDSs);

(2) IV compatibility references;

(3) Stability and extended stability references;

(4) Websites and electronic references authored by established medical publishers recognized within the field of infusion pharmacy practice as a supplement to its printed library;

(5) Pediatric dosing reference, if applicable; and

(6) Appropriate clinical references for the population served.