Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 34 BOARD OF PHARMACY

10.34.36 Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes

Authority: Health Occupations Article, §§12-205, 12-301, 12-401, 12-403, 12-501, and 12-503-12-506, Annotated Code of Maryland

.01 Scope.

This chapter applies to pharmacies and licensed pharmacists serving assisted living programs or group homes as defined in Regulation .02 of this chapter, except for pharmacies providing only emergency services for assisted living programs or group homes.

.02 Definitions.

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

B. Terms Defined.

(1) Assisted Living Program.

(a) "Assisted living program" means a residential or facility-based program that provides housing and supportive services, supervision, personalized assistance, health-related services, or a combination of these services 24 hours a day, 7 days a week, to meet the needs of individuals who are unable to perform, or who need assistance in performing, the activities of daily living or instrumental activities of daily living, in a way that promotes optimum dignity and independence for the individuals.

(b) "Assisted living program" does not include:

(i) A nursing home or comprehensive care facility, as defined under Health-General Article, §19-301, Annotated Code of Maryland;

(ii) A State facility, as defined under Health-General Article, §10-101, Annotated Code of Maryland;

(iii) A program licensed or approved by the Department under Health-General Article, Title 7 or Title 10, Annotated Code of Maryland;

(iv) A hospice care program licensed by the Department under Health-General Article, Title 19, Annotated Code of Maryland;

(v) Services provided by family members;

(vi) Services provided by a licensed residential service agency or licensed home health agency in an individual's own home; or

(vii) A Certified Adult Residential Environment Program that is certified by the Department of Human Services under Article 88A, §140, Annotated Code of Maryland.

(2) “Chart order” means a lawful order entered on the chart or a medical record of a resident of an assisted living program or group home by an authorized prescriber or the authorized prescriber’s designated agent for a drug or device.

(3) "Group home" means a residence owned, leased, or operated by a licensed group home provider that:

(a) Provides residential services for individuals who, because of a developmental disability, require specialized living arrangements;

(b) Admits at least two, but not more than eight individuals; and

(c) Provides 10 or more hours of supervision per week.

(4) "Interim box" means a tamper evident container or an electronic system holding minimal quantities of medications:

(a) Agreed upon by the appropriate committee of the assisted living program; and

(b) Intended to expedite immediate initiation of emergency or nonemergency dosing until the pharmacy is able to provide a regular supply.

(5) "Licensed pharmacist" means a pharmacist who is licensed by the Board to practice pharmacy.

(6) "Packaging" means the process by which a medication is:

(a) Removed from a:

(i) Non-patient specific manufacturer's original container; or

(ii) Patient specific container directly received from another pharmacy licensed in Maryland or operated by the government of the United States provided that the manufacturer's name is present on the container;

(b) Placed into a new container by a licensed pharmacist or registered pharmacy technician under the direct supervision of a pharmacist; and

(c) Packaged as further defined in Regulation .07 of this chapter.

(7) "Pharmaceutical services" means the care within practice standards, laws, regulations, and guidelines which is afforded by a licensed pharmacist to the residents of an assisted living program or group home.

(8) "Pharmacy area" means that portion of the licensed pharmacy where over-the-counter medications and other products requiring a prescription by federal or State law are stored and where the prescriptions are compounded or prepared.

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

(a) Licensed to engage in the practice of pharmacy in Maryland;

(b) Knowledgeable in, and thoroughly familiar with, the specialized functions of an assisted living program's or group home's pharmaceutical services; and

(c) Responsible for and in full and actual charge of the pharmacy and its personnel.

(10) "Responsible pharmacist" means a pharmacist who is:

(a) Licensed to engage in the practice of pharmacy in Maryland;

(b) Knowledgeable in, and thoroughly familiar with, the specialized functions of an assisted living program's or group home's pharmaceutical services; and

(c) Responsible for and in full and actual charge of the pharmacy and its personnel .

(11) "Verbal order" means a directive that is orally communicated to a licensed pharmacist to accept a prescription order by a person who is authorized to communicate a prescription.

(12) "Written order" means a directive that is directly written by an authorized prescriber or a transcription of an order from an authorized prescriber by a person authorized to transcribe an order.

.03 Policies and Procedures.

The permit holder shall establish and operate under a policies and procedures manual which:

A. Complies with this chapter;

B. Defines the scope and method of pharmacy services provided to the residents of the assisted living program or group home;

C. Determines under what circumstances personnel may have access to the pharmacy area;

D. Provides for the safe and efficient dispensing and delivery of pharmaceutical products as outlined in this subtitle;

E. Includes:

(1) Labeling requirements and distribution methods for medication provided in a single container, slot, blister package, or other method of delivering an entire single dosing unit; and

(2) The conditions in which an interim box may be replenished or prepared, delivered, and stored by the assisted living program;

F. Is provided to:

(1) The personnel of the pharmacy;

(2) The assisted living program;

(3) Group home; and

(4) Upon request, an agent of the Board; and

G. Is in a form that is:

(1) Written or electronic; and

(2) Readily retrievable.

.04 Personnel.

A. The permit holder shall appoint a responsible pharmacist who shall:

(1) Be responsible for the operations of the pharmacy and for compliance with the requirements of Health Occupations Article, Title 12, Annotated Code of Maryland, and the regulations promulgated under that title;

(2) Be responsible for reviewing the policies and procedures manual of the pharmacy annually and revising it as necessary;

(3) Be responsible for the safe and efficient dispensing, delivery, and control of, and be accountable for, medications and devices dispensed or distributed by the pharmacy;

(4) Work in cooperation with the other professional staff of the assisted living program or group home in meeting the responsibilities set forth in Regulation .06 of this chapter and in ordering, storing, and accounting for pharmaceutical materials; and

(5) Develop a process for the pharmacy to be notified of medications which have been discontinued.

B. Staff.

(1) The permit holder:

(a) May employ registered pharmacy technicians as required to provide pharmaceutical services to the residents of the assisted living program or group home; and

(b) Shall provide policies and procedures that specify the duties that may be performed by registered pharmacy technicians under the supervision of a licensed pharmacist and the duties that may be performed only by a licensed pharmacist.

(2) The permit holder may employ unlicensed personnel to provide operational support as defined in COMAR 10.34.21.02B.

.05 Physical Requirements.

A. Storage. The permit holder or designee shall ensure that medications and supplies within the pharmacy are properly stored according to the manufacturer's specifications and State and federal laws and regulations with respect to:

(1) Sanitation;

(2) Temperature;

(3) Light;

(4) Ventilation;

(5) Segregation; and

(6) Security.

B. Equipment and Materials.

(1) The permit holder or designee shall ensure that the pharmacy contains as appropriate to the level of services provided:

(a) Equipment;

(b) Supplies; and

(c) Physical facilities for proper compounding, preparation, and dispensing of medications as outlined in COMAR 10.34.19.

(2) The permit holder or designee shall ensure that the pharmacy contains appropriate reference materials to enable personnel to prepare and dispense medications properly as outlined in COMAR 10.34.07.

C. Security.

(1) The permit holder or designee shall ensure that no individual enters the pharmacy area unless a licensed pharmacist is on duty.

(2) The permit holder or designee shall ensure compliance with COMAR 10.34.05.

.06 Medication and Device Distribution and Pharmaceutical Services.

A. The responsible pharmacist shall be accountable for, at a minimum:

(1) The preparation of medications compounded in the pharmacy as applicable;

(2) The proper preparation, storage, and distribution of compounded sterile preparations according to COMAR 10.34.19 to the extent that the functions are performed at the pharmacy;

(3) The packaging and labeling of medications;

(4) Records of transactions of the pharmacy as may be required by applicable law and as may be necessary to maintain accurate control over and accountability for pharmaceuticals;

B. In addition to §A of this regulation, the responsible pharmacist may:

(1) Participate in those aspects of the assisted living program's or group home's quality assurance improvement program, if such program exists, which relate to pharmaceutical care and effectiveness; and

(2) Implement the policies and decisions of the appropriate committee or committees of the assisted living program or group home related to these regulations and to other regulations of the assisted living program or group home.

.07 Medication Packaging.

A. A licensed pharmacist shall verify the:

(1) Selection of medication to be packaged; and

(2) Completed packaging of medication performed by registered pharmacy technicians for the following:

(a) Accuracy;

(b) Completeness;

(c) Appropriateness; and

(d) Compliance with the U.S. Food and Drug Administration and current United States Pharmacopeia approved packaging.

B. A licensed pharmacist shall ensure that labeling of the medication container includes the:

(1) Brand or generic name of the medication;

(2) Strength of the medication;

(3) Name of the pharmacy; and

(4) Expiration date of the medication.

C. Unless a pharmacist has reason to reduce the time period, the expiration date of the medication is the lesser of:

(1) 12 months from the date of packaging;

(2) The manufacturer's or distributor's listed expiration date; or

(3) The maximum time period allowed for the specific packaging used for the medication.

D. Packaged from the Manufacturer's Original Container. The pharmacy may use a lot number and expiration date assigned by the pharmacy instead of the distributor or manufacturer information in a master log if kept with respect to drugs that are packaged within the pharmacy facility from the original manufacturer's container which includes the:

(1) Name of the drug;

(2) Strength;

(3) Manufacturer;

(4) Lot number assigned by the pharmacy;

(5) Lot number assigned by the distributor or manufacturer;

(6) Quantity packaged;

(7) Expiration date as defined in §C of this regulation;

(8) Manufacturer's expiration date;

(9) Date of packaging;

(10) Name of pharmacy technician packaging; and

(11) Name and initials of verifying licensed pharmacist.

E. Packaged from Another Pharmacy. A licensed pharmacist may package medication received directly from another pharmacy licensed in Maryland or operated by the government of the United States provided that:

(1) A licensed pharmacist determines that the medication has been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the time it was dispensed by the original pharmacy and received by the packaging pharmacy;

(2) A licensed pharmacist packages and dispenses all at one time the entire quantity of the prescription medications received from another pharmacy for packaging;

(3) The manufacturer’s name is present on the container received from the other pharmacy; and

(4) A licensed pharmacist maintains a master log that includes the following information:

(a) Name of the drug;

(b) Lot number assigned by the packaging pharmacy;

(c) Strength;

(d) Manufacturer;

(e) Name, address, and telephone number of the original dispensing pharmacy;

(f) Prescription number from the original dispensing pharmacy;

(g) Quantity packaged;

(h) Expiration date as assigned by the original dispensing pharmacy;

(i) Date of packaging;

(j) Name of pharmacy technician packaging;

(k) Name and initials of verifying licensed pharmacist; and

(l) Name of the resident.

.08 Labeling of Resident Medications.

A. A licensed pharmacist shall ensure that medications dispensed by the pharmacy and intended for use within an assisted living program or group home are dispensed in appropriate containers and are labeled with the:

(1) Name and address of the pharmacy;

(2) Date of dispensing;

(3) Prescription number assigned by the pharmacy;

(4) Name of the resident, patient, or consumer, as appropriate;

(5) Name, quantity, and strength of the drug;

(6) Name of the prescriber;

(7) Expiration date of the drug;

(8) Required precautionary information regarding controlled substances;

(9) Directions for use as set forth in the:

(a) Medication administration record; and

(b) Prescriber's orders; and

(10) Further cautionary information as may be required or necessary for proper use of the medication.

B. A licensed pharmacist shall ensure that medication provided per dosing period in a single container, slot, blister package, any other method of delivering an entire single dosing unit, or as part of a multi-dose dispensing package, are labeled with at least the following:

(1) Drug name;

(2) Drug strength;

(3) Name of manufacturer;

(4) Name of the resident, patient or consumer, as appropriate;

(5) Lot number, unless prepared extemporaneously;

(6) Directions for use as set forth in the:

(a) Medication administration record; or

(b) Prescriber's orders; and

(7) Expiration date.

C. Compounded Sterile Preparations. When compounding sterile preparations a licensed pharmacist or a registered pharmacy technician under the licensed pharmacist's supervision, shall comply with the compounding and labeling requirements of COMAR 10.34.19.

.09 Drug Control and Accountability.

A. Medications may be accepted for return if:

(1) The returned medication is properly labeled and properly sealed in the manufacturer's package or an individually labeled unit dose of a drug or a device;

(2) A licensed pharmacist determines that procedures are in place that the returned medication has been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the sale of the drug or device and its return to the pharmacy; and

(3) The permit holder otherwise complies with COMAR 10.34.10.07.

B. Discontinued Medications — Controlled Dangerous Substances.

(1) Except as provided in §§B(2) and C(2) of this regulations, drugs classified as Schedule II, Schedule III, Schedule IV, and Schedule V may not be returned to the inventory of the pharmacy.

(2) Schedule III, Schedule IV, and Schedule V medications may be returned to inventory of a pharmacy when the pharmacy uses a distribution system that classifies medications as pharmacy inventory until the utilization of the medication by the resident.

C. A compounded sterile preparation may not be returned to the inventory of a pharmacy.

D. Drugs requiring refrigeration may not be returned to the inventory of a pharmacy.

E. Interim Box. An interim box may be provided to an assisted living program by a permit holder if:

(1) A licensed nurse is present on site 24 hours a day, 7 days a week;

(2) The assisted living program is compliant with the pharmacy's policies and procedures regarding usage of the interim box under Regulation .03 of this chapter; and

(3) The contents of the interim box are part of the pharmacy inventory until administered.

F. Prescriber Orders.

(1) A licensed pharmacist shall dispense medications from the pharmacy only upon receipt of a valid written prescription, chart order, or verbal order from an authorized prescriber.

(2) A chart order shall be considered a prescription drug order provided that the prescription drug order contains:

(a) The full name of the resident, patient, or consumer, as appropriate;

(b) The date of issuance;

(c) The name, strength, and dosage form of the drug prescribed;

(d) The name, type, and specifications of any device;

(e) The directions for use;

(f) If written, the authorized prescriber's signature or the signature of the authorized prescriber's agent (including the name of the authorized prescriber);

(g) If electronically transmitted, prescription requirements as described in COMAR 10.34.20; and

(h) If verbal, the name of the prescriber and the prescriber's agent, if applicable.

(3) A written order may be received by the pharmacy by facsimile, electronic transmission, or as the original physician order.

(4) The licensed pharmacist shall document immediately a verbal order in writing.

(5) A licensed pharmacist may receive a verbal order:

(a) By telephone with the licensed pharmacist reading back the prescription to the prescriber or the prescriber's agent; or

(b) By a voice messaging system.

G. Controlled Dangerous Substances.

(1) Drug Accountability. The permit holder shall ensure that personnel employed by the pharmacy abide by the laws and regulations as defined in:

(a) Health-General Article, Title 27, Annotated Code of Maryland; and

(b) COMAR 10.19.03.

(2) Storage and Security. The permit holder shall establish effective procedures for storage and security of Schedule II controlled dangerous substances including limitation of access to these drugs in the pharmacy to licensed pharmacists and registered pharmacy technicians.

H. Drug Recalls. The licensed pharmacist shall develop and implement a recall procedure that can be readily activated to ensure that drugs which have been recalled are:

(a) Returned to the pharmacy;

(b) Sequestered; and

(c) Handled as appropriate to the level of the recall.

I. Adverse Drug Reactions.

(1) The licensed pharmacist shall participate on the appropriate committee, if applicable of the assisted living program or group home, to establish procedures to report and record adverse drug reactions.

(2) The licensed pharmacist shall ensure the procedures established include, at a minimum:

(a) The reporting of significant adverse drug reactions to the attending prescriber or designee and other parties as specified by the appropriate committee of the assisted living program or group home; and

(b) The recording in writing of an adverse reaction on the resident's chart at the time it is reported.

J. Records and Reports. The licensed pharmacist shall maintain records and reports as may be required by law, this chapter, and the policies of the assisted living program or group home.

.10 Quality Management.

A. The responsible pharmacist, in cooperation with the appropriate committee of the assisted living program, shall develop procedures for an ongoing quality management program that includes a mechanism for reviewing and evaluating pharmaceutical services as defined in this chapter and COMAR 10.07.14.29 where appropriate.

B. The responsible pharmacist, in cooperation with the appropriate committee of the group home, if applicable, may develop procedures for an ongoing quality management program that includes a mechanism for reviewing and evaluating pharmaceutical services as defined in this chapter.