Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 34 BOARD OF PHARMACY

10.34.16 Portable Drug Kits for Licensed Home Health Agencies, Hospices, and Home Infusion Providers Licensed as Residential Service Agencies.

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) "Committee" means, in this chapter, a joint committee of representatives form the Board of Pharmacy and the Board of Nursing.
   (2) "Portable drug kit" means a container comprising prescription drugs and other emergency medical supplies or drugs for use in licensed home health and licensed hospice settings, and by home infusion providers licensed as residential service agencies.
   (3) "Prescription protocol" means an order for a portable drug kit signed by the medical director of a licensed home health agency, licensed general hospice, or a home infusion provider licensed as a residential services agency.

.02 Requirements for Prescription Protocol.

Before distributing a portable drug kit, the pharmacist shall ensure that the prescription protocol includes:

A. The name, strength, and quantity of a drug to be included in the portable drug kit;
B. The name of the receiving agency or designated agent;
C. The directions for use;
D. Conditions for use;
E. Contraindications for use; and
F. The signature, printed name, and telephone number of the physician authorizing the kid.

.03 Records.

A pharmacist shall:

A. File the prescription protocol in a readily retrievable manner;
B. Document the:
   (1) Date of distribution of the portable drug kit,
   (2) Name of the person or agency to whom the kit is delivered, and
   (3) Date of delivery for each kit distributed;
C. File an administration record for all drugs administered from a kit upon return of the kit to the pharmacy; and
D. Notify the Board of Pharmacy before distributing portable drug kits under this chapter.

.04 Requirements of the Portable Drug Kit.

A. The pharmacist shall ensure that the portable drug kit:

(1) Is sealed with a tamper evident tag or other means for detecting entry to the kit;
(2) Displays on the outside of the kit:
    a) A serial number unique to the kit;
    b) An expiration date which reflects the earliest expiration date of any item contained in the kit;
    c) The contents of the kit;
    d) The contents are or are not sterile;
    e) The legend "To be returned to the pharmacy within 5 days of breaking seal, with a completed administration record or prescription enclosed"; and
    f) Storage requirements for the contents;
(3) Contains:
    a) Only prescription drugs and nonprescription items approved for the kit by a committee as defined in Regulation .01B(1) of this chapter;
    b) A temperature monitor to indicate maintenance of proper storage conditions; and
    c) A written administration record to be completed by the licensed health care provider using the kit, which includes the administration record indicating:
        i. The name of the patient,
        ii. The name of the prescriber,
        iii. Drug name, form, and dosage,
        iv. Date the drug was used or wasted,
        v. The reason for administration or wastage of the drug, and
        vi. The name of the licensed health care provider utilizing the kit;
(4) Displays or includes written information inside the kit listing contraindications to use of the kit; and
(5) Does not contain a controlled dangerous substance.

B. A pharmacist shall only distribute a portable drug kit which complies with the requirements of this chapter.

.05 Contents of Portable Drug Kit.

The committee shall review annually the approved prescription drugs and nonprescription items to ensure that the contents of a portable drug kit are appropriate.

.06 Distribution of Portable Drug Kits.

Portable drug kits may only be distributed to licensed health care providers who are authorized by law to administer the contents of a portable drug kit.