

Department of Legislative Services
Maryland General Assembly
2008 Session

FISCAL AND POLICY NOTE

Revised

Senate Bill 767

(Senator Conway)

Education, Health, and Environmental Affairs

Health and Government Operations

**Health Occupations - Board of Pharmacy - Remote Automated Medication
Systems**

This bill allows a nursing home to use a remote automated medication system for the dispensation of medication if it meets specified requirements, including the use of bar code technology and electronic reporting; the implementation of a comprehensive training program; and the implementation of a quality assurance program that complies with Board of Pharmacy regulations. Facilities that elect to use the system • need not have a pharmacist physically present to review the selection, packaging, or repackaging of medications; • may deliver a starter dose or a dose in response to an emergency without prior review by a pharmacist if a pharmacist reviews the delivery within 24 hours of dispensation; and • may allow simultaneous access to multiple drug strengths, dosage forms, or drug entities if the medication is contained within a patient-specific package. A pharmacist has to be available for consultation 24 hours per day. The board must monitor and report on such automated medication systems.

The bill takes effect June 1, 2008.

Fiscal Summary

State Effect: The bill's requirements could be handled with existing resources.

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Bill Summary: The bill requires the board to adopt regulations that authorize a pharmacist to dispense medication from a remote location for the benefit of a nursing home that uses an automated mechanical system in which medication is stored in a manner that may be patient specific. The pharmacist is responsible for the safe and efficient dispensing, repackaging, delivery, control, bar coding, transaction records, dispensation records, labeling, and accountability for all medications in the system. After being entered into the system, a pharmacist has to review all orders for accuracy, completeness, and appropriateness. If a pharmacist is not physically present where the remote automated system is located, the pharmacist has to have electronic and visual access to the system.

Requirements that have to be met in order for the provisions of the bill to apply include

- the use of bar code technology;
- electronic reporting capability;
- a picture of the medication if available, or a written report if a picture is not available;
- 24-hour availability of a pharmacist for consultation;
- 24-hour availability of technical assistance for the system; and
- a quality assurance program including daily inspections, a plan for addressing medication errors, proper labeling procedures, policies and procedures for the safe handling and return of unused medications, and any other requirements set forth by the board in regulations.

A pharmacist who operates a remote automated medication system has to limit system access to authorized individuals by requiring individual security codes for all functions. In the case of a power outage or otherwise unforeseen situation, a pharmacist has to (1) ensure that a back-up power source from the system is available by a connection with the health care facility's generator; and (2) that only a registered nurse or a licensed practical nurse has access to the medications contained within the system.

The board has to monitor remote automated systems in nursing homes and report on their effect on patient safety to specified legislative committees. Two reports are required – the first by January 1, 2009 and the second by January 1, 2010.

Current Law: Maryland regulations define the parameters under which a pharmacy can facilitate the use of automated medication systems in hospitals, which includes remote automated medication systems. Included in the regulations is a requirement that all remote or decentralized automated medication systems operate in a way that *limits* simultaneous access to multiple drug strengths, dosage forms, or drug entities. In addition, before a medication is dispensed by an automated medication system, a licensed pharmacist has to check each medication removed from the system *unless*

- the medication is being administered by a health professional permitted by law to administer

medication; • a licensed pharmacist performs a daily quality assurance check on the system; and • the participating pharmacy is in compliance with all other applicable regulations. The regulations also require that a participating pharmacy follow a specified quality assurance program on an automated medication system.

Background: Pharmacy inspections, including those that allow for automated medication systems, are conducted by the Maryland Division of Drug Control. However, beginning July 1, 2008, these inspection responsibilities will be transferred to the Board of Pharmacy.

Almost every hospital in Maryland has some type of automated medication system where a pharmacist is *on site*. According to the board, certain provisions of the bill conflict with existing regulations regarding automated medication systems.

Additional Information

Prior Introductions: None.

Cross File: HB 1387 (Delegate Mizeur, *et al.*) – Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene, Department of Legislative Services

Fiscal Note History: First Reader - March 9, 2008
ncs/ljm Revised - Senate Third Reader - March 25, 2008
Revised - Enrolled Bill - April 23, 2008

Analysis by: Sarah K. Harvey

Direct Inquiries to:
(410) 946-5510
(301) 970-5510