

CHAPTER 216

(House Bill 1387)

AN ACT concerning

Health Occupations – Board of Pharmacy – Remote Automated Medication Systems

FOR the purpose of ~~authorizing~~ requiring the Board of Pharmacy to adopt regulations to authorize certain pharmacists to dispense certain medication from certain pharmacies or from certain remote locations; requiring certain pharmacists to be responsible for certain dispensing, repackaging, delivery, control of, bar coding, transaction records, dispensation records, labeling, and accountability of certain medications in certain remote automated medication systems; requiring certain pharmacists to have certain access to certain systems under certain circumstances; requiring certain pharmacists to review certain medication orders for accuracy, completeness, and appropriateness ~~before~~ after being ~~placed~~ entered in certain systems subject to certain exceptions; exempting certain health care facilities and certain systems from certain requirements under certain circumstances; requiring certain pharmacists, in consultation with certain health care facilities, to develop and implement certain quality assurance programs; requiring certain pharmacists to limit certain access to certain systems by requiring individual security codes for certain functions; requiring certain records to be kept; requiring certain pharmacists to maintain certain logs and repair records; requiring certain pharmacists to ensure a certain back-up power source and that only certain individuals have access to certain systems under certain circumstances; defining certain terms; requiring the Board of Pharmacy to monitor the experience of remote automated medication systems in nursing homes in the State and to report to specified legislative committees on the effect of remote automated medication systems on patient safety in nursing homes; and generally relating to remote automated medication systems regulated by the Board of Pharmacy.

BY repealing and reenacting, without amendments,

Article – Health Occupations

Section 12-307(b)

Annotated Code of Maryland

(2005 Replacement Volume and 2007 Supplement)

BY repealing and reenacting, with amendments,

Article – Health Occupations

Section 12-307(c)

Annotated Code of Maryland

(2005 Replacement Volume and 2007 Supplement)

BY adding to

Article – Health Occupations

Section 12–605

Annotated Code of Maryland

(2005 Replacement Volume and 2007 Supplement)

Preamble

WHEREAS, The ability of the Board of Pharmacy to regulate the dispensing, pre–packaging, and repackaging of medications to residents in the State is of vital importance; and

WHEREAS, There is a national pharmacist shortage, and current pharmaceutical practices utilizing remote automated medication systems have demonstrated reduction of human error, improvements to patient safety, and the effective provision of pharmacist care services to patients from a distance; and

WHEREAS, There is a need for the Board of Pharmacy to regulate remote automated medication systems for residents in the State while being flexible enough to adapt future technologies and the economic and efficiency benefits such technologies provide in the health care setting; and

WHEREAS, Additional structure and guidance will improve pharmaceutical services for residents in health care facilities utilizing remote automated medication systems; now, therefore,

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Health Occupations

12–307.

(b) Except as otherwise provided in this section, a pharmacist may engage in dispensing or distributing only from a pharmacy holding a pharmacy permit issued by the Board.

(c) (1) Pursuant to regulations adopted by the Board, a licensed pharmacist may engage in dispensing or distributing from a setting not holding a pharmacy permit only upon receiving the prior approval of the Board.

(2) THE BOARD SHALL ADOPT REGULATIONS THAT AUTHORIZE A PHARMACIST TO DISPENSE OR DISTRIBUTE FROM A REMOTE LOCATION FOR THE BENEFIT OF A HEALTH CARE FACILITY THAT USES A REMOTE AUTOMATED MEDICATION SYSTEM IN ACCORDANCE WITH § 12–605 OF THIS TITLE.

12-605.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "HEALTH CARE FACILITY" MEANS ~~A HOSPITAL AS DEFINED IN § 19-301 OF THE HEALTH - GENERAL ARTICLE~~ OR A RELATED INSTITUTION AS DEFINED IN § 19-301 OF THE HEALTH - GENERAL ARTICLE.

(3) "REMOTE AUTOMATED MEDICATION SYSTEM" MEANS AN AUTOMATED MECHANICAL SYSTEM THAT IS LOCATED IN A HEALTH CARE FACILITY THAT DOES NOT HAVE AN ON-SITE PHARMACY AND IN WHICH MEDICATION IS STORED IN A MANNER THAT MAY BE PATIENT-SPECIFIC.

(4) "STARTER DOSE" MEANS A DOSE OF MEDICATION REMOVED FROM A REMOTE AUTOMATED MEDICATION SYSTEM WITHIN THE FIRST 24 HOURS AFTER IT IS ORDERED.

~~(B) A PHARMACIST MAY DISPENSE MEDICATION FROM:~~

~~(1) A PHARMACY; OR~~

~~(2) A REMOTE LOCATION FOR THE BENEFIT OF A HEALTH CARE FACILITY THAT USES A REMOTE AUTOMATED MEDICATION SYSTEM.~~

~~(B)~~ (1) A PHARMACIST SHALL BE RESPONSIBLE FOR THE SAFE AND EFFICIENT DISPENSING, REPACKAGING, DELIVERY, CONTROL, BAR CODING, TRANSACTION RECORDS, DISPENSATION RECORDS, LABELING, AND ACCOUNTABILITY FOR ALL MEDICATIONS IN A REMOTE AUTOMATED MEDICATION SYSTEM LOCATED IN A HEALTH CARE FACILITY THAT DOES NOT HAVE A PHARMACY PRESENT ON-SITE.

(2) IF A PHARMACIST IS NOT PHYSICALLY PRESENT WHERE THE REMOTE AUTOMATED MEDICATION SYSTEM IS LOCATED IN A HEALTH CARE FACILITY, THE PHARMACIST SHALL HAVE ACCESS TO THE SYSTEM BY ELECTRONIC AND VISUAL MEANS IN ORDER TO ENSURE THE SAFE AND EFFICIENT DISPENSING, REPACKAGING, DELIVERY, CONTROL, BAR CODING, TRANSACTION RECORDS, DISPENSATION RECORDS, LABELING, AND ACCOUNTABILITY FOR ALL MEDICATIONS IN THE SYSTEM.

~~(D)~~ (C) IF A HEALTH CARE FACILITY USES A REMOTE AUTOMATED MEDICATION SYSTEM, A PHARMACIST SHALL REVIEW FOR ACCURACY,

**COMPLETENESS, AND APPROPRIATENESS ALL MEDICATION ORDERS ~~BEFORE~~
AFTER BEING ENTERED INTO THE SYSTEM.**

~~(E)~~ **(D) (1) IF A REMOTE AUTOMATED MEDICATION SYSTEM, THE
~~COMPANY PHARMACY PERMIT HOLDER~~ THAT MANAGES THE SYSTEM, AND THE
HEALTH CARE FACILITY WHERE THE SYSTEM IS LOCATED MEET THE
REQUIREMENTS OF THIS SUBSECTION:**

**(I) A HEALTH CARE FACILITY THAT USES A SYSTEM DOES
NOT NEED TO HAVE A PHARMACIST PHYSICALLY PRESENT TO REVIEW THE
SELECTION, PACKAGING, OR REPACKAGING OF MEDICATIONS BY THE SYSTEM;**

**(II) ~~A~~ IF THE STARTER DOSE IS REVIEWED BY A
PHARMACIST WITHIN 24 HOURS OF DELIVERY FROM A SYSTEM, A SYSTEM MAY
DELIVER A STARTER DOSE OR A DOSE IN RESPONSE TO AN EMERGENCY
WITHOUT PRIOR REVIEW BY A PHARMACIST; AND**

**(III) A SYSTEM MAY ALLOW SIMULTANEOUS ACCESS TO
MULTIPLE DRUG STRENGTHS, DOSAGE FORMS, OR DRUG ENTITIES IF
CONTAINED WITHIN A PATIENT-SPECIFIC PACKAGE.**

**(2) A REMOTE AUTOMATED MEDICATION SYSTEM SHALL AT
LEAST:**

**(I) USE BAR CODE TECHNOLOGY TO ENSURE ACCURACY IN
LOADING AND SELECTION OF MEDICATIONS IN THE SYSTEM;**

**(II) HAVE ELECTRONIC REPORTING CAPABILITY
REGARDING THE IDENTITY OF ALL PERSONS WITH ACCESS TO THE SYSTEM AND
REGARDING ALL MEDICATIONS REMOVED FROM THE SYSTEM; AND**

**(III) BEFORE ADMINISTRATION OF A MEDICATION TO A
PATIENT BY AN INDIVIDUAL AUTHORIZED TO ADMINISTER MEDICATION UNDER
THIS ARTICLE, PROVIDE:**

**1. ~~A WRITTEN REPORT THAT DESCRIBES THE
MEDICATION; OR~~**

**~~2.~~ A PICTURE OF THE MEDICATION IF AVAILABLE;
OR**

**2. IF A PICTURE IS NOT AVAILABLE, A WRITTEN
REPORT THAT DESCRIBES THE MEDICATION.**

(3) THE HEALTH CARE FACILITY WHERE THE SYSTEM IS LOCATED SHALL HAVE AT LEAST:

(I) A PHARMACIST AVAILABLE FOR CONSULTATION 24 HOURS PER DAY;

(II) TECHNICAL ASSISTANCE REGARDING OPERATION OF THE SYSTEM AVAILABLE 24 HOURS PER DAY; AND

(III) A QUALITY ASSURANCE PROGRAM AS DESCRIBED UNDER SUBSECTION ~~(F)~~ (E) OF THIS SECTION.

(4) ~~A COMPANY~~ THE PHARMACY PERMIT HOLDER THAT MANAGES A REMOTE AUTOMATED MEDICATION SYSTEM SHALL PROVIDE A COMPREHENSIVE TRAINING PROGRAM TO ALL PERSONS WITH ACCESS TO THE SYSTEM.

~~(F)~~ (E) (1) A PHARMACIST THAT OPERATES A REMOTE AUTOMATED MEDICATION SYSTEM, IN CONSULTATION WITH THE HEALTH CARE FACILITY WHERE THE SYSTEM IS LOCATED, SHALL DEVELOP AND IMPLEMENT A QUALITY ASSURANCE PROGRAM IN ACCORDANCE WITH ~~THIS SUBSECTION~~ REGULATIONS ADOPTED BY THE BOARD.

(2) THE QUALITY ASSURANCE PROGRAM DEVELOPED UNDER THIS SUBSECTION SHALL INCLUDE:

(I) POLICIES AND PROCEDURES AT BOTH THE PHARMACY WHERE THE SYSTEM RECEIVES AN ORDER AND THE HEALTH CARE FACILITY WHERE THE SYSTEM ADMINISTERS THE MEDICATION REGARDING OPERATION OF THE SYSTEM;

(II) DAILY INSPECTION OF THE INTEGRITY OF THE SYSTEM;

(III) A PLAN FOR ADDRESSING MEDICATION ERRORS;

(IV) A PLAN FOR REVIEWING INCIDENTS REGARDING INAPPROPRIATE USE AND ACCESS TO THE SYSTEM;

(V) PROPER LABELING PROCEDURES THAT COMPLY WITH APPLICABLE STATE AND FEDERAL LAWS; ~~AND~~

(VI) POLICIES AND PROCEDURES FOR THE SAFE HANDLING AND RETURN OF UNUSED MEDICATIONS; AND

(VII) ANY OTHER REQUIREMENTS DETERMINED BY THE BOARD AND SET FORTH IN REGULATIONS.

(F) (1) A PHARMACIST THAT OPERATES A REMOTE AUTOMATED MEDICATION SYSTEM SHALL LIMIT ACCESS TO THE SYSTEM TO INDIVIDUALS AUTHORIZED TO ACCESS THE SYSTEM BY REQUIRING INDIVIDUAL SECURITY CODES FOR ALL FUNCTIONS.

(2) A RECORD SHALL BE KEPT OF EACH TRANSACTION CONTAINING USER IDENTIFICATION INFORMATION.

(G) (1) A PHARMACIST WHO OPERATES A REMOTE AUTOMATED MEDICATION SYSTEM SHALL MAINTAIN MAINTENANCE LOGS AND REPAIR RECORDS FOR THE SYSTEM.

(2) IN A POWER OUTAGE OR OTHERWISE UNFORESEEN SITUATION, A PHARMACIST SHALL ENSURE THAT:

(I) A BACK-UP POWER SOURCE FOR THE SYSTEM IS AVAILABLE BY A CONNECTION WITH THE HEALTH CARE FACILITY'S GENERATOR; AND

(II) ONLY A REGISTERED NURSE OR A LICENSED PRACTICAL NURSE HAS ACCESS TO THE MEDICATIONS CONTAINED WITHIN THE SYSTEM.

SECTION 2. AND BE IT FURTHER ENACTED, That the Board of Pharmacy shall monitor the experience of remote automated medication systems in nursing homes in the State and shall report on or before January 1, 2009 and on or before January 1, 2010, in accordance with § 2-1246 of the State Government Article, to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee on the effect of remote automated medication systems on patient safety in nursing homes.

SECTION ~~2~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect ~~October~~ June 1, 2008.

Approved by the Governor, April 24, 2008.