

SENATE BILL 767

J2

(8lr2056)

ENROLLED BILL

—*Education, Health, and Environmental Affairs / Health and Government
Operations*—

Introduced by **Senator Conway**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

_____ day of _____ at _____ o'clock, _____ M.

President.

CHAPTER _____

1 AN ACT concerning

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

4 FOR the purpose of ~~authorizing~~ requiring the Board of Pharmacy to adopt regulations
5 to authorize certain pharmacists to dispense certain medication from certain
6 pharmacies or from certain remote locations; requiring certain pharmacists to
7 be responsible for certain dispensing, repackaging, delivery, control of, bar
8 coding, transaction records, dispensation records, labeling, and accountability of
9 certain medications in certain remote automated medication systems; requiring
10 certain pharmacists to have certain access to certain systems under certain
11 circumstances; requiring certain pharmacists to review certain medication
12 orders for accuracy, completeness, and appropriateness ~~before~~ after being ~~placed~~
13 entered in certain systems subject to certain exceptions; exempting certain
14 health care facilities and certain systems from certain requirements under

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

Italics indicate opposite chamber / conference committee amendments.



1 certain circumstances; requiring certain pharmacists, in consultation with
 2 certain health care facilities, to develop and implement certain quality
 3 assurance programs; requiring certain pharmacists to limit certain access to
 4 certain systems by requiring individual security codes for certain functions;
 5 requiring certain records to be kept; requiring certain pharmacists to maintain
 6 certain logs and repair records; requiring certain pharmacists to ensure a
 7 certain back-up power source and that only certain individuals have access to
 8 certain systems under certain circumstances; defining certain terms; *requiring*
 9 *the Board of Pharmacy to monitor the experience of remote automated*
 10 *medication systems in nursing homes in the State and to report to specified*
 11 *legislative committees on the effect of remote automated medication systems on*
 12 *patient safety in nursing homes;* and generally relating to remote automated
 13 medication systems regulated by the Board of Pharmacy.

14 BY repealing and reenacting, without amendments,
 15 Article – Health Occupations
 16 Section 12–307(b)
 17 Annotated Code of Maryland
 18 (2005 Replacement Volume and 2007 Supplement)

19 BY repealing and reenacting, with amendments,
 20 Article – Health Occupations
 21 Section 12–307(c)
 22 Annotated Code of Maryland
 23 (2005 Replacement Volume and 2007 Supplement)

24 BY adding to
 25 Article – Health Occupations
 26 Section 12–605
 27 Annotated Code of Maryland
 28 (2005 Replacement Volume and 2007 Supplement)

29 Preamble

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

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

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

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

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

6 **Article - Health Occupations**

7 12-307.

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

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

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

18 **12-605.**

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

21 (2) **“HEALTH CARE FACILITY” MEANS ~~A HOSPITAL AS DEFINED IN~~**
 22 **~~§ 19-301 OF THE HEALTH – GENERAL ARTICLE OR A RELATED INSTITUTION AS~~**
 23 **DEFINED IN § 19-301 OF THE HEALTH – GENERAL ARTICLE.**

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

28 (4) **“STARTER DOSE” MEANS A DOSE OF MEDICATION REMOVED**
 29 **FROM A REMOTE AUTOMATED MEDICATION SYSTEM WITHIN THE FIRST 24**
 30 **HOURS AFTER IT IS ORDERED.**

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

1 ~~(1) A PHARMACY; OR~~

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

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

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

17 ~~(D)~~ (C) IF A HEALTH CARE FACILITY USES A REMOTE AUTOMATED
 18 MEDICATION SYSTEM, A PHARMACIST SHALL REVIEW FOR ACCURACY,
 19 COMPLETENESS, AND APPROPRIATENESS ALL MEDICATION ORDERS ~~BEFORE~~
 20 AFTER BEING ENTERED INTO THE SYSTEM.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

29 ~~(F)~~ (E) (1) A PHARMACIST THAT OPERATES A REMOTE AUTOMATED
30 MEDICATION SYSTEM, IN CONSULTATION WITH THE HEALTH CARE FACILITY
31 WHERE THE SYSTEM IS LOCATED, SHALL DEVELOP AND IMPLEMENT A QUALITY

1 ASSURANCE PROGRAM IN ACCORDANCE WITH ~~THIS SUBSECTION~~ REGULATIONS
2 ADOPTED BY THE BOARD.

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

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

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

10 (III) A PLAN FOR ADDRESSING MEDICATION ERRORS;

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

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

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

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

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

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

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

28 (2) IN AN ~~EMERGENCY~~ A POWER OUTAGE OR OTHERWISE
29 UNFORESEEN SITUATION, A PHARMACIST SHALL ENSURE THAT:

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

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

6 *SECTION 2. AND BE IT FURTHER ENACTED, That the Board of Pharmacy*
7 *shall monitor the experience of remote automated medication systems in nursing homes*
8 *in the State and shall report on or before January 1, 2009 and on or before January 1,*
9 *2010, in accordance with § 2-1246 of the State Government Article, to the Senate*
10 *Education, Health, and Environmental Affairs Committee and the House Health and*
11 *Government Operations Committee on the effect of remote automated medication*
12 *systems on patient safety in nursing homes.*

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

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.