

SENATE BILL 767

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8lr2056
CF HB 1387

By: **Senator Conway**

Introduced and read first time: February 1, 2008

Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 19, 2008

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
15 certain circumstances; requiring certain pharmacists, in consultation with
16 certain health care facilities, to develop and implement certain quality
17 assurance programs; requiring certain pharmacists to limit certain access to
18 certain systems by requiring individual security codes for certain functions;
19 requiring certain records to be kept; requiring certain pharmacists to maintain
20 certain logs and repair records; requiring certain pharmacists to ensure a
21 certain back-up power source and that only certain individuals have access to
22 certain systems under certain circumstances; defining certain terms; and
23 generally relating to remote automated medication systems regulated by the
24 Board of Pharmacy.

25 BY repealing and reenacting, without amendments,

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.



1 Article – Health Occupations
2 Section 12–307(b)
3 Annotated Code of Maryland
4 (2005 Replacement Volume and 2007 Supplement)

5 BY repealing and reenacting, with amendments,
6 Article – Health Occupations
7 Section 12–307(c)
8 Annotated Code of Maryland
9 (2005 Replacement Volume and 2007 Supplement)

10 BY adding to
11 Article – Health Occupations
12 Section 12–605
13 Annotated Code of Maryland
14 (2005 Replacement Volume and 2007 Supplement)

15 Preamble

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

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

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

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

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

32 **Article – Health Occupations**

33 12–307.

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

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

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

8 **12-605.**

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

11 (2) “HEALTH CARE FACILITY” MEANS ~~A HOSPITAL AS DEFINED IN~~
12 ~~§ 19-301 OF THE HEALTH – GENERAL ARTICLE OR A RELATED INSTITUTION AS~~
13 ~~DEFINED IN § 19-301 OF THE HEALTH – GENERAL ARTICLE.~~

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

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

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

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

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

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

31 (2) IF A PHARMACIST IS NOT PHYSICALLY PRESENT WHERE THE
32 REMOTE AUTOMATED MEDICATION SYSTEM IS LOCATED IN A HEALTH CARE
33 FACILITY, THE PHARMACIST SHALL HAVE ACCESS TO THE SYSTEM BY
34 ELECTRONIC AND VISUAL MEANS IN ORDER TO ENSURE THE SAFE AND

1 EFFICIENT DISPENSING, REPACKAGING, DELIVERY, CONTROL, BAR CODING,
 2 TRANSACTION RECORDS, DISPENSATION RECORDS, LABELING, AND
 3 ACCOUNTABILITY FOR ALL MEDICATIONS IN THE SYSTEM.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

29 **(III) A PLAN FOR ADDRESSING MEDICATION ERRORS;**

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

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

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

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

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

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

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

16 (2) IN AN EMERGENCY OR OTHERWISE UNFORESEEN SITUATION,
17 A PHARMACIST SHALL ENSURE THAT:

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

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

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

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.