

HOUSE BILL 1387

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8lr2622
CF SB 767

By: **Delegates Mizeur, Costa, Davis, Donoghue, Elliott, Hubbard, Pena-Melnyk, ~~and Riley~~ Riley, Benson, Hammen, Kach, Kipke, Kullen, McDonough, Montgomery, Morhaim, Nathan-Pulliam, Oaks, Pendergrass, Reznik, Tarrant, V. Turner, and Weldon**

Introduced and read first time: February 8, 2008
Assigned to: Health and Government Operations

Committee Report: Favorable with amendments
House 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; requiring
23 the Board of Pharmacy to monitor the experience of remote automated

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 medication systems in nursing homes in the State and to report to specified
2 legislative committees on the effect of remote automated medication systems on
3 patient safety in nursing homes; and generally relating to remote automated
4 medication systems regulated by the Board of Pharmacy.

5 BY repealing and reenacting, without amendments,
6 Article – Health Occupations
7 Section 12–307(b)
8 Annotated Code of Maryland
9 (2005 Replacement Volume and 2007 Supplement)

10 BY repealing and reenacting, with amendments,
11 Article – Health Occupations
12 Section 12–307(c)
13 Annotated Code of Maryland
14 (2005 Replacement Volume and 2007 Supplement)

15 BY adding to
16 Article – Health Occupations
17 Section 12–605
18 Annotated Code of Maryland
19 (2005 Replacement Volume and 2007 Supplement)

20 Preamble

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

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

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

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

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

37 **Article – Health Occupations**

1 12-307.

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

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

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

12 **12-605.**

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

15 (2) "HEALTH CARE FACILITY" MEANS ~~A HOSPITAL AS DEFINED IN~~
16 ~~§ 19-301 OF THE HEALTH - GENERAL ARTICLE OR~~ A RELATED INSTITUTION AS
17 DEFINED IN § 19-301 OF THE HEALTH - GENERAL ARTICLE.

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

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

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

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

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

29 ~~(C)~~ (B) (1) A PHARMACIST SHALL BE RESPONSIBLE FOR THE SAFE
30 AND EFFICIENT DISPENSING, REPACKAGING, DELIVERY, CONTROL, BAR
31 CODING, TRANSACTION RECORDS, DISPENSATION RECORDS, LABELING, AND
32 ACCOUNTABILITY FOR ALL MEDICATIONS IN A REMOTE AUTOMATED

1 MEDICATION SYSTEM LOCATED IN A HEALTH CARE FACILITY THAT DOES NOT
2 HAVE A PHARMACY PRESENT ON-SITE.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 (III) A PLAN FOR ADDRESSING MEDICATION ERRORS;

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

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

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

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

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

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

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

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

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

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

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

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.