J2 8lr2622 CF SB 767

By: Delegates Mizeur, Costa, Davis, Donoghue, Elliott, Hubbard, Pena-Melnyk, and Riley

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

A BILL ENTITLED

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1 A.	N ACT	concerning

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Health Occupations - Board of Pharmacy - Remote Automated Medication Systems

4 FOR the purpose of authorizing certain pharmacists to dispense certain medication from certain pharmacies or from certain remote locations; requiring certain 5 pharmacists to be responsible for certain dispensing, repackaging, delivery, 6 7 control of, and accountability of certain medications in certain remote automated medication systems; requiring certain pharmacists to review certain 8 9 medication orders for accuracy, completeness, and appropriateness before being 10 placed in certain systems subject to certain exceptions; exempting certain health care facilities and certain systems from certain requirements under 11 certain circumstances; requiring certain pharmacists, in consultation with 12 13 certain health care facilities, to develop and implement certain quality assurance programs; defining certain terms; and generally relating to remote 14 automated medication systems regulated by the Board of Pharmacy. 15

16 BY adding to

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- 17 Article Health Occupations
- 18 Section 12–605
- 19 Annotated Code of Maryland
- 20 (2005 Replacement Volume and 2007 Supplement)

21 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:

12 Article - Health Occupations

- 13 **12–605.**
- 14 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE 15 MEANINGS INDICATED.
- 16 (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.
- 19 (3) "REMOTE AUTOMATED MEDICATION SYSTEM" MEANS AN 20 AUTOMATED MECHANICAL SYSTEM THAT IS LOCATED IN A HEALTH CARE 21 FACILITY THAT DOES NOT HAVE AN ON-SITE PHARMACY AND IN WHICH 22 MEDICATION IS STORED IN A MANNER THAT MAY BE PATIENT-SPECIFIC.
- 23 (4) "STARTER DOSE" MEANS A DOSE OF MEDICATION REMOVED 24 FROM A REMOTE AUTOMATED MEDICATION SYSTEM WITHIN THE FIRST 24 25 HOURS AFTER IT IS ORDERED.
- 26 (B) A PHARMACIST MAY DISPENSE MEDICATION FROM:
- 27 **(1) A PHARMACY; OR**
- 28 (2) A REMOTE LOCATION FOR THE BENEFIT OF A HEALTH CARE 29 FACILITY THAT USES A REMOTE AUTOMATED MEDICATION SYSTEM.
- 30 (C) A PHARMACIST SHALL BE RESPONSIBLE FOR THE SAFE AND 31 EFFICIENT DISPENSING, REPACKAGING, DELIVERY, CONTROL, 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 (D) IF A HEALTH CARE FACILITY USES A REMOTE AUTOMATED
- 4 MEDICATION SYSTEM, A PHARMACIST SHALL REVIEW FOR ACCURACY,
- 5 COMPLETENESS, AND APPROPRIATENESS ALL MEDICATION ORDERS BEFORE
- 6 BEING ENTERED INTO THE SYSTEM.
- 7 (E) (1) IF A REMOTE AUTOMATED MEDICATION SYSTEM, THE
- 8 COMPANY THAT MANAGES THE SYSTEM, AND THE HEALTH CARE FACILITY
- 9 WHERE THE SYSTEM IS LOCATED MEET THE REQUIREMENTS OF THIS
- 10 SUBSECTION:
- 11 (I) A HEALTH CARE FACILITY THAT USES A SYSTEM DOES
- 12 NOT NEED TO HAVE A PHARMACIST PHYSICALLY PRESENT TO REVIEW THE
- 13 SELECTION, PACKAGING, OR REPACKAGING OF MEDICATIONS BY THE SYSTEM;
- 14 (II) A SYSTEM MAY DELIVER A STARTER DOSE OR A DOSE IN
- 15 RESPONSE TO AN EMERGENCY WITHOUT PRIOR REVIEW BY A PHARMACIST; AND
- 16 (III) A SYSTEM MAY ALLOW SIMULTANEOUS ACCESS TO
- 17 MULTIPLE DRUG STRENGTHS, DOSAGE FORMS, OR DRUG ENTITIES.
- 18 (2) A REMOTE AUTOMATED MEDICATION SYSTEM SHALL AT
- 19 **LEAST:**
- 20 (I) USE BAR CODE TECHNOLOGY TO ENSURE ACCURACY IN
- 21 LOADING AND SELECTION OF MEDICATIONS IN THE SYSTEM;
- 22 (II) HAVE ELECTRONIC REPORTING CAPABILITY
- 23 REGARDING THE IDENTITY OF ALL PERSONS WITH ACCESS TO THE SYSTEM AND
- 24 REGARDING ALL MEDICATIONS REMOVED FROM THE SYSTEM; AND
- 25 (III) BEFORE ADMINISTRATION OF A MEDICATION TO A
- 26 PATIENT, PROVIDE:
- 27 1. A WRITTEN REPORT THAT DESCRIBES THE
- 28 **MEDICATION; OR**
- 29 **2.** A PICTURE OF THE MEDICATION.
- 30 (3) THE HEALTH CARE FACILITY WHERE THE SYSTEM IS LOCATED
- 31 SHALL HAVE AT LEAST:

1	(I) A PHARMACIST AVAILABLE FOR CONSULTATION 24
2	HOURS PER DAY;
3	(II) TECHNICAL ASSISTANCE REGARDING OPERATION OF
4	THE SYSTEM AVAILABLE 24 HOURS PER DAY; AND
5	(III) A QUALITY ASSURANCE PROGRAM AS DESCRIBED
6	UNDER SUBSECTION (F) OF THIS SECTION.
7	(4) A COMPANY THAT MANAGES A REMOTE AUTOMATED
8	MEDICATION SYSTEM SHALL PROVIDE A COMPREHENSIVE TRAINING PROGRAM
9	TO ALL PERSONS WITH ACCESS TO THE SYSTEM.
10	(F) (1) A PHARMACIST THAT OPERATES A REMOTE AUTOMATED
11	MEDICATION SYSTEM, IN CONSULTATION WITH THE HEALTH CARE FACILITY
12	WHERE THE SYSTEM IS LOCATED, SHALL DEVELOP AND IMPLEMENT A QUALITY
13	ASSURANCE PROGRAM IN ACCORDANCE WITH THIS SUBSECTION.
14	(2) THE QUALITY ASSURANCE PROGRAM DEVELOPED UNDER
15	THIS SUBSECTION SHALL INCLUDE:
16	(I) POLICIES AND PROCEDURES AT BOTH THE PHARMACY
17	WHERE THE SYSTEM RECEIVES AN ORDER AND THE HEALTH CARE FACILITY
18	WHERE THE SYSTEM ADMINISTERS THE MEDICATION REGARDING OPERATION
19	OF THE SYSTEM;
20	(II) DAILY INSPECTION OF THE INTEGRITY OF THE SYSTEM;
21	(III) A PLAN FOR ADDRESSING MEDICATION ERRORS;
22	(IV) A PLAN FOR REVIEWING INCIDENTS REGARDING
23	INAPPROPRIATE USE AND ACCESS TO THE SYSTEM;
24	(V) PROPER LABELING PROCEDURES THAT COMPLY WITH
25	APPLICABLE STATE AND FEDERAL LAWS; AND
26	(VI) POLICIES AND PROCEDURES FOR THE SAFE HANDLING
27	AND RETURN OF UNUSED MEDICATIONS.
28	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
29	October 1, 2008.