



**MARYLAND
BOARD OF PHARMACY**

**ANNUAL REPORT TO THE SENATE
EDUCATION, HEALTH AND
ENVIRONMENTAL AFFAIRS AND HOUSE
HEALTH AND GOVERNMENT
OPERATIONS COMMITTEES**

**ON THE EFFECT OF REMOTE
AUTOMATED MEDICATION SYSTEMS ON
PATIENT SAFETY IN NURSING HOMES IN
MARYLAND**

January 1, 2010

**ANNUAL REPORT ON THE EFFECT OF REMOTE AUTOMATED
MEDICATION SYSTEMS ON PATIENT SAFETY IN NURSING HOMES IN
MARYLAND**

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EXECUTIVE SUMMARY

This is the second and final report required by Section 2, of SB 767 and HB 1387, Health Occupations - Board of Pharmacy - Remote Automated Medication Systems. The legislation requires that the Board of Pharmacy (the "Board") monitor the experience of remote automated medication systems in nursing homes in the State and 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 (EHE) and the House Health and Government Operations Committee (HGO) on the effect of remote automated medication systems on patient safety in nursing homes. A copy of the legislation is attached as Appendix I.

As was reported last year, the use of remote automated medication systems in Maryland is not widespread. The Board monitored the experience of remote automated medication systems in nursing homes by conducting the same inspections and performing the same telephone survey as last year of the nursing homes in Maryland that utilized remote automated medication systems or responded that they used automated medication systems last year. As a result of this year's survey, the Board learned that there are now seven (7) long term care pharmacies in Maryland that utilize automated medication systems; one less than last year. Only one pharmacy: Advanced Pharmacy, uses remote automated medication systems in several nursing homes. Although there are a greater number of automated medications machines in use by the seven (7) long term care pharmacies, it is difficult to draw any conclusions regarding the experience of utilizing these machines in nursing homes during the calendar year 2009 in Maryland.

As was reported last year, with the lack of bar code checks during the initial filling of the cassettes at Advanced Pharmacy, medication aides performing the final checks and limited procedures for reporting medication misfills or partial fills, the Board has concerns with the potential of errors for an entire facility.

STATUS OF REGULATIONS

The Board of Pharmacy's Practice Committee began considering revisions to COMAR 10.34.28 Automated Medication Systems in the spring of 2008, shortly after the legislation passed. A Notice of Regulatory Development was filed with the Department of Health and Mental Hygiene's Office of Regulation and Policy Coordination on June 16, 2008. Once the Practice Committee had completed their revisions, the draft regulations were then considered by the Board's Disciplinary Committee. The revisions were presented to the full Board at the September 17, 2008 Public Board Meeting and the draft regulations were released to interested stakeholders on October 3, 2008 with the request that any informal comments be received by October 20, 2008. The following stakeholders submitted informal comments: Maryland Pharmacists Association, Advanced Pharmacy, Delegate Heather R. Mizeur, Melvin Rubin, HMIS, Inc. (Omnicare), and the American Society of Consultant Pharmacists.

The informal comments were considered by the Practice Committee at its October 29, 2008 meeting. The informal comments and Practice Committee responses were considered at the November 5, 2008 Disciplinary Committee Meeting and presented to the Board at the November 19, 2008, December 17, 2008, and January 21, 2009 Public Board Meetings. Copies of the Board's responses sent in 2008 were included in last year's report. The last Board response, which is to HMIS, Inc. (Ominicare), is attached as Appendix II.

The Board continued to consider and revise the draft regulations during the winter and spring of 2009. The proposed regulations were finally approved at the May 20, 2009 Board Meeting. The Board released the proposed regulations again for informal comment on May 21, 2009. One comment was received from Kaiser Permanente and is attached as Appendix III. The Board approved a response to Kaiser Permanente at the July 15, 2009 Public Board Meeting and that response is attached as Appendix IV.

At the request of the Long Term Care Workgroup, made up of industry stakeholders and two Board Members, the proposed regulations were released yet again informally on June 29, 2009. The Board received one comment from the Board of Nursing requesting that nurses be removed from the proposed COMAR 10.34.28.07B(2)(a) which allows them to stock automated dispensing machines. The Board of Nursing made this request because there is no statutory authority for nurses to stock automated medication systems and that function is not within the scope of nursing practice. The Board of Nursing letter is attached as Appendix V. The Board's response was approved at the August 19, 2009 Public Board Meeting and is attached as Appendix VI. The Board noted that stocking an automated medication system by a nurse was optional and the Board voted not to change the proposed regulations.

After the Board sent its response to the Board of Nursing, the Board of Nursing voted at its August Board Meeting to further pursue deleting nurses from the proposed COMAR 10.34.28 which allowed nurses to stock automated dispensing machines. The Board revisited the Board of Nursing's request and voted at the September 16, 2009 Board Meeting to delete nurses from COMAR 10.34.28.07B(2)(a). The Board's response is attached as Appendix VII. The final version of the proposed regulations that were submitted for Departmental sign-off on September 29, 2009 is attached as Appendix VIII. As of the writing of this report, the proposed regulations are anticipated to be published in the Maryland Register on December 4, 2009 with a 30-day comment period to follow.

SURVEY OF NURSING HOMES

The Board's Compliance Unit contacted twenty-one long term care pharmacies in September and October 2009. They identified only one pharmacy that uses remote automated dispensing device.. The Board's Compliance Unit asked specific survey questions of the one identified pharmacy, plus six additional long term care pharmacies which were surveyed in detail for last year's report. Those six pharmacies: Millenium Pharmacy Services, Allied Pharmaceutical, Omnicare of Annapolis Junction, Omnicare of Hebrew Home, Omnicare of Salisbury and HMIS, use dispensing machines as interim medication storage devices to store a limited supply of unit-dose medication (both IV and PO medications) for first and missed doses. Four different types of machines are used among the seven pharmacies: Passport Systems (7), Med Dispense Machines (21), Pyxis (1) and Omnicell (39). None of the pharmacies reported any problems with the various types of machines. All of the pharmacies have quality assurance programs. When surveyed again concerning the error rate with the various machines, only the Med Dispense Machine had dispensed two tablets instead of one, on one occasion, for each location. In both cases the error was discovered and the patient received the correct amount of medication.

Survey Process:

1. Conducted the survey with the same facilities that responded to the survey last year, even if this year they did not use remote automated medication systems.

2. Contacted the facilities and spoke with the Director of Pharmacy or the Managing Pharmacist.
3. Explained the purpose of the call and that the survey questions they would be asked were the same as last year and were a result of legislation from the 2008 Maryland Legislative Session requiring the Board of Pharmacy to report on the experience of remote automated medication systems in long term care facilities or nursing homes.
4. Provided the definition of a remote automated medication system as meaning an automated medication 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, but need not be, patient specific.

Survey Questions:

1. Does your organization use remote automated medication systems?
2. If no, does your company use a drug dispensing machine in any client long term care facilities? How?
3. What type(s) of machine does the company use?
4. How does it dispense the medication?
5. How many do you currently use?
6. What types of medications do you have in the machine?
7. Who is allowed to access the machine? Who determines who will be allowed to access the machine?
8. How have the systems helped the pharmacy in the delivery and management of medication?
9. How often is the inventory reviewed?
10. Have you had any problems with the machine?
11. Does the pharmacy have a Quality Assurance program for the machine?

Survey results

	Advanced Pharmacy	Millenium Pharmacy	Allied Pharmaceu-ticals	HMIS	OmniCare of Salisbury	OmniCare of Hebrew Home	OmniCare of Annapolis
1) Use RAMS?	Yes	Yes	Yes	No	No	No	No
2) Use drug dispensing machine in LTC?	Yes	Yes, dispenses medications after physician order entered	Yes	Yes, used as an interim box, not patient specific	Yes, used as an interim box, not linked to order entry system	Yes, used as an interim box, not linked to order entry system	Yes, used as an interim box, not linked to order entry system
3) Type of machine?	Passport System	Med Dispense Machine	Med Dispense Machine	Pyxis Machine	Omnnicell	Omnnicell	Omnnicell

	Advanced Pharmacy	Millenium Pharmacy	Allied Pharmaceu-ticals	HMIS	OmniCare of Salisbury	OmniCare of Hebrew Home	OmniCare of Annapolis
4) How does the machine work?	System provides patient specific dispensing doses, the pharmacist checks the bulk med cassette at the pharmacy, then ships the meds to the LTC, loaded into machine by pharmacy technician.	When a nurse or physician orders meds, the health care worker with valid security code & password may gain entry to the machine for administration.	1. Medication order is processed by pharmacist 2. Quantity taken from machine by nurse for administration 3. Verification at end of each shift.	Only dispenses first dose for patient at LTC. Pharmacy Technician runs report from pharmacy, med in Pyxis is replenished twice a week by Pharmacy Technician.	Physician orders meds for LTC patient. The order is reviewed by a nurse & faxed to Pharmacy. Pharmacist reviews the order & the meds are delivered to the patient. The first dose is available on Omnicell.	Dispenses medications by unit dose, not patient specific. Only dispenses first dose from Omnicell, rest of doses delivered to nursing homes are filled at pharmacy.	Dispenses medications by unit dose, not patient specific. Only dispenses first dose from Omnicell, rest of doses delivered to nursing homes are filled at pharmacy.
5) How many machines?	7	20	1	1	10	1	28
6) Types of medications?	Bulk container of tablets & capsules cassettes	A wide variety commonly used in a geriatric community, IV and CII's included	First doses only are dispensed.	Unit doses of by mouth (PO), Intramuscular (IM) and Intravenous (IV).	Unit dose of PO, IM and IV.	Unit dose of PO, IM and IV. (including Controlled Dangerous Substances (CDS))	Unit dose of PO, IM and IV. (including CDS)
7) Who has access to the machines?	Access defined by Director of Nursing.	Authorized users who are identified by Director of Nursing, Millenium pharmacist & the facility.	Authorized nurse and pharmacy personnel. Director of Nursing and Pharmacy Director chose who has access.	Access limited to Registered Nurses (RNs) & refilled by pharmacy technicians. Omnicare & LTC determine who has access.	Access Limited to RNs & refilled by pharmacy technicians. Omnicare & LTC determine who has access.	Access Limited to RNs & refilled by pharmacy technicians. Omnicare & LTC determine who has access.	Access Limited to RNs & refilled by pharmacy technicians. Omnicare & LTC determine who has access.

	Advanced Pharmacy	Millenium Pharmacy	Allied Pharmaceu-ticals	HMIS	OmniCare of Salisbury	OmniCare of Hebrew Home	OmniCare of Annapolis
8) How have the systems helped the pharmacy in the delivery and management of medication?	Reduces the time for packaging and delivery	Provided immediate access to meds.	Expedites administration of first time doses.	Security features limit access to only persons with codes. The system automatically tracks the quantity of meds used.	Security features limit access to only persons with codes. Convenient to have first dose from Omnicell.	Security features limit access to only persons with codes. Convenient to have first dose from Omnicell.	Security features limit access to only persons with codes. Convenient to have first dose from Omnicell.
9) How often is the system inventoried?	Daily quantity reviewed every day. Inventoried quarterly	Once a month	Three times daily per shift change	Twice a week	Quarterly	Quarterly	Quarterly
10) Problems?	No	No	No	No	No	No	No
11) Quality Assurance Program in place?	Yes	Yes Standard Operating Procedures govern the quality of the machines.	Yes	Yes Have policies and procedures.	Yes Have policies and procedures.	Yes Have policies and procedures.	Yes Have policies and procedures.

CONCLUSION

The Board's mission is to protect Maryland consumers and to promote quality healthcare in the field of pharmacy through licensing pharmacists, registering pharmacy technicians and issuing permits to pharmacies and distributors, setting standards for the practice of pharmacy through regulations and legislation, educating consumers, receiving and resolving complaints from the public regarding pharmacists, pharmacies and distributors. The Board welcomes new technology when it has been tested in an impartial scientific manner and proven to be safe and effective for Maryland consumers. Board monitoring of the experience of remote automated dispensing in Maryland indicated that there is only one pharmacy using remote automated dispensing machines in nursing homes in Maryland. The pharmacy uses the Passport System, where cassettes are filled at the pharmacy and transported to the Passport System, and is located in a nursing home. The final medications dispensed by the Passport System machine for administration to patients are not checked by a pharmacist. The certified medication aid compares pictures and descriptions of the medication with what has been dispensed by the machine. The similarity in appearance of some medications may make that comparison problematic. Although no

problems have been identified or reported to the Board, the Board remains guarded regarding the safe and accurate administration of medications from these machines.

The experience of utilizing true remote automated medication systems is still in its infancy stage. Though serious adverse events did not occur with patients based on the limited Quality Assurance Program notations documented in the nursing homes currently utilizing remote automation systems, the potential for patient injury remains a reality. If and when the industry begins to utilize this technology on a broader scale, the potential problems identified in this report may be better addressed. Only then may a set of shared best practices be developed to improve dispensing accuracy and patient safety when remote automated systems are employed.

APPENDIX I

SENATE BILL 767

J2 (81r2056)

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 _____

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.~~

~~(C)~~ (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 AN EMERGENCY, 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:

Governor.

President of the Senate.

Speaker of the House of Delegates.

APPENDIX II



STATE OF MARYLAND

MH

Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Donald Taylor, Board President - LaVerne G. Naesea, Executive Director

January 13, 2009

Bruce Krug, Pharm.D
General Manager
HMIS, Inc.
10945 McCormick Road
Hunt Valley, Maryland 21031

Bruce.Krug@Omnicare.com

Dear Mr. Krug:

Thank you for submitting an informal comment concerning the Maryland Board of Pharmacy's draft proposed regulations for COMAR 10.34.28 Automated Medication Systems. Below you will find the Board's responses to your concerns.

.04C

You had suggested that .04C be revised to require electronic "or" visual means as the method a licensed pharmacist, not physically present where the automated medication system is located, would use to perform final checks of medications distributed from the system in order to insure the safe and efficient operation of the system. Health Occupations Article, 12-605(b)(2), Annotated Code of Maryland, requires that 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." Therefore, the regulation may not deviate from the law as written.

.04D

You had questioned why the requirements for a remote automated system would be more stringent than the current manual medication cabinet regulations. The regulations are more stringent because some remote automated medication systems allow access to all the medications at a particular health care facility.

You also mentioned that remote automated medication systems currently in use for "interim" or "starter doses" may not currently have the ability to limit simultaneous access to multiple drug strengths, dosage forms or drug entities. You questioned why the implementation of automated devices for use to store and document use of starter doses should result in more stringent requirements concerning limiting access to multiple items than is currently the case with manual

Bruce Krug, Pharm.D
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starter dose systems. The Board would like to emphasize that an interim box contains a limited number of products. Remote automated medication systems may allow access to all the medications at a particular health care facility and therefore; there is a greater need to limit access.

To avoid confusion the Board has restructured the regulations to create a new Regulation .05 that would address decentralized systems and will renumber Regulation .05 to be .06 to address only remote automated medication systems. Therefore, the Board will be moving Section .04B and C into the renumbered Regulation .06 Additional Usage Requirements for Remote Automated Medication Systems, since Section .04B and C only apply to remote systems. Section .04D, which limits simultaneous access, will be moved and repeated in both the decentralized and remote regulations, since it applies to both.

.05A(3) and .06B and C

You had suggested in your comment that licensed nurses be allowed to stock an automated medication system. The Board has revised its proposed regulations to allow a licensed nurse to stock an automated medication system that uses unit dose packages. Keep in mind that Regulations .05 and .06 will be renumbered to be Regulations .06 and .07.

The Board would like to thank you again for your thorough reading of, and informal comments to, the proposed COMAR 10.34.28 Automated Medication Systems. The proposed regulations are still under consideration by the Board and will be presented at a future Board Public Meeting for approval, pending the 2009 Legislative Session.

Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794.

Sincerely,

LaVerne G. Naesea
Executive Director

cc: Anna D. Jeffers, Legislation and Regulations Manager, Board of Pharmacy
Linda Bethman, Board Counsel, Board of Pharmacy

APPENDIX III

June 16, 2009

Ms. Anna Jeffers

Maryland Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215

Dear Ms. Jeffers:

Thank you for opportunity to provide informal comment on draft revisions to COMAR 10.34.28 Automated Medication Systems.

I offer remarks on the following sections:

Definitions (.02)

We are unclear about the definition of "Unit Dose." Typically, this means one single dose of a medication in a sealed container. We wonder if this is still true or is the Board of Pharmacy's intent to include a single vial filled with one drug (e.g. one filled prescription). Our other comments are in large part based on this interpretation.

Stocking of Automated Medication Systems (.07)

Kaiser Permanente supports the requirement that a licensed pharmacist verify the accuracy of medications selected for stocking and replenishment of the automated system before the medications are stocked in the system.

Stocking of the Automated Medication System (B.)

We do have concerns about this section. Kaiser Permanente supports registered technicians being able to select drugs for stocking and replenishment before they are stocked in the system, provided the system uses positive drug identification such as bar code technology. If unit dose packaging means one dose in a sealed container, then this section would not allow our technicians to select the medication for the system since we do not use unit dose packaging by that definition. Robotic systems in the outpatient pharmacy environment that use bar code technology for positive drug identification, match the drug stock bottles with each individual cell to help ensure the correct medications are placed in the correct cells. Given that the pharmacist verifies the accuracy of medications before they are stocked, we feel strongly that technicians can certainly handle the technical function of setting up the medications. It is not necessary for a pharmacist to select the drugs for an automated medication system. Therefore, we request that section (B.) (1) be reworded as follows:

- (a) Is stocked with unit dose packaging; OR
- (b) Uses positive drug identification such as bar code technology.

A minor grammar change is needed in (B.) (1); the word "mediations" should be "medications."

Return of Unused Medication (.08)

Kaiser Permanente supports the return to stock of unused medication and pharmacists making a determination as to whether the medication is in an unadulterated form. We also support having the pharmacist return medications directly to the automated medication system. However, we do not support the requirement that only automated medication systems that

distribute medications in single-drug unit dose packaging may allow for return of unused medications to the system. We take this position, assuming the definition of single-unit dose is defined as sealed single dose packaging.

We request that systems which use bar coding for positive drug identification allow for return of unused medication, even when not packaged as a single-unit dose. There are at least two specific situations where this is reasonable:

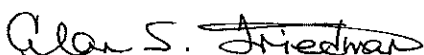
1. In an outpatient pharmacy, when a robotic system jams or encounters a technical difficulty, the cell stops counting, and may kick out a partially filled vial of medication. Once the system is reset, the unique bar code on that vial is scanned, as is the cell that then opens, and the drug can be returned to stock so the prescription may be filled in complete form. Bar code scanning ensures the correct medication is being placed in the correct cell, and vial.
2. Completed prescriptions may be filled and awaiting pick-up by a patient. After a reasonable period of time, if the patient does not present to pick up their medication, it can be returned to stock. Again, the unique bar code on the prescription vial is scanned, and the correct cell opens so the drug can be returned to stock. Bar code scanning helps ensure the accuracy of returning drugs to the correct cell.

Unfortunately, too many patients do not pick up their filled prescriptions, for one reason or another. Not returning stock is a waste of resources, and leads to unnecessary destruction of medication. Particularly with sophisticated robotic systems, functions are tracked by drug and the individual performing the function – both for filling/replenishing and returning drugs to stock. In addition, a number of monitoring and reporting functions are available.

We are unclear what is meant by (1) (a), “the medication is returned to a designated common, secure, one-way returns bin.” If the intent is to have all prescription vials, which are eligible for return to stock, in one place for pharmacist review and return, that is fine. In our outpatient pharmacy, we want to return the unused medication to the automated medication system. This is achieved by use of bar code technology. Each prescription vial has a unique bar code, which when scanned, only opens the unique cell it is linked to.

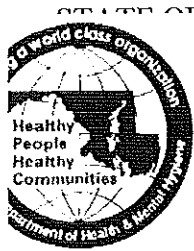
Our suggestion and request is to modify Section .08 so that the requirement for single drug unit dose packaging is removed. Change section (A.) (1) to allow return to stock for automated medication systems that distribute medications.

Thank you, again, for the chance to offer informal comments on suggested revisions to COMAR 10.34.28. Please feel free to contact me should you have questions.



Alan S. Friedman, RPh
Government Relations and Regulatory Affairs Coordinator
Department of Pharmacy Services

APPENDIX IV



STATE OF MARYLAND

MH

Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Donald Taylor, Board President - LaVerne G. Naesea, Executive Director

July 24, 2009

Alan S. Friedman
Government Relations and Regulatory Affairs Coordinator
Department of Pharmacy Services
Kaiser Permanente
2101 East Jefferson Street
Pharmacy, 3-West
Rockville, MD 20852

Dear Mr. Friedman:

Thank you for submitting an informal comment concerning the Maryland Board of Pharmacy's draft proposed regulations for COMAR 10.34.28 Automated Medication Systems. Below you will find the Board's responses to your concerns.

.02 Definitions

Kaiser Permanente has indicated that the definition of "Unit Dose" was unclear. The definition of "Unit Dose" in the regulations does not refer to one complete multi-dose filled prescription. It refers to one pharmaceutical dose in a packaged form.

Stocking of Automated Medication Systems

Kaiser Permanente (KP) indicated that it believed that pharmacy technicians should be allowed to stock bulk medications in automated medication systems without a prior pharmacist check. In Health Occupations Article, 12-605(c), Annotated Code of Maryland, a licensed pharmacist is required to verify the accuracy of medications selected for stocking and replenishment of **remote automated medication systems** (not robotic systems in a retail pharmacy) before the medications are stocked in the system.

.08 Return of Unused Medication

KP indicated that it did not support the requirement that only automated medication systems that distribute medications in a single-drug unit dose packaging may allow for return of unused medications to the system. KP suggested that systems which use bar coding for positive drug identification allow for the return of unused medication, even when it is not packaged as a single-unit dose.

The intent of COMAR 10.34.28.08A(1)(a) is to have all prescription vials, which are eligible for reuse, placed on the shelf for subsequent prescription use. Replenishing to a stock container or cell may result in error. The one-way returns bin does not apply to centralized systems in a retail pharmacy setting.

The Board would like to thank you again for your thorough reading of, and informal comments to, the proposed COMAR 10.34.28 Automated Medication Systems. The proposed regulations are still under consideration by the Board and will be presented at a future Board Public Meeting for approval.

Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794.

Sincerely,

LaVerne G. Naesea
Executive Director

cc: Anna D. Jeffers, Legislation and Regulations Manager, Board of Pharmacy
Linda Bethman, Board Counsel, Board of Pharmacy

APPENDIX V

June 30, 2009

LaVerne G. Naesea
Executive Director
Board of Pharmacy
4201 Patterson Avenue
Baltimore, MD 21215

Dear Ms. Naesea:

The Board of Nursing has reviewed the proposed regulations under COMAR 10.34.28 – Automated Medication Systems, and requests that nurses not be included in the list of individuals who stock these automated dispensing machines. This function would not be within the scope of nursing practice. We believe that stocking these machines should be done by a trained Licensed pharmacist or a Registered pharmacy technician.

There is no statutory authority for nurses to stock automated medication systems. Accordingly, please revise the regulations by deleting B.(2)(a) Licensed Nurse, under Regulation 07.

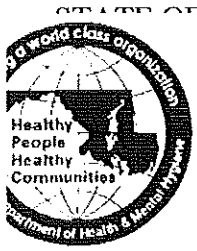
If you have any questions please contact me at 410-585-1902. Thank you.

Yours truly,

Shirley A. Devaris, RN, JD
Director, Policy Analysis and Legislation

cc: Anna D. Jeffers
Barbara Newman
Patricia A. Noble
Nancy Tennis
Nancy Adams

APPENDIX VI



STATE OF MARYLAND

MH

Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Donald Taylor, Board President - LaVerne G. Naesea, Executive Director

August 19, 2009

Shirley A. Devaris, RN, JD
Director, Policy Analysis and Legislation
Maryland Board of Nursing
4140 Patterson Avenue
Baltimore, Maryland 21215-2254

sdevaris@dhhm.state.md.us

Dear Ms Devaris:

Thank you for submitting an informal comment concerning the Maryland Board of Pharmacy's draft proposed regulations for COMAR 10.34.28 Automated Medication Systems.

You requested that nurses not be included in the list of individuals who stock these automated dispensing machines because it is not within their scope of practice. In the proposed COMAR 10.34.28.07B(2), automated medication systems stocked with unit dose packaging that use positive drug identification, such as bar code technology, to insure accuracy of the stocking and replenishment of the system MAY be stocked by a licensed nurse, licensed pharmacist, or registered pharmacy technician. It is not a requirement that nurses stock the machines and the Board of Nursing may instruct their licensees as appropriate.

The Board would like to thank you again for your thorough reading of, and informal comments to, the draft proposed COMAR 10.34.28 Automated Medication Systems. The Board will not be making any further revisions pursuant to your request and voted today to approve the proposed COMAR 10.34.28 Automated Medication Systems.

Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794.

Sincerely,

LaVerne G. Naesea
Executive Director

cc: Anna D. Jeffers, Legislation and Regulations Manager, Board of Pharmacy
Linda Bethman, Board Counsel, Board of Pharmacy
Patricia A. Noble, Executive Director, Board of Nursing
Nancy Tennis, Board Counsel, Board of Nursing
Nancy Adams, Board of Nursing

APPENDIX VII



STATE OF MARYLAND

MH

Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Donald Taylor, Board President - LaVerne G. Naesea, Executive Director

September 17, 2009

Shirley A. Devaris, RN, JD
Director, Policy Analysis and Legislation
Maryland Board of Nursing
4140 Patterson Avenue
Baltimore, Maryland 21215-2254
sdevaris@dhmh.state.md.us

Dear Ms Devaris:

Thank you for your email of August 24, 2009 expressing the Board of Nursing's continued concern with nurses specifically listed in COMAR 10.34.28 Automated Medication Systems as individuals that may stock an automated dispensing machine that is stocked with unit dose packaging and uses positive drug identification to ensure accuracy of the stocking and replenishment of the system.

You have requested that nurses not be included in the list of individuals who stock these automated dispensing machines because it is not within their scope of practice. Since it is not a *requirement* that nurses stock the machines, and the Board of Nursing may instruct their licensees as appropriate, the Board of Pharmacy voted at its September 16, 2009 Board Meeting to delete nurses from COMAR 10.34.28.07B(2)(a).

The Board of Pharmacy initially included nurses in COMAR 10.34.28.07B(2) so that nurses would have the *option* to stock an automated medication system with unit dose packaging that uses positive drug identification, if necessary. The Board understands, however, your concerns that nurses should be practicing nursing and attending to patient care, rather than extending their duties to non-nursing functions.

The Board would like to thank you again for your thorough consideration of the draft proposed COMAR 10.34.28 Automated Medication Systems. The Board voted on September 16, 2009 to delete nurses from COMAR 10.34.28.07B(2)(a) and approved the remainder of the revisions for submission into the Departmental regulatory process.

Shirley A. Devaris
September 17, 2009
Page Two

Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794.

Sincerely,

LaVerne G. Naesea
Executive Director

cc: Nancy Adams, Board of Nursing
Linda Bethman, Board Counsel, Board of Pharmacy
Margie Heald, Acting Director, OHCQ
Anna D. Jeffers, Legislation and Regulations Manager, Board of Pharmacy
Dana Kaufman, Lifespan
Ethan Moore, HFAM
Patricia A. Noble, Executive Director, Board of Nursing
Ed Suddath, Executive Director, Maryland Nurses Association
Nancy Tennis, Board Counsel, Board of Nursing

APPENDIX VIII

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee 10/20/2009	TO BE COMPLETED BY DSD Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 12/4/2009

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	34	28	01, .02, .04-.14

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator	Telephone Number
Michele Phinney	410-767-5623

Mailing Address

201 W. Preston Street

City	State	Zip Code
Baltimore	MD	21201

Email
phinneym@dhmh.state.md.us

5. Name of Person to Call About this Document	Telephone No.
Anna Jeffers	410-764-3833

Email Address
ADJeffers@dhmh.state.md.us

6. Check applicable items:

- New Regulations
 - Amendments to Existing Regulations
- Date when existing text was downloaded from COMAR online: August 28, 2008.

Notice of Proposed Action

□

The Department of Health and Mental Hygiene proposes to amend Regulations .01, .02, .04, .09—.11, repeal and adopt new Regulations .05—.08, adopt new Regulation .12, amend and recodify Regulation .12 to be Regulation .13, and recodify Regulation .13 to be Regulation .14 under COMAR 10.34.28 Automated Medication Systems.

This action was considered by the Board of Pharmacy at a public meeting held September 16, 2009, notice of which was given by publication on the Board of Pharmacy web site www.mdbop.org from September 11, 2009—September 16, 2009, pursuant to the State Government Article, §10-506(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to revise the regulations to accommodate remote automated medication systems. The definition of “health care facility” was added from HB 1387 and a definition of “responsible pharmacist” was added for clarification. Regulations .05 - .08 were repealed because they restricted the use of remote automated medication systems and did not accommodate the recent uses of automated medication systems. The remainder of the revisions reflects the language of SB 767/HB 1387 Health Occupations - Board of Pharmacy - Remote Automated Medication Systems. Regulations .03 and .13 were not revised.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

The revisions proposed will have no economic impact on the Board of Pharmacy, the Department of Health and Mental Hygiene, other state agencies or local governments. Pharmacies will continue to be inspected by the Board in the same manner. The long term care inspection form, which is periodically revised, will be revised pursuant to these changes. There may be an unquantifiable benefit to some pharmacies that choose to use remote automated medication systems. The public may benefit because there may be a decrease in medication errors where these machines are utilized.

II. Types of Economic Impact.

Revenue (R+/R-)	Magnitude
Expenditure (E+/E-)	Magnitude

A. On issuing agency:	NONE
B. On other State agencies:	NONE
C. On local governments:	NONE

Benefit (+)	Magnitude
Cost (-)	

- | | | |
|---|------|----------------|
| D. On regulated industries or trade groups: | (+) | Unquantifiable |
| E. On other industries or trade groups: | NONE | |
| F. Direct and indirect effects on public: | (+) | Unquantifiable |

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

- D. There may be an unquantifiable benefit to some pharmacies that choose to use remote automated medication systems, making access to medications more efficient in some settings.
- F. The public may benefit because there may be a minimal decrease in medication errors where these machines are utilized.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 512, Baltimore, Maryland 21201, or call 410-767-6499, or email to regs@dhmh.state.md.us, or fax to 410-333-7687. Comments will be accepted through January 4, 2010. A public hearing has not been scheduled.

Economic Impact Statement Part C

- A. Fiscal Year in which regulations will become effective: FY 2010
- B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?
- C. If 'yes', state whether general, special (exact name), or federal funds will be used:
- D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:
- E. If these regulations have no economic impact under Part A, indicate reason briefly:
- F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.
The Board is not required to obtain information concerning which pharmacies are also small businesses. These amendments accommodate emerging technologies in automated medication systems which may be beneficial to some small businesses.
- G. Small Business Worksheet:

Attached Document:

10.34.28.01 (September 18, 2009)

.01 Scope.

This chapter defines the parameters under which a permit holder may allow the use of automated medication systems [for the] to facilitate the dispensing and distribution of medication.

10.34.28.02 (September 18, 2009)

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Automated medication system" means a centralized, decentralized, or remote robotic or computerized device and that device's components designed to:

(a) Distribute medications in a licensed health care facility or a related institution; or

(b) Prepare medications for final dispensing by a licensed pharmacist [to a patient or a patient's agent].

(2)—(4) (text unchanged)

(5) "Health care facility" means a hospital or related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland.

(6) "Interim box" means a tamper evident and secure container or electronic storage system holding minimal quantities of medications agreed upon by the comprehensive care facility's pharmaceutical services committee, as defined in COMAR 10.07.02.15, intended to expedite immediate initiation of emergency or nonemergency dosing until the pharmacy is able to provide a regular supply.

[(5)] (7) Remote Automated Medication System.

(a) "Remote automated medication system" means an automated medication system that is located in a health care facility or related institution, as defined in Health-General Article, §19-301, Annotated Code

of Maryland, that does not have an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.

(b) "Remote automated medication system" does not include an interim box or other similar medication storage container that:

(i) Does not operate pursuant to the entry of a medication order;

(ii) Does not require a pharmacist's review before access to medication;

(iii) Is stocked with unit dose medications;

(iv) Has the sole purpose of providing a medication dosage pending the next pharmacy delivery to the facility; and

(v) Is located in a patient care setting that does not have a pharmacy on site.

(8) "Responsible pharmacist" means a licensed pharmacist who ensures the safe and efficient dispensing, repackaging, delivery, control, positive drug identification including bar coding, transaction records, dispensation records, labeling, and accountability for medications in an automated medication system.

[(6)] (9) (text unchanged)

[(7) "Supervision" means the direction of and responsibility for ancillary personnel performing pharmaceutical tasks delegated by a licensed pharmacist, including determining whether the ancillary personnel are competent to perform the delegated tasks.]

(10) "Unit dose" means a medication container or package containing one discrete pharmaceutical dosage form labeled according to federal and State law.

10.34.28.04 (September 18, 2009)

.04 Usage Requirements for Centralized Automated Medication Systems.

A. An automated medication system [shall] may only be used if:

(1) Records concerning transactions or operations are maintained in accordance with Regulation .11 of this chapter;

(2) [A licensed pharmacist controls access to the system and defines a method for delegating access to the system to qualified pharmacy personnel under the licensed pharmacist's supervision or to individuals permitted by law to administer medication] A responsible pharmacist has been designated by the permit holder to supervise and manage the operations of the centralized automated medication system; and

(3) [A licensed pharmacist:

(a) Reviews:

(i) Each order for medication before the medication is removed from the remote or decentralized automated medication system, except if the order is for a starter dose; or

(ii) The order for a starter dose within 24 hours of removal of the starter dose from the remote or decentralized automated medication system, if the patient is still under the care of the facility when the review is to be performed; or

(b) Except as provided in Regulation .08 of this chapter, utilizing a centralized automated medication system, makes a final check of the prescription before dispensing the medication to the patient;

(4)] The permit holder ensures that:

(a) Patients have prompt access to [all] pharmacy services necessary for the provision of good pharmaceutical care as defined in Health Occupations Article, [§12-101(l)] §12-101(n), Annotated Code of Maryland;

(b) The centralized automated medication system maintains the integrity of the information in the system and protects patient confidentiality; and

(c) [A comprehensive program of quality assurance for the system is in place as established in] The centralized automated medication system is subject to a quality assurance program in accordance with Regulation .10 of this chapter[; and] .

[(5) The permit holder and licensed pharmacist responsible for the automated medication system:

(a) Maintain policies and procedures related to:

- (i) The operation of the system;
 - (ii) Training of personnel using the system; and
 - (iii) Operations during system downtime; and
- (b) Establish a process to:
- (i) Ensure the security of the system; and
 - (ii) Account for medication added to and removed from the system.

B. All remote or decentralized automated medication systems initially placed in service after September 1, 2003, shall operate in a manner which:

- (1) Limits simultaneous access to multiple:
 - (a) Drug strengths;
 - (b) Dosage forms; or
 - (c) Drug entities; and
- (2) Minimizes the potential for misidentification of medications, dosages, and dosage forms by those accessing the automated medication system.]

B. A permit holder shall indicate on the initial, renewal and reinstatement applications:

- (1) Whether the permit holder operates a centralized automated medication system; and
- (2) Any other information regarding the system that the Board deems necessary to determine compliance with this chapter.

ALL NEW

.05 Usage Requirements for Decentralized Automated Medication Systems.

A. A decentralized automated medication system may only be used if:

- (1) Records concerning transactions or operations are maintained in accordance with Regulation .11 of this chapter;
- (2) A responsible pharmacist has been designated by the permit holder to supervise and manage the operations of the automated medication system;

(3) Except for starter doses, a licensed pharmacist reviews each order for medication:

- (a) After the order has been entered into the system; and
- (b) Before the system permits access to the medication; and

(4) The permit holder ensures that:

- (a) Patients have prompt access to pharmacy services necessary for the provision of good pharmaceutical care as defined in Health Occupations Article, §12-101(n), Annotated Code of Maryland;
- (b) The decentralized automated medication system maintains the integrity of the information in the system and protects patient confidentiality; and
- (c) The decentralized automated medication system is subject to a quality assurance program in accordance with Regulation .10 of this chapter.

B. A starter dose, or a dose in response to an emergency, may be distributed without prior review by a pharmacist of the order if the pharmacist reviews the order within 24 hours of removal from the decentralized automated medication system.

C. Decentralized automated medication systems shall operate in a manner which:

(1) Limits simultaneous access to multiple:

- (a) Drug strengths;
- (b) Dosage forms; or
- (c) Drug entities;

(2) Prevents access to medications not ordered for the patient; and

(3) Safeguards against the misidentification of medications, dosages, and dosage forms by those accessing the decentralized automated medication system.

D. A permit holder shall indicate on the initial, renewal and reinstatement applications:

(1) Whether the permit holder operates a decentralized automated medication system; and

(2) Any other information regarding the system that the Board deems necessary to determine compliance with this chapter.

.06 Usage Requirements for Remote Automated Medication Systems.

A. A remote automated medication system may only be used if:

(1) Records concerning transactions or operations are maintained in accordance with Regulation .11 of this chapter;

(2) A responsible pharmacist has been designated by the permit holder to supervise and manage the operations of the remote automated medication system;

(3) Except for starter doses, a licensed pharmacist reviews each order for medication:

(a) After the order has been entered into the system; and

(b) Before the system permits access to the medication; and

(4) The permit holder ensures that:

(a) Patients have prompt access to pharmacy services necessary for the provision of good pharmaceutical care as defined in Health Occupations Article, §12-101(n), Annotated Code of Maryland;

(b) The remote automated medication system maintains the integrity of the information in the system and protects patient confidentiality; and

(c) The remote automated medication system is subject to a quality assurance program in accordance with Regulation .10 of this chapter.

B. A starter dose, or a dose in response to an emergency, may be distributed without prior review by a pharmacist of the order if the pharmacist reviews the order within 24 hours of removal from the remote automated medication system.

C. If a licensed pharmacist is not physically present where the remote automated medication system is located to perform final checks of medications distributed from the system, the pharmacist shall have

access to the system by electronic and visual means in order to ensure the safe and efficient operation of the system.

D. Remote automated medication systems shall operate in a manner which:

(1) Unless packaging and labeling for a specific patient, limits simultaneous access to multiple:

(a) Drug strengths;

(b) Dosage forms; or

(c) Drug entities;

(2) Prevents access to medication not ordered for the patient; and

(3) Safeguards against the misidentification of medications, dosages, and dosage forms by those accessing the remote automated medication system.

E. A remote automated medication system may be used only if the system:

(1) Uses positive drug identification, such as bar code technology, to ensure accuracy in:

(a) Loading and selection of medications in the pharmacy for stocking and replenishment of the remote automated medication system; and

(b) Loading medications into the remote automated medication system where it is located;

(2) Has electronic reporting capability regarding the identity of persons with access to the system and regarding medications removed from the system;

(3) Restricts access to medications to a licensed pharmacist or an individual authorized to administer medication under the Health Occupation Article; and

(4) Before administration of a medication to a patient, provides:

(a) A picture of the medication, if available; or

(b) If a picture is not available, a written description of the medication specifically by color, shape, and unique manufacturer markings.

F. The permit holder shall ensure that the health care facility where the remote automated medication system is located provides, at a minimum:

- (1) A licensed pharmacist available for consultation 24 hours per day;
- (2) Technical assistance regarding operation of the system available 24 hours per day; and
- (3) A quality assurance program as set forth in Regulation .10 of this chapter.

G. A permit holder shall indicate on the initial, renewal and reinstatement applications:

- (1) Whether the permit holder operated a remote automated medication system; and
- (2) Any other information regarding the system that the Board deems necessary to determine compliance with this chapter.

.07 Stocking of Automated Medication Systems.

A. Selection of Medication for Stocking. Except as provided in §B, a licensed pharmacist shall verify the accuracy of medications selected for stocking and replenishment of the automated medication system before the medications are stocked in the system.

B. Stocking of Automated Medication System.

(1) A registered pharmacy technician may select for stocking and replenishment of the automated medication system before the medications are stocked into the system provided that the system:

- (a) Is stocked with unit dose packaging; and
- (b) Uses positive drug identification such as bar code technology.

(2) Automated medication systems stocked with unit dose packaging that use positive drug identification, such as bar code technology, to ensure accuracy of the stocking and replenishment of the system may be stocked by a:

- (a) Licensed pharmacist; or
- (b) Registered pharmacy technician.

(3) Automated medication systems, stocked with bulk medications, that use positive drug identification, such as bar code technology, to ensure accuracy of the stocking and replenishment of the system may be stocked by a:

- (a) Licensed pharmacist; or
- (b) Registered pharmacy technician.

.08 Return of Unused Medication.

A. Single-drug unit dose packaging.

(1) Automated medication systems that distribute medications in single-drug unit dose packaging may allow for return of unused medications to the system provided that:

- (a) The medication is returned to a designated common, secure, one-way returns bin; and
- (b) A licensed pharmacist determines whether the medication is in an unadulterated form:

(2) Only a licensed pharmacist may return medications directly to the automated medication system under this section.

B. Unused medications distributed from a remote or decentralized automated medication system in a manner other than single-drug unit dose packaging shall be:

- (1) Returned to a designated common, secure, one-way returns bin; and
- (2) Returned to the permit holder for propped disposal.

END NEW

10.34.28.09 (September 18, 2009)

.09 Education and Training.

The permit holder shall ensure that individuals [working with the] authorized to utilize centralized, decentralized or remote automated medication [system] systems receive initial and annual training regarding:

- A. (text unchanged)
- B. [The] Procedures for the operation of the system; and
- C. (text unchanged)

10.34.28.10 (September 18, 2009)

.10 Quality Assurance Program.

[The permit holder shall maintain a quality assurance program regarding the automated medication system that shall include:]

A. [Review of system overrides;] The responsible pharmacist, in consultation with the health care facility, shall develop, maintain, and review annually, a quality assurance program regarding the automated medication system that addresses, at minimum:

(1) A testing program which includes daily accuracy sampling that verifies the integrity of the system;

[B.] (2) Investigation of medication errors related to the automated medication system and remedial actions taken;

[C.] Review of discrepancies and transaction reports to identify patterns of inappropriate use and access; [and]

[D.] (4) Review of the overall functioning of the system[.];

(5) Security and access;

(6) Preventative maintenance;

(7) Sanitation;

(8) Storage conditions;

(9) Inventory of drugs;

(10) Drug procurement, delivery, and receipt;

(11) Recordkeeping;

(12) Proper labeling procedures; and

(13) Protocols in the event of a power outage or other situation in which the services of the system are interrupted, that include:

(a) A plan for insuring continuity of pharmacy services to patients; and

(b) A plan for system recovery.

B. The responsible pharmacist, in consultation with the health care facility, shall develop, maintain, and review annually, a quality assurance program regarding the remote or decentralized automated medication system that addresses, at a minimum, system override management, to include:

(1) A list of medications that can be overridden which is limited to starter doses; and

(2) Review of system overrides to ensure appropriate utilization.

10.34.28.11 (September 18, 2009)

.11 Record Keeping.

A. The permit holder and the [licensed] responsible pharmacist [responsible for the automated medication system] shall maintain records regarding the automated medication system in a readily retrievable manner for at least [2] 5 years.

B. The records referred to in §A of this regulation shall include:

(1) Maintenance records and service logs;

(2) System failure reports;

(3) Documentation of patient outcomes resulting from system failures;

(4) Accuracy audits and system performance audits;

[(4)] (5) Copies of reports and analyses generated as part of the quality assurance program, including daily accuracy sampling;

[(5)] (6) Reports or databases related to level of access and changes in the level of access to the system;
[and]

[(6)] (7) Training records including:

(a)—(b) (text unchanged)

(c) The identity of those attending the training program[.] ;

(8) Records of destruction of medication waste removed from the system, to include an independent witness signature; and

(9) Transaction information as follows:

(a) Transactions involving medications stored in, removed, dispensed, or distributed from the system;

(b) Medications dispensed or distributed for a patient shall be recorded to include the:

(i) Identity of the particular automated medication system accessed;

(ii) Identification of the individual access the system;

(iii) Date of transaction;

(iv) Name, strength, dosage form, and quantity of drug accessed; and

(v) Name of the patient for whom the drug was accessed; and

(c) Records of stocking or removal of medications from an automated medication system shall include the:

(i) Date;

(ii) Name, strength, dosage form, and quantity of drug stocked or removed; and

(iii) Name, initials, or identification code of the individual stocking or removing drugs from the system.

[C. The permit holder and the licensed pharmacist responsible for the automated medication system shall maintain transaction records for all prescription drugs or devices dispensed or distributed for the preceding 5 years.]

.12 Security.

A. The responsible pharmacist shall ensure the security of the automated medication system.

B. In order to restrict access to the automated medication system to authorized individuals, the responsible pharmacist shall, at a minimum:

(1) Establish a clear process of how passwords will be assigned;

(2) Develop procedures that prohibit the sharing of passwords and reuse of passwords;

(3) Require that the system database be updated daily to remove inactive passwords; and

(4) Require remote locking mechanisms for refrigerated storage associated with the system.

10.34.28.12 (September 18, 2009)

[.12] .13 Laws and Compendial Standards.

The [licensed] responsible pharmacist [responsible for the automated medication system] shall ensure compliance with the laws and compendial standards for packaging and labeling.

10.34.28.13 (September 18, 2009)

[.13] .14 (text unchanged)

JOHN M. COLMERS

Secretary of Health and Mental Hygiene