



**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, 2009

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

This is the first of two reports 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. The Board is in the process of revising the existing COMAR 10.34.28 Automated Medication Systems regulations to comply with the new law.

At the present time, 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 inspections and performing a phone survey of the nursing homes in Maryland that utilize remote automated medication systems. As a result of the survey, the Board learned that there are only eight long term care pharmacies in Maryland that utilize automated medication systems. Only one pharmacy, Advanced Pharmacy, uses actual remote automated medication systems in two nursing homes. Since the use of automated medications systems in Maryland is not widespread, it is difficult to draw any conclusions regarding the experience of utilizing these machines in nursing homes during the calendar year 2008 in Maryland, except for the experience of Advanced Pharmacy's Passport System which has a documented error rate of .0000136 percent. Yet with the lack of bar code checks during the initial filling of the cassettes at the pharmacy, medication aides performing the final checks and limited procedures for reporting 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 20th. A copy of that draft is attached as Appendix II. 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 the October 29, 2008 meeting and Committee responses were drafted. 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 Public Board Meeting. The responses to the Maryland Pharmacists Association, Advanced Pharmacy and Delegate Heather R. Mizeur were approved at the November 19, 2008 Board Meeting and were e-mailed to the respective parties on December 1, 2008. See Appendices III, IV, and V. The responses to Melvin Rubin and the American Society of Consultant Pharmacists were sent back to the November Practice Committee for further consideration and revisions. Those

responses were approved at the December 17, 2008 Public Board Meeting. See Appendices VI, and VII. The Practice Committee will continue to revise a response to HMIS, Inc. (Omnicare) and will continue to draft the regulations so that they are clear, comply with the law, and address the issues presented in the informal comments. The Board anticipates that the draft regulations will be presented for final discussion and approval at a Public Board Meeting in the spring.

SURVEY OF NURSING HOMES

The Board's Compliance Unit contacted thirty long term care pharmacies in September and October 2008. Eight out of the thirty pharmacies surveyed (27%) use dispensing machines in their client nursing facilities. Only one of the pharmacies uses the dispensing machine as a remote automated dispensing device in two nursing homes (two units in each nursing home). The other pharmacies use dispensing machines as interim medication storage devices. These pharmacies use the device to store a very limited supply of unit-dose medication (both IV and PO medications) for first and missed doses. They also use the devices to store non-drug supplies.

The survey answers were obtained from the pharmacist or the director of each pharmacy. OmniCare of Salisbury, OmniCare of Annapolis Junction, OmniCare of Hebrew Home, Allied Pharmaceutical, HMIS, Contract Pharmacy Services, Inc., and Millennium Pharmacy Services, Inc. reported that they have automated dispensing devices that create unit dose medications in the pharmacies. They indicated that they have not put remote automated medication systems into long term care facilities because they did not feel that they were safe enough to be used without physical monitoring by a pharmacist.

Survey Process:

1. Contacted the facility and spoke with the Director of Pharmacy or the Managing Pharmacist.
2. Explained the purpose of the call and that the survey questions they would be asked 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.
3. Provided the definition of a remote automated medication system 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

I. Pharmacies that Use Automated Dispensing Machines as Interim Medication Storage Devices.

OmniCare of Salisbury

1. Does your organization use remote automated medication systems?
 - No
2. If no, does your company use a drug dispensing machine in any of the client long term care facilities?
How?
 - They do not consider it remote automated dispensing because it is not directly linked to the order entry system. Used as interim box, NOT linked to the pharmacy order entry system. Pharmacy can see what is removed or replaced remotely.
3. What types of machines does the company use?
 - Omnicell
4. How does it dispense the medication?
 - Dispense medication by manufacturer's unit dose, patient specific.
5. How many do you currently use?
 - 2 units
6. What types of medications do you have in the machine?
 - Medication in Omnicell: Unit Dose, IV and PO, no controlled dangerous substances
7. Who is allowed to access the machine? Who determines who will access the machine?
 - Access determined by nursing facility based on regulation, managerial level and necessity to have (all three determinants together)
 - Security features limit access to only persons with codes
8. How has the systems helped the pharmacy in the delivery and management of medication?
 - Usage tracking
9. How often is the inventory reviewed?
 - There is constant replenishment.
10. Have you had problems with the machine?
 - No
11. Does the pharmacy have a Quality Assurance program for the machine?
 - Yes for inventory and tracking use

OmniCare of Annapolis Junction

1. Does your organization use remote automated medication systems?
 - No
2. If no, does your company use a drug dispensing machine in any of the client long term care facilities?
How?
 - They do not consider it remote automated dispensing because it is not directly linked to the order entry system. Used as interim box, NOT linked to the pharmacy order entry system. Pharmacy can see what is removed or replaced remotely.
3. What type of machine does the company use?
 - Omnicell
4. How does it dispense the medication?
 - Dispense medication by manufacturer's unit dose, patient specific.
5. How many do you currently use?

- 5 units
6. What types of medications do you have in the machine?
 - Medication in Omnicell: Unit Dose, IV and PO, no controlled dangerous substances
 7. Who is allowed to access the machine? Who determines who will access the machine?
 - Access determined by nursing facility based on regulation, managerial level and necessity to have (all three determinants together)
 - Security features limit access to only persons with codes
 8. How has the systems helped the pharmacy in the delivery and management of medication?
 - Useful for tracking of use and diversion prevention; they have not experienced any break-ins
 9. How often is the inventory reviewed?
 - Monthly expired medication check and removal; Annual check of complete medication inventory
 10. Have you had any problems with the machine?
 - Admits system is costly, but very good mechanism to track inventory and prevent diversion.
 - Has system in the main pharmacy that is similar to Advance Pharmacy system, reluctant to put it in a skilled nursing facility, because it breaks-down often, perceived/experienced risk of misadventure great; therefore; they have limited the use only to pharmacists and with bar coding.
 11. Does the pharmacy have a Quality Assurance program for the machine?
 - Quality Assurance-yes, inventory, tracking use

OmniCare of Hebrew Home

1. Does your organization use remote automated medication systems?
 - No
2. If no, does your company use a drug dispensing machine in any of the client long term care facilities? How?
 - They do not consider it remote automated dispensing because it is not directly linked to the order entry system. Used as interim box, NOT linked to the pharmacy order entry system. Pharmacy can see what is removed or replaced remotely.
3. What type of machine does the company use?
 - Omnicell
4. How does it dispense the medication?
 - Dispense medication by manufacturer's unit dose, patient specific.
5. How many do you currently use?
 - 1 unit
6. What types of medications do you have in the machine?
 - Medication in Omnicell: Unit Dose, IV and PO, no controlled dangerous substances
7. Who is allowed to access the machine? Who determines who will access the machine?
 - Access determined by nursing facility based on regulation, managerial level and necessity to have (all three determinants together)
 - Security features limit access to only persons with codes
8. How has the systems helped the pharmacy in the delivery and management of medication?
 - Useful for tracking of use and diversion prevention; they have not experienced any break-ins
9. How often is the inventory reviewed?

- Monthly expired medication check and removal; Annual check of complete medication inventory
10. Have you had any problems with the machine?
- Expensive, but very good mechanism to track inventory and prevent diversion.
11. Does the pharmacy have a Quality Assurance program for the machine?
- (Pharmacy on site)
 - Quality Assurance-yes, inventory, tracking use

Allied Pharmaceutical

1. Does your organization use remote automated medication systems?
- No
2. If no, does your company use a drug dispensing machine in any of the client long term care facilities?
How?
- They do not consider it remote automated medication system because it is not directly linked to the order entry system. Used as interim box, NOT linked to the pharmacy order entry system. Pharmacy can see what is removed or replaced remotely.
3. What type of machine does the company use?
- Medispense
4. How does it dispense the medication?
- Dispense medication by manufacturer's unit dose, patient specific.
5. How many do you currently use?
- 1 unit
6. What types of medications do you have in the machine?
- Medication in Medispense: Unit Dose (IV, PO), manufacturer prepacked bags, no controlled dangerous substances.
7. Who is allowed to access the machine? Who determines who will access the machine?
- Access is limited to LPN and RN staff.
8. How has the systems helped the pharmacy in the delivery and management of medication?
- Useful for tracking of use and diversion prevention
9. How often is the inventory reviewed?
- There is constant replenishment.
10. Have you had any problems with the machine?
- Security features limit access to only persons with codes. Locks out if powered down or power outage.
11. Does the pharmacy have a Quality Assurance program for the machine?
- Quality Assurance-yes, inventory, tracking use

HMIS

1. Does your organization use remote automated medication systems?
- No
2. If no, does your company use a drug dispensing machine in any of the client long term care facilities?
How?
- They do not consider it a remote automated dispensing system because it is not directly linked to the order entry system. Used as interim box, NOT linked to the pharmacy order entry system. Pharmacy can see what is removed or replaced remotely.
3. What type of machine does the company use?
- Pyxis

4. How does it dispense the medication?
 - Dispense medication by manufacturer's unit dose, patient specific.
5. How many do you currently use?
 - 2 units
6. What types of medications do you have in the machine?
 - Medication in pyxis: Unit Dose (IV, PO), no controlled dangerous substances
 - Used for storage for interim cabinet
 - No regular doses are dispensed from the cabinet
7. Who is allowed to access the machine? Who determines who will access the machine?
 - Access is limited to LPN and RN staff.
8. How has the systems helped the pharmacy in the delivery and management of medication?
 - Tracking
9. How often is the inventory reviewed?
 - There is constant replenishment.
10. Have you had any problems with the machine?
 - No
11. Does the pharmacy have a Quality Assurance program for the machine?
 - Quality Assurance-yes, inventory, tracking use

Contract Pharmacy Services Inc

1. Does your organization use remote automated medication systems?
 - No
2. If no, does your company use a drug dispensing machine in any of the client long term care facilities?
How?
 - They do not consider it a remote automated medication system because it is not directly linked to the order entry system. Used as interim box, NOT linked to the pharmacy order entry system. Pharmacy can see what is removed or replaced remotely.
3. What type of machine does the company use?
 - Pyxis
4. How does it dispense the medication?
 - Dispense medication by manufacturer's unit dose, patient specific.
5. How many do you currently use?
 - 1 unit
6. What types of medications do you have in the machine?
 - Medication in pyxis: Unit Dose (IV, PO), no controlled dangerous substances
7. Who is allowed to access the machine? Who determines who will access the machine?
 - Access is limited to LPN and RN staff; System is refilled by technicians
8. How has the systems helped the pharmacy in the delivery and management of medication?
 - System has been very useful in tracking the use and possible diversion
9. How often is the inventory reviewed?
 - There is constant replenishment.
10. Have you had any problems with the machine?
 - No
11. Does the pharmacy have a Quality Assurance program for the machine?
 - Quality Assurance-yes, inventory, tracking use

Millennium Pharmacy Services Inc

1. Does your organization use remote automated medication systems?
 - No
2. If no, does your company use a drug dispensing machine in any of the client long term care facilities? How?
 - They do not consider it a remote automated medication system because it is not directly linked to the order entry system. Used as interim box, NOT linked to the pharmacy order entry system. Pharmacy can see what is removed or replaced remote.
3. What type of machine does the company use?
 - Medispense
4. How does it dispense the medication?
 - Interim meds
5. How many do you currently use?
 - 13 (1 for each home)
6. What types of medications do you have in the machine?
 - Unit Dose, IV, PO, supplies, controlled dangerous substances, IV start kits
7. Who is allowed to access the machine? Who determines who will access the machine?
 - Director of Nursing adds the access for RN and LPN
8. How has the systems helped the pharmacy in the delivery and management of medication?
 - Reduces # of stat delivery; tracking; prevention of diversion
 - Patient specific dispensing
9. How often is the inventory reviewed?
 - Inventory is performed every 6 by 1 or 2 of the pharmacists
10. Have you had any problems with the machine?
 - Problems include computer shut down, but machine locks so there is no risk of drug loss of diversion.
11. Does the pharmacy have a Quality Assurance program for the machine?
 - Quality Assurance-yes, inventory, tracking use

II. Pharmacy Using Remote Automated System

Advanced Pharmacy

1. Does your organization use remote automated medication systems?
 - Yes, they have four machines in two nursing homes
2. If no, does your company use a drug dispensing machine in any of the client long term care facilities? How?
 - They do not consider it a remote automated medication system because it is not directly linked to the order entry system. Used as interim box, NOT linked to the pharmacy order entry system. Pharmacy can see what is removed or replaced remote.
3. What type of machine does the company use?
 - Passport System
4. How does it dispense the medication?
 - This system provides patient specific dispensing of doses from the machine of all patient doses. The machine pre-packages the medication from pre-loaded cassettes within the machine. Medication is not unit dose, but pre-packed in bulk cassette containers and shipped to the long term care facility and loaded into the machine by a pharmacy technician.
5. How many do you currently use?
 - Four units in two nursing homes
6. What types of medications do you have in the machine?
 - Individual tablets and capsules in cassettes
7. Who is allowed to access the machine? Who determines who will access the machine?
 - Director of Nursing adds the access for RN and LPN

- Access by nursing staff, medication aides for medication dosing to patients; by pharmacist and pharmacy technician to prepare scheduled dosing totes. Access defined by Director of Nursing.
8. How has the systems helped the pharmacy in the delivery and management of medication?
- Patient specific packaging
9. How often is the inventory reviewed?
- Inventory is audited daily to determine the quantities needed. There are weekly and monthly reviews of the mechanical components of the system. The vacuum pump is checked on a weekly basis. Final check, when the package (containing that “pass” dose) comes out of the machine, is performed by a medication aide. The medication aide uses a pre-printed sheet to determine if the drug is what it’s purported to be from pictures, if available or written descriptions
10. Have you had any problems with the machine?
- They did show error occurrence reports – 5 reports (5 doses) out of 367,000 doses in a six month period, an error rate of .0000136%. They identified corrective actions for each error, and it was specific for that error.
 - The types of errors that were identified and documented were:
 - 2 Extra doses in a packet – This was corrected by reviewing the cassette and replacing it
 - 1 dessicant (small paper packet for humidity control) in the packet – This was corrected by requiring pharmacy staff to pour meds out on a tray and then place the medications into the cassette to make sure there is no dessicant present in the cassette.
 - 1 packet minus the medication that should have been in the packet – This was corrected by beginning to perform weekly planned maintenance.
 - 1 Crushed tablet – This was corrected by beginning to perform weekly planned maintenance.
11. Does the pharmacy have a Quality Assurance program for the machine?

The pharmacy has a Quality Assurance Program, but the main quality control issue is the stocking of the machine. The cassette is filled manually by a pharmacy technician and checked manually by a pharmacist. There is no bar code match between the manufacturer’s packaging and the cassette that is inserted in the machine. The bar code that is visible in Appendix VIII is the bar code read by the machine, not by the pharmacist in the pharmacy. Additionally, the pharmacy staff indicated they only fill the cassettes as needed and they do not reuse cassettes once returned from the nursing home. The Board’s inspector, however, observed returned cassettes on a shelf of the pharmacy and she inspected and shook them. The cassettes still had tablets inside of them. This is an area of concern because of the possibility of those cassettes being sent to another nursing home and potentially containing different medications or strengths of medications. The pharmacist on duty may not be able to verify what is inside those returned cassettes that have been stored on a shelf. Other quality checks included a review of paper jams involving the small paper envelopes that contain the patient’s doses. There was no internal audit of the general accuracy of data recorded/collected for filling the machine, dispensing, delivery or errors.

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 showed that there is only one pharmacy truly using remote automated dispensing machines in two nursing homes in Maryland. The first year has shown an extremely optimistic error rate of .0000136 percent. Upon closer inspection, however; the Board remains concerned about the filling of the cassettes and the final medication checks before administration to the patient.

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 two 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 grander scale, the problems identified in this report, as well as those noted through other anecdotal reports, 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

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34

10.34.28 Automated Medication Systems

Authority: Health Occupations Article, §12-205(a) and §12-605, Annotated Code of Maryland

10.34.28.01 (August 28, 2008)

.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 (August 28, 2008)

.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]~~.

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

(2) "Centralized automated medication system" means an automated medication system located in a pharmacy from which medication is distributed or prepared for final dispensing by a licensed pharmacist for a specific patient.

(3) "Decentralized automated medication system" means an automated medication system that is located outside of the pharmacy in a health care facility with an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.

(4) "Distribution" means the process resulting in the provision of a prescription or nonprescription drug or device to a separate, intervening individual, licensed and practicing under Health Occupations Article, Annotated Code of Maryland, before the administration of the provided drug or device to a patient and pursuant to an order issued by an authorized prescriber.

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

[(5)] (6) "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.

(7) "Responsible pharmacist" means a licensed pharmacist who insures 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.

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

[(6)] (8) "Starter dose" means a single first dose of medication removed from a remote or decentralized automated medication system within the first 24 hours after it is ordered.

~~[(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.]~~

.03 Limitation on Privileges to Administer (text unchanged)

10.34.28.04 (August 28, 2008)

.04 Usage Requirements.

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

(1) Records concerning transactions or operations are maintained in accordance with Regulation .10 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 automated medication system;

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

~~[(a) Reviews:~~

~~(i) Each order for medication before the medication is removed from the remote or decentralized~~

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

~~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;]~~

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

(b) Before the system permits access to the medication.

(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), Annotated Code of Maryland;

(b) The 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 Regulation .10]~~ The automated medication system is subject to a quality assurance program in accordance with Regulation .09 of this chapter[; and] .

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

~~(a) Maintain policies and procedures related to:~~

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

(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. 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 or decentralized system.

C. If a licensed pharmacist is not physically present where the 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 insure the safe and efficient operation of the system.

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

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

(a) Drug strengths;

(b) Dosage forms; or

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

(c) Drug entities; ~~[and]~~

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

~~-(2)~~ (3) [Minimizes the potential for] Safeguards against the misidentification of medications, dosages, and dosage forms by those accessing the automated medication system.

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

(1) Whether the permit holder operates a centralized, decentralized or remote automated medication system; and

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

10.34.28.05 (August 28, 2008)

~~*f.05 Multidisciplinary Committee for Remote and Decentralized Automated Medication Systems.*~~

~~The permit holder shall convene or identify a multidisciplinary committee, that includes a licensed pharmacist, that is charged with oversight of the remote or decentralized automated medication system, and shall:~~

~~(A) Establish criteria and a process for determining which drugs may be stored in a remote or decentralized automated medication system;~~

~~(B) Review the decisions, referred to in §A of this regulation, on a regular basis;~~

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

~~(C) Develop policies and procedures regarding the remote or decentralized automated medication system; and~~

~~(D) Ensure that the system complies with this chapter.~~

~~10.34.28.06 (August 28, 2008)~~

~~.06 Filling of Automated Medication System.~~

~~A. Except as provided in §B of this regulation, only a licensed pharmacist may fill an automated medication system.~~

~~B. Systems that possess sufficient safeguards to ensure accuracy of the replenishment may be filled by:~~

~~(1) Personnel supervised by a licensed pharmacist; or~~

~~(2) Health care professionals licensed under Health Occupations Article, Annotated Code of Maryland, and permitted access to an automated medication system due to the health care professionals' privileges to administer medication.~~

~~10.34.28.07 (August 28, 2008)~~

~~.07 Return of Medication to an Automated Medication System.~~

~~A. Except as provided in §B of this regulation, only a licensed pharmacist may return medication to the automated medication system.~~

~~B. Exceptions:~~

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

~~(1) Systems that possess sufficient safeguards to ensure accuracy of the replenishment may have medication returned to these systems by:~~

~~(a) Personnel supervised by a licensed pharmacist; or~~

~~(b) Health care professionals licensed under Health Occupations Article, Annotated Code of Maryland, and permitted access to an automated medication system due to the health care professionals' privileges to administer medication.~~

~~(2) Personnel supervised by a licensed pharmacist, or health care professionals licensed under Health Occupations Article, Annotated Code of Maryland, and permitted access to an automated medication system due to the health care professionals' privileges to administer medication, may return medication to an automated medication system which possesses sufficient safeguards to ensure the accuracy of the return, for subsequent administration provided:~~

~~(a) The medication is in an unadulterated form;~~

~~(b) If in a unit of use package, the medication is in the intact package that the medication was in when initially removed from the system;~~

~~(c) The return of medication is documented within the system or in other records maintained by a licensed pharmacist; and~~

~~(d) The return of medication is conducted in accordance with written procedures.~~

10.34.28.08 (August 28, 2008)

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

~~.08 Final Check of Medication for Centralized Automated Medication Systems:~~

~~A. Except as provided in §B of this regulation, before distribution or dispensing, a licensed pharmacist shall check each medication removed from the centralized automated medication system.~~

~~B. Exception. A licensed pharmacist utilizing a centralized automated medication system may distribute patient specific medications within the licensed health care facility without checking each medication selected by the system, if:~~

~~(1) The medication is distributed for subsequent administration by a health care professional permitted by law to administer medication;~~

~~(2) A licensed pharmacist performs a daily quality assurance check of the integrity of the system that includes random sampling of the output; and~~

~~(3) The permit holder otherwise complies with this chapter.]~~

.05 Additional Usage Requirements for Remote Automated Medication Systems.

A. In addition to the requirements set forth in Regulation .04 of this chapter, a remote automated medication system may be used only if the system:

(1) Uses positive drug identification such as bar code technology to insure 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;

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

(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 Occupations 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.

B. The permit holder shall insure 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 .09 of this chapter.

.06 Stocking of Automated Medication Systems.

A. A licensed pharmacist shall verify the accuracy of medications selected for stocking and replenishment of the automated medication system before the medications are stocked into the system.

B. Except as provided in §C of this regulation, automated medication systems shall be stocked by a

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

licensed pharmacist.

C. Automated medication systems 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:

(1) Licensed pharmacist; or

(2) Registered pharmacy technician.

.07 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 disposal.

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

10.34.28.09 (August 28, 2008)

~~f.09]~~ .08 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. The capabilities and limitations of the system;
- B. ~~[The]~~ Procedures for the operation of the system; and
- C. Procedures for system downtime.

10.34.28.10 (August 28, 2008)

~~f.10]~~ .09 Quality Assurance Program.

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

- A. ~~[Review of system overrides;]~~ 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 insure appropriate utilization;

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

B. A testing program which includes daily accuracy sampling that verifies the integrity of the system;

~~{B.}~~ C. Investigation of medication errors related to the automated medication system, and remedial actions taken;

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

~~{D.}~~ E. Review of the overall functioning of the system[.];

F. Security and access;

G. Preventative maintenance;

H. Sanitation;

I. Storage conditions

J. Inventory of drugs;

K. Drug procurement, delivery, and receipt;

L. Recordkeeping;

M. Proper labeling procedures; and

N. Protocols in the event of a power outage or other situation in which the services of the system are interrupted, that include;

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

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

(2) A plan for recovery.

10.34.28.11 (August 28, 2008)

~~[11]~~ .10 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;

~~[(3)]~~ (4) Accuracy audits and system performance audits;

~~[(4)]~~ (5) Copies of reports and analyses generated as part of the quality assurance program, including the 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) Contents of the training program;

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

(b) Dates of training completion; and

(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;

and

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

(i) Identity of the system accessed;

(ii) Identification of the individual accessing 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;

(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

[DRAFT regulations, originally approved at Sept. 17, 2008 Board Meeting, still in revision process]

(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.]~~

.11 Security.

A. The responsible pharmacist shall insure 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 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 2, 2008)

.12 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.

.13 Controlled Dangerous Substances (text unchanged)

JOHN M. COLMERS
Secretary of Health and Mental Hygiene

APPENDIX III



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

November 26, 2008

Howard Schiff
Executive Director
Maryland Pharmacists Association
650 West Lombard Street
Baltimore, Maryland 21201

schiff@marylandpharmacist.org

Dear Mr. Schiff:

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.

.06C(2)

You had asked why the Board included pharmacy technicians in the regulations. Pharmacy technicians are included because it provides the pharmacist and permit holder with other stocking options and pharmacy technicians are always supervised by a pharmacist.

.07B

.07B provides for the return of unused medications distributed from a remote or decentralized automated medication system. The method of return is a one-way returns bin that is subsequently returned to the permit holder. A pharmacist is not included in this section because a pharmacist would not be available at a remote or decentralized automated medication system that may possible be located in a health care facility that is miles from the pharmacy. The Board feels that return medications to a one-way return bin is equivalent to returning to a pharmacy.

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,

A handwritten signature in cursive script, appearing to read "LaVerne G. Naesea".

LaVerne G. Naesea
Executive Director

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

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

November 26, 2008

Jim Moncrief
Chairman
Advanced Pharmacy
8910 Route 108, Suite C
Columbia, Maryland 21045

jmoncrief@advancedpharmacy.com

Dear Mr. Moncrief:

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.

.05A(4)(b)

You suggested that this section be revised to read "If a picture is not available, a written description of the medication specifically by unique manufacturer markings." because it would be burdensome to include the color and shape for 10% of all medications where pictures are not available. The Board feels that 10% of all medications are just as critical to patient safety as the other 90%. If a picture is not available, the certified medication aide should have as much information as possible when checking the medications dispensed by the remote automated medication system such as color and shape.

.06C

You commented that because a licensed pharmacist must already verify the accuracy of the medications to go into an automated medication system, and because of the overall accountability for all aspects of the automated medication system, it is redundant to require a licensed pharmacist or registered pharmacy technician to stock the system. The Board is aware the pharmacist checks the medication before it leaves the pharmacy, however, the Board believes that a positive identification of the medications be made before the medications are deposited into the device. The checking process requires two distinct steps to assure that the correct medications are deposited into a machine that has the potential to dispense an incorrect medication to an entire health care facility.

.09B

You commented that daily accuracy sampling is not required by the statute, not intended by the statute, does not further the objective of ensuring the integrity of the overall system and vitiates the efficiencies that can be obtained by having a remote automated medication system. The Board maintains that a

pharmacist can not do an integrated test of the device without entering an order and verifying that the right result occurred, which would be sampling what is dispensed by the machine.

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 Board acknowledges that you would like an opportunity to meet with the Board to discuss your concerns. Due to the varied entities that have provided informal comments to the draft regulations which apply to all automated medication systems, not just remote automated medication systems, the Board will not be able to meet with individual entities. 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
Constance H. Baker, Esq.
Robin Shavitz
Ann Hubbard, Director, Office of Governmental Affairs
Shawn Cain, Assistant Director, Office of Governmental Affairs

APPENDIX V



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

November 26, 2008

The Honorable Heather R. Mizur
Delegate, Maryland General Assembly
6 Bladen Street, Room 219
Annapolis, Maryland 21401

Heather.Mizur@house.state.md.us

Dear Delegate Mizur:

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 and thank you for your support of this endeavor. Below you will find the Board's responses to your concerns.

.05A(4)(b)

You had commented that in those instances where a picture is not available, the unique manufacturer markings would provide more useful and accurate information than a written description of the pill. Although pictures are available for 90% of all medications, the Board feels that the other 10% of all medications are just as critical to patient safety. If a picture is not available, the certified medication aide should have as much information as possible when checking the medications dispensed by the remote automated medication system such as color and shape.

.06C

You commented that because a licensed pharmacist must already verify the accuracy of the medications to go into an automated medication system, and because of the overall accountability for all aspects of the automated medication system, it is redundant to require a licensed pharmacist or registered pharmacy technician to stock the system. The Board is aware the pharmacist checks the medication before it leaves the pharmacy, however, the Board believes that a positive identification of the medications be made before the medications are deposited into the device. The checking process requires two distinct steps to assure that the correct medications are deposited into a machine that has the potential to dispense an incorrect medication to an entire health care facility.

.09B

You had commented that you hoped that the quality assurance provisions included in the regulations can be written in such a way as to assure a system's day-to-day integrity without creating overly burdensome requirements that might negate the efficiencies made possible by a remote automated medication

system. The Board included a daily accuracy sampling because the Board maintains that a pharmacist can not do an integrated test of the device without entering an order and verifying that the right result occurred, which would be sampling what is dispensed from the machine.

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,

A handwritten signature in cursive script, appearing to read "LaVerne G. Naesea", written in dark ink on a white background.

LaVerne G. Naesea
Executive Director

cc: Anna D. Jeffers, Legislation and Regulations Manager, Board of Pharmacy
Linda Bethman, Board Counsel, Board of Pharmacy
Ann Hubbard, Director, Office of Governmental Affairs
Shawn Cain, Assistant Director, Office of Governmental Affairs

APPENDIX VI

December 17, 2008

Melvin Rubin
4001 Old Court Road, #419
Baltimore, Maryland 21208
mnrubin@verizon.net

Dear Mr. Rubin:

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.

.04A(3)(a) and (b)

You are correct that it does appear as if there would be a double check required for a retail pharmacist using an automated system. 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 .04A(3)(a) and (b) into the renumbered Regulation .06 Additional Usage Requirements for Remote Automated Medication Systems, since Section .04A(3)(a) and (b) only applies to remote systems. Sections .04B and C will also be moved to the new .06 Additional Usage Requirements for Remote Automated Medication Systems. Those sections address starter doses and the absent pharmacist having access to the system by electronic and visual means. Section .04D, which limits simultaneous access, will be moved and repeated in both the decentralized and remote regulations, since it applies to both.

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 VII

December 17, 2008

Claudia Schlosberg, J.D.
Director, Policy and Advocacy
American Society of Consultant Pharmacists
1321 Duke Street
Alexandria, Virginia 22314-3563

cschlosberg@ascp.com

Dear Ms. Schlosberg:

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.

.04A(3) and .04B

You had asked why an exception has been made in the draft regulations for "starter doses." An exception has been made for "starter doses" because Health Occupations Article, 12-605(d)(1)(ii), Annotated Code of Maryland, allows for that exception.

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 .04A(3) into the renumbered Regulation .06 Additional Usage Requirements for Remote Automated Medication Systems, since Section .04A(3) only applies to remote systems. Sections .04B and C will also be moved to the new .06 Additional Usage Requirements for Remote Automated Medication Systems. Those sections address starter doses and the absent pharmacist having access to the system by electronic and visual means. Section .04D, which limits simultaneous access, will be moved and repeated in both the decentralized and remote regulations, since it applies to both.

.04C

In this section "visual means" does indeed mean a video camera. The Board believes this does add value because it serves as a second check for the pharmacist who is not physically present where the automated medication system is located. Additionally, 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

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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. Also, keep in mind that .04C will be moved under the new Regulation .06 Additional Usage Requirements for Remote Automated Medication Systems.

.04D

You had asked if this section allows only one drug product to be accessed at a time. This section was drafted to allow for access to multiple drugs prescribed for a specific patient. Access to multiple non-patient specific medications is not allowed.

You had also asked that “Does not impede timely access to ordered medications” be added to this section. You indicated that there may be lag time between when the order is written and when it is recorded into the dispensing system, especially if the facility relies on paper records. .04D is exclusively for remote or decentralized automated medication systems. These systems were developed to eliminate lag time so this phrase would not need to be added. Keep in mind that Section .04D, which limits simultaneous access, will be moved and repeated in both the .05 decentralized and .06 remote regulations, since it applies to both.

.05A(1)

You had asked that other examples of positive drug identification be added to this subsection to exemplify that other technologies are permitted. The Board feels that this subsection does allow for other forms of positive drug identification technology since it uses the words “such as” to mean that bar code technology is one of the options available. Keep in mind that this regulation will be renumbered to be .06.

.09B and .10B(5)

You had asked for clarification of a testing program requiring “daily activity” or “daily accuracy sampling” and indicated that it may be a burden. “Daily inspection of the integrity of the system” is required to be included in a quality assurance program for remote automated medication systems. See Health Occupations Article, 12-605(e)(2)(ii), Annotated Code of Maryland. The Board included a daily accuracy sampling because the Board maintains that a pharmacist can not do an integrated test of the device without entering an order and verifying that the right result occurred, which would be sampling what is dispensed from the machine. Keep in mind that this regulation will be renumbered.

.10B

Regulation .10 set forth the record keeping requirements for all automated medication systems. One of the requirements is documentation of patient outcomes resulting from system failures. You had requested further clarification concerning what may constitute a system failure. Since there may be a myriad of reasons for system failures which have the potential to impact patient care, the Board feels that this definition should be open ended to include any known or unknown system failure that may occur. Keep in mind that this regulation will be renumbered.

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.11A

The regulations set forth that the responsible pharmacist shall insure the security of the automated medication system because that responsibility is given to the pharmacist in two places in the statute. See Health Occupations Article, 12-605(b) and (f), Annotated Code of Maryland. Keep in mind that this regulation will be renumbered.

.11B(3)

You had commented that requiring the system database to be updated daily to remove inactive passwords may be burden over the weekend. The Board feels that daily updates of the system database are essential since someone with password access may be fired or leave a position over the weekend or on a holiday. Furthermore, the statute requires that the health care facility where the system is located shall have at least technical assistance regarding operation of the system available 24 hours per day. See Health Occupations Article, 12-605(d)(3)(ii), Annotated Code of Maryland. Keep in mind that this regulation will be renumbered.

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 VIII

(See next page)

