

REGULATION PUBLICATION FORMS (Revised 9/06)

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

10.34.23 Pharmaceutical Services to [Residents] Patients in [Long-Term] Comprehensive Care Facilities

Authority: Health Occupations Article, § 12-205, 12-301, 12-401, 12-403, 12-501, 12-503, 12-504, 12-505, 12-506, 12-509, Annotated Code of Maryland

Is There Emergency Text That is Identical to the Proposed Text:

Yes No

Is There an Incorporation by Reference Document Associated with this Proposal?

Yes No

Does this Proposal have an impact on environmental hazards affecting the health of children as defined in Health-General Article, §13-1501(c)?

Yes (explain) No

Notice of Proposed Action

The Department of Health and Mental Hygiene proposes to amend Regulations .01 and .02, repeal Regulation .03, and amend and recodify Regulations .04 - .11 to be Regulations .03 - .10 under COMAR 10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities. This action was considered by the Board of Pharmacy at a public meeting held November 18, 2009, notice of which was given by publication on the Board of Pharmacy web site www.mdbop.org from November 16, 2009—November 18, 2009, pursuant to the State Government Article, §10-506(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this proposal is to revise this chapter to reflect the current practice of pharmacy in a comprehensive care facility and to revise outdated terminology and regulatory references. The broader definition of “long term care facility” has been deleted and the definition of a “comprehensive care facility” has been added which narrows the focus of these regulations to facilities that admit patients suffering from disease or disabilities or advance age, requiring medical service and nursing service rendered by or under the supervision of a registered nurse. The policies and procedures of the permit holder must now include access to a pharmacy, provisions for safe and efficient dispensing and delivery, and appropriate labeling and storage. Requirements have been added for packaging medications received from another pharmacy. The regulation that covers drug control and accountability now sets forth requirements for 1) returns and discontinued medications; and 2) the content of prescriptions, chart orders and verbal orders; and 3) the manner in which prescriptions, chart orders and verbal orders are received by the pharmacy.

Comparison to Federal Standards (Check one option)

- There is no corresponding federal standard to this proposed action.
or
 There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

The corresponding federal standard is:

- or
 In compliance with Executive Order 01.01.1996.03, this proposed action is more restrictive or stringent than corresponding federal standards as follows:

- (1) Regulation citation and manner in which it is more restrictive than the applicable federal standard:
- (2) Benefit to the public health, safety or welfare, or the environment:
- (3) Analysis of additional burden or cost on the regulated person:

(4) Justification for the need for more restrictive standards:

Impact Statements
Part A
(check one option)

Estimate of Economic Impact

The proposed action has no economic impact.

Or

The proposed action has an economic impact. (IF this is checked, complete the following form in its entirety)

I. Summary of Economic Impact. Pharmacies that service comprehensive care facilities may be required to rewrite their policies and procedures, which should be reviewed periodically as a matter of course. Most revisions in this proposal reflect or refine the current practice of pharmacy. Revisions may include adapting pharmacy labels to reflect requirements in the regulations or adapting already existing packaging procedures.

II. Types of Economic Impact. <u>Magnitude</u>	Revenue (R+/R-) <u>Expenditure (E+/E-)</u>	
A. On issuing agency:	(E-)	Minimal
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) <u>Cost (-)</u>	
<u>Magnitude</u>		
D. On regulated industries or trade groups: (-) Unquantifiable		
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public: Unquantifiable	(+)	

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

II. A. The Board of Pharmacy would have to revise the Long Term Care Inspection Form, which is revised periodically as a matter of course.

II. D. The cost to pharmacies that service comprehensive care facilities is difficult to determine because some pharmacies may already comply with the revisions. Other pharmacies may have to make minimal adjustments to labeling content and packaging procedures.

II. F. There may be a reduction in medication errors or labeling errors for patients in comprehensive care facilities.

Part B
Economic Impact on Small Businesses
(check one option)

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

or

The proposed action has a meaningful economic impact on small businesses. An analysis of this economic impact follows.

Impact on Individuals with Disabilities
(check one option)

The proposed action has no impact on individuals with disabilities.

or

The proposed action has an impact on individuals with disabilities as follows:

(Agency to complete this assessment)

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 1-877-4MD-DHMH, extension 6499, or fax to (410) 333-7687, or email to regs@dhmh.state.md.us. Comments will be accepted through

Part C
(For legislative use only; not for publication)

A. Fiscal Year in which regulations will become effective: FY 2010

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B. Does the budget for fiscal year in which regulations become effective contain funds to implement the regulations?

Yes No N/A

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.

The Board is not required to obtain information concerning which pharmacies are also small businesses. Pharmacies that service comprehensive care facilities may be required to rewrite their policies and procedures, which should be reviewed periodically as a matter of course. Some pharmacies that service comprehensive care facilities may need to adapt their labels or packaging procedures to reflect the requirements in the regulations.

10.34.23.01 (*September 24, 2009*)

.01 Scope.

This chapter applies to [all] pharmacies and licensed pharmacists serving comprehensive care facilities as defined in Regulation .02 of this chapter, except for pharmacies providing only emergency services for these facilities.

10.34.23.02 (*September 24, 2009*)

.02 Definitions.

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

B. Terms Defined.

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(1) ["Correctional facility" means a place of incarceration maintained by a government agency where persons are confined after committing a violation of the law.

(2) "Chart order" means a lawful order entered on the chart or a medical record of a patient of a comprehensive care facility by an authorized prescriber or the authorized prescriber's designated agent for a drug or device.

(2) Comprehensive Care Facility.

(a) "Comprehensive care facility" means a facility which admits patients suffering from disease or disabilities or advanced age, requiring medical service and nursing service rendered by or under the supervision of a registered nurse.

(b) "Comprehensive care facility" does not mean an establishment which provides only:

(i) Acute care; or

(ii) Assisted living care.

(3) "Emergency drug kit" means a [box] container or electronic storage system containing medications which [may]:

(a) May be required for the emergency need of a [resident] patient and [which may]

(b) Are not [be] available from [any other] an authorized source in a timely manner.

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

[(4) Long-Term Care Facility.

(a) "Long-term care facility" means a setting which arranges for the provision of pharmaceutical services to residents, including but not limited to the following:

(i) "Comprehensive care facility" as defined in COMAR 10.07.02.01B(6);

(ii) "Correctional facility" as defined in §B(1) of this regulation;

(iii) "Domiciliary care home" as defined in COMAR 10.07.03.01B(6);

(iv) "Extended care facility" as defined in COMAR 10.07.02.01B(12); and

(v) "Nursing facility" as defined in COMAR 10.07.02.01B(25).

(b) "Long-term care facility" does not mean an establishment which provides only acute care.]

(5) "Licensed pharmacist" means, unless the context requires otherwise, a pharmacist who is licensed by the Board to practice pharmacy.

(6) "Packaging" means the process by which a medication is:

(a) Removed from a:

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(i) Non-patient specific manufacturer's original container; or

(ii) Patient specific container directly received from another pharmacy licensed in Maryland or operated by the government of the United States provided that the manufacturer's name is present on the container; and

(b) Placed into a new container by a licensed pharmacist or registered pharmacy technician under the supervision of a pharmacist.

(7) "Pharmaceutical services" means the care within practice standards, laws, regulations, and guidelines which is afforded by [the] a licensed pharmacist [or licensed pharmacy] to the [residents of a] patients of a comprehensive care facility.

[(6)] (8) "Pharmacy" means a holder of a pharmacy permit issued by the Board of Pharmacy, located either on the premises of or outside the [long-term] comprehensive care facility and which provides pharmaceutical services to [residents in a long-term] patients in a comprehensive care facility.

[(7)] (9) "Pharmacy area" means that portion of the licensed pharmacy where medication and other products requiring a prescription by federal or State law are stored and where the prescriptions are compounded or prepared.

(10) "Registered pharmacy technician" means an individual who is registered with the Board to perform delegated pharmacy acts.

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[(8)] (11) "Verbal order" means a directive that is orally communicated to a [person authorized] licensed pharmacist to accept a prescription order by a person who is authorized to communicate a prescription.

[(9)] (12) "Written order" means a directive that is directly written by an authorized prescriber or a transcription of an order from an authorized prescriber by a person authorized to transcribe an order.

10.34.23.04 (September 24, 2009)

[.04 Policy] .03 Policies and Procedures.

The permit holder shall establish and operate under [written] a policies and procedures manual which [comply];

A. Complies with this [subtitle and which define] chapter;

B. Defines the scope and method of pharmacy services provided to the [residents] patients of the comprehensive care facility. [The pharmacy shall provide the written policies and procedures manual to the personnel of the pharmacy and, upon request, to an agent of the Board.]

C. Determines when personnel may have access to the pharmacy area;

D. Provides for the safe and efficient dispensing and delivery of pharmaceutical products as outlined in this subtitle;

E. Includes:

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(1) Labeling requirements and distribution methods for medication provided in a single container, slot, blister package, or other method of delivering an entire single dosing unit; and

(2) The conditions in which an interim box may be replenished or prepared, delivered and stored by the comprehensive care facility;

F. Is provided to:

(1) The personnel of the pharmacy;

(2) The comprehensive care facility; and

(3) Upon request, an agent of the Board; and

G. Is in a form that is:

(1) Written or electronic; and

(2) Readily retrievable.

10.34.23.05 *(September 24, 2009)*

[.05] .04 Personnel.

A. Director of Pharmacy. The permit holder shall appoint a licensed pharmacist as director of pharmacy who is:

(1) Licensed to engage in the practice of pharmacy in Maryland;

(2) Knowledgeable in, and thoroughly familiar with, the specialized functions of [long-term] comprehensive care facility pharmaceutical services;

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(3) Responsible for and in full and actual charge of the pharmacy and its personnel;

(4) Responsible for the operations of the pharmacy and for compliance with the requirements of Health Occupations Article, Title 12, Annotated Code of Maryland, and the regulations promulgated under that title; and

(5) Responsible for reviewing the policies and procedures manual of the pharmacy annually and revising it as necessary.

B. Staff.

(1) The permit holder [shall]:

(a) May employ [ancillary personnel] registered pharmacy technicians as required to provide pharmaceutical services to the [residents] patients of [the] comprehensive care facilities [which it serves competently and safely] ; and [shall]

(b) Shall provide [written] policies and procedures that specify the duties that may be performed by [ancillary personnel] registered pharmacy technicians under the [direct and personal] supervision of a licensed pharmacist and the duties that may be performed only by a licensed pharmacist.

(2) The permit holder may employ [non-licensed] unlicensed personnel to provide [secretarial and clerical] operational support as [required to assist with

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record keeping, report submission, and any other administrative duties] defined in COMAR 10.34.21.02B(2).

10.34.23.06 (September 24, 2009)

[.06] .05 Physical Requirements.

A. Storage. The director [or the director's pharmacist] of pharmacy or designee shall ensure that [all] medications and supplies within the pharmacy are properly stored according to the manufacturer's specifications, State and federal laws and regulations with respect to [sanitation, temperature, light, ventilation, moisture control, segregation, and security according to the manufacturer's specifications.]:

(1) Sanitation;

(2) Temperature;

(3) Light;

(4) Ventilation;

(5) Moisture control;

(6) Segregation; and

(7) Security.

B. Equipment and Materials.

(1) The director [or the director's pharmacist] of pharmacy or designee shall ensure that the pharmacy contains appropriate [professional]:

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(a) Equipment[, supplies,];

(b) Supplies; and [physical]

(c) Physical facilities for proper compounding, preparation, and dispensing of medications, [including parenteral preparations, if applicable,] as outlined in COMAR 10.34.19.

(2) The director [or the director's pharmacist] of pharmacy or designee shall ensure that the pharmacy contains appropriate reference materials to enable personnel to prepare and dispense medications properly as outlined in COMAR 10.34.07.

C. Security.

(1) [The director or the director's pharmacist designee shall develop policies and procedures regarding personnel who have access to the pharmacy area and shall ensure that the policies and procedures are written and readily available as reference to the pharmacy personnel.

(2)] The director of pharmacy or designee shall ensure that no [authorized personnel] individual enters the pharmacy area unless a licensed pharmacist is on duty.

[(3) The director or the director's pharmacist designee shall ensure that the pharmacy area is enclosed as outlined in COMAR 10.34.05.02A and B.

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(4) The director shall ensure that the enclosure of the pharmacy area protects the prescription medication stock against unauthorized entry as outlined in COMAR 10.34.05.02A and B.]

(2) The permit holder and the director of pharmacy or designee shall ensure compliance with COMAR 10.34.05.

10.34.23.07 (September 24, 2009)

[.07] .06 Medication and Device Distribution and Pharmaceutical Services.

A. [The director shall ensure that the policies and procedures of the pharmacy provide for the safe and efficient dispensing and delivery of pharmaceutical products as outlined in this subtitle, and that a copy of the policies and procedures manual is in the pharmacy area for inspection by the Board.

B.] The director [or the director's pharmacist] of pharmacy or designee shall be responsible for the safe and efficient dispensing, delivery, control of, and accountability for [all] medications and [for] devices [requiring a prescription under federal or State law] dispensed or distributed by the permit holder.

B.The director of pharmacy or designee shall work in cooperation with the professional staff of the comprehensive care facility in meeting [this responsibility] the responsibilities set forth in § C of this regulation and in

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ordering, storing, and accounting for pharmaceutical materials. [Accordingly, the]

C. The director of pharmacy or designee shall be responsible for, at a minimum:

(1) The preparation [under aseptic conditions] medications compounded in the pharmacy, as applicable;

(2) The proper preparation, storage, and distribution of [parenteral admixtures] compounded sterile preparations according to COMAR 10.34.19 to the extent that the functions are performed at the pharmacy;

(3) The [prepackaging] packaging and [prelabeling] labeling of medications;

(4) [The repackaging of medications at the pharmacy;

(5)] Records of [all] transactions of the pharmacy as may be required by applicable law and as may be necessary to maintain accurate control over and accountability for [all] pharmaceuticals, including [resident] patient medication profiles;

[(6)] (5) Participation in those aspects of the comprehensive care facility's quality assurance improvement program which relate to pharmaceutical care and effectiveness; and

[(7)] (6) Implementation of the policies and decisions of the appropriate committee or committees of the comprehensive care facility related to these regulations and to other regulations of the comprehensive care facility.

10.34.23.08 (September 24, 2009)

[.08] .07 Medication [Prepackaging and Repackaging] Packaging.

A.[The pharmacist shall verify the manual or automated selection of prepackaged and prelabeled doses of medication and the repackaging of medication in unit dose packages or any other form of repackaging performed by ancillary personnel for the following:]

A licensed pharmacist shall verify the selection of medication to be packaged and verify the completed packaging of medication performed by registered pharmacy technicians for the following:

- (1) Accuracy;
- (2) Completeness; [and]
- (3) Appropriateness[.]; and
- (4) Compliance with the U.S. Food and Drug Administration and current United States Pharmacopeia approved packaging.

B. The licensed pharmacist shall ensure that labeling of the medication container includes the:

- (1) Brand or generic name of the medication;
- (2) Strength of the medication, if appropriate;
- (3) Name of the [distributor or manufacturer,] pharmacy; and
- (4) [Lot number of the distributor or manufacturer; and

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(5)] Expiration date of the medication.

C. Unless the licensed pharmacist has reason to reduce the time period, the expiration date of the medication is the lesser of:

(1) 12 months from the date of [repackaging] packaging;

(2) The manufacturer's or distributor's listed expiration date; or

(3) The maximum time period allowed for the specific packaging used for the medication.

D. Packaged from the Manufacturer's original container.

The pharmacy may use a lot number and expiration date assigned by the pharmacy instead of the distributor or manufacturer information [if] in a master log [is] if kept with respect to [all] drugs that are [repackaged] packaged within the pharmacy facility from the original manufacturer's container which includes the:

(1) Name of the drug;

(2) Strength;

(3) Manufacturer;

(4) Lot number assigned by the pharmacy;

(5) Lot number assigned by the distributor or manufacturer;

[(5)] (6) Quantity [repackaged] packaged;

[(6)] (7) Expiration date as defined in §C of this regulation;

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[(7)] (8) Manufacturer's expiration date;

[(8) Lot number assigned by the distributor or manufacturer;]

(9) Date of [repackaging] packaging;

(10) Name of person [repackaging] packaging; and

(11) Name and initials of verifying licensed pharmacist.

E. Packaged from Another Pharmacy.

(1) The licensed pharmacist determines that the prescription medication received from another pharmacy has been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the time it was dispensed by the original pharmacy and received by the packaging pharmacy.

(2) The licensed pharmacist shall package and dispense at one time the entire quantity of the prescription medications received from another pharmacy for packaging.

(3) The licensed pharmacist shall package medications only if the manufacturer's name is present on the container.

(4) The licensed pharmacist may use a lot number and expiration date assigned by the pharmacy instead of the distributor or manufacturer information in a master log that includes the following information:

(a) Name of the drug;

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(b) Strength;

(c) Manufacturer;

(d) Name, address, and phone number of the original dispensing pharmacy;

(e) Prescription number for the original dispensing pharmacy;

(f) Quantity packaged;

(g) Expiration date as assigned by the original dispensing pharmacy;

(h) Date of packaging;

(i) Name of individual packaging;

(j) Name and initials of verifying licensed pharmacist; and

(k) Name of the patient.

10.34.23.09 (September 24, 2009)

[.09] .08 Labeling of Patient Medications.

A. The director [or the director's pharmacist] of pharmacy or designee shall ensure that [all] medications dispensed by the pharmacy and intended for use within the comprehensive care facility are dispensed in appropriate containers and are labeled with the:

(1) Name and address of the pharmacy;

(2) Date of dispensing;

(3) Prescription number assigned by the pharmacy;

(4) Name of the [resident] patient;

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(5) Name, quantity, and strength of the drug;

(6) Name of the prescriber;

(7) Expiration date of the drug [when required by law];

(8) Required precautionary information regarding controlled substances; and

(9) Further cautionary information as may be required or desirable for proper use of the medication.

B. Labeling requirements for medication provided per dosing period in a single container, slot, blister package, or any other method of delivering an entire single dosing unit may be established as policies and procedures of the comprehensive care facility. [The director or the director's pharmacist designee shall ensure that the method of delivering medication utilized by the pharmacy ensures that the patient receives the proper medication and that all other information identified in Regulation .08 of this chapter is provided on the individual doses or in some other form.]

C. The director of pharmacy or designee shall be responsible for the safe and efficient dispensing, delivery, control or, and accountability for medications and devices dispensed or distributed by the permit holder.

D. The director of pharmacy or designee shall work in cooperation with the other professional staff of the comprehensive care facility in meeting the

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responsibilities set forth in §B of the regulation and in ordering, storing, and accounting for pharmaceutical materials.

E. Compounded Sterile Preparations.

When compounding sterile preparations a licensed pharmacist or a registered pharmacy technician under the licensed pharmacist's supervision, shall comply with the compounding and labeling requirements of COMAR 10.34.19.

10.34.23.10 (September 24, 2009)

[.10] .09 Drug Control and Accountability.

A. [Discontinued Medications.

(1)] The director of pharmacy or designee shall develop a process for the pharmacy to be notified of medications which have been discontinued.

[(2) Only sealed, unopened packages or individual unit dose blisters may be returned to the inventory of the pharmacy.

(3) Drugs classified as Schedule II, Schedule III, Schedule IV, and Schedule V may not be returned to the inventory of the pharmacy.

(4) Drugs requiring refrigeration may not be returned to the inventory of the pharmacy.

(5) Section A(2)----(4) of this regulation does not apply to a pharmacy using a distribution system which classifies all medication as pharmacy inventory until after actual utilization of the medication by a patient.]

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B. Medications may be accepted for return if:

(1) The returned medication is properly labeled and properly sealed in the manufacturer's package or an individually labeled unit dose of a drug or a device;

(2) The licensed pharmacist determines that the returned medication has been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the sale of the drug or device and its return to the pharmacy; and

(3) The permit holder otherwise complies with COMAR 10.34.10.07.

C. Discontinued Medications – Controlled Dangerous Substances.

(1) Except as provided in §§B(2) and C(2) of this regulations, drugs classified as Schedule II, Schedule III, Schedule IV and Schedule V may not be returned to the inventory of the pharmacy.

(2) Schedule III, Schedule IV and Schedule V medications may be returned to inventory of a pharmacy when the pharmacy uses a distribution system that classifies medications as pharmacy inventory until the utilization of the medication by the patient.

D. A compounded sterile preparation may not be returned to the inventory of a pharmacy.

E. Drugs requiring refrigeration may not be returned to the inventory of a pharmacy.

[B.] F. Emergency Drug Kit.

(1) The director [or the director's] of pharmacy or designee shall ensure that the emergency drug kit is secured with a tamper-evident seal or electronic security system which will indicate the opening of the kit.

(2) Labeling. The director [or the director's] of pharmacy or designee shall ensure that the emergency drug kit meets the following specifications:

(a) The exterior of the emergency drug kit is labeled to indicate clearly and unmistakably that it is an emergency drug kit and that it is for use in emergencies only;

(b) The exterior of the emergency drug kit is labeled to indicate the:

(i) Names of the drugs contained in the emergency drug kit,

(ii) Strengths of the drugs contained in the emergency drug kit,

(iii) [Expiration dates of the drugs contained in the emergency drug kit.] List of contents with expiration dates, with the date of the first item to expire in bold print; and

(iv) The quantity of each drug contained in the emergency drug kit.

(c) [All medications] Medications contained in the emergency drug kit are labeled with the:

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(i) Name of the drug,

(ii) Strength of the drug,

(iii) Expiration date of the drug,

(iv) Lot number of the drug, and

(v) [Any other] Other information required by the medical staff.

(3) Replacement of Medications.

(a) A licensed pharmacist or licensed pharmacist's designee shall replace the emergency drug kit or [restock any] replenish used or expired drugs contained in the emergency drug kit within 72 hours of notification of use or expiration.

(b) A licensed pharmacist shall perform the final check on the contents of the emergency drug kit.

[C.] G. Interim Box. An interim box may be provided by the pharmacy and kept at the comprehensive care facility if the comprehensive care facility policies and procedures of the comprehensive care facility address an interim box and the pharmacy complies with these policies and procedures.

[D.] H. Prescriber Orders.

(1) A licensed pharmacist shall dispense medications from the pharmacy only upon receipt of valid written prescription, chart order or verbal [orders] order from an authorized prescriber.

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(2) A chart order shall be considered a prescription drug order provided that the prescription drug order contains:

(a) The full name of the patient;

(b) The date of issuance;

(c) The name, strength, and dosage form of the drug prescriber;

(d) The name, type and specifications of any device;

(e) The directions for use;

(f) If written, the authorized prescriber's signature or the signature of the authorized prescriber's agent (including the name of the authorized prescriber);

(g) If electronically transmitted complies with COMAR 10.34.20; and

(h) If verbal, the name of the prescriber and the prescriber's agent, if applicable.

(3) A written order may be received by the pharmacy by facsimile, electronic transmission, or as the original physician order.

~~[(3)]~~ (4) The licensed pharmacist shall document immediately a verbal order in writing.

(4) [The pharmacist shall document a written order to verify the verbal order.]

A licensed pharmacist may receive a verbal order:

(a) By phone with the licensed pharmacist reading back the prescription to the prescriber or the prescriber's agent.

(b) By a voice messaging system.

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[E.] I. Controlled Dangerous Substances.

(1) Drug Accountability. The [permit holder] permit holder shall ensure that personnel employed by the pharmacy abide by [all] the laws and regulations as defined in Health-General Article, Title 27, Annotated Code of Maryland, and COMAR 10.19.03.

(2) Storage and Security. The permit holder shall establish effective procedures for storage and security of Schedule II controlled dangerous substances including limitation of access to these drugs in the pharmacy to licensed pharmacists and registered pharmacy technicians.

[F.] J. Drug Recalls. The director [or the director's pharmacist] of pharmacy or designee shall develop and implement a recall procedure that can be readily activated to ensure that [all] drugs which have been recalled are returned to the pharmacy, sequestered, and handled as appropriate to the level of the recall

[G.] K. Adverse Drug Reactions.

(1) The director [or the director's pharmacist] of pharmacy or designee shall participate on the appropriate comprehensive care facility's committee to establish procedures to report and record adverse drug reactions.

(2) The director [or the director's pharmacist] of pharmacy or designee shall ensure the procedures established include, at a minimum:

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(a) The reporting of significant adverse drug reactions to the attending prescriber or designee and other parties as specified by the committee of the comprehensive care facility; and

(b) The recording in writing of an adverse reaction on the [resident's] patient's chart at the time it is reported.

[H.] L. Records and Reports. The director [or the director's pharmacist] of pharmacy or designee shall maintain records and reports as may be required by law, this chapter, and the policies of the comprehensive care facility.

10.34.23.11 (September 24, 2009)

[.11] .10 Quality Management.

The director of pharmacy or designee, in cooperation with the pharmaceutical services committee of the comprehensive care facility, shall be responsible for developing procedures for an ongoing quality management program that includes a mechanism for reviewing and evaluating pharmaceutical services as defined in this chapter.

JOHN M COLMERS
Secretary of Health and Mental Hygiene