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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 01 Disciplinary Proceedings (Refs & Annos)
.01 Scope.

This chapter governs procedures for disciplinary matters and hearings before the Board.

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.02 Definitions.

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

B. Terms Defined.

(1) “Administrative law judge” means the hearing officer assigned to preside over a hearing in a case that the Board has delegated to the Office of Administrative Hearings under State Government Article, §10-205, Annotated Code of Maryland.

(2) “Administrative Procedure Act” means State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland, which governs contested cases arising from charges issued by the Board.

(3) “Board” means the State Board of Pharmacy.

(4) “Case resolution conference” means a voluntary, informal, and confidential meeting between the parties to a contested case and the Board's case resolution conference committee to discuss possible settlement of a disciplinary matter pending before the Board.

(5) “Case resolution conference committee” means a committee comprised of one or more members of the Board who make recommendations to the Board regarding settlement of disciplinary matters.

(6) “Cease and desist letter” means a public letter issued by the Board ordering:

(a) A registrant or licensee to cease doing a specified activity; or

(b) An unlicensed person to cease the unauthorized practice of pharmacy or the unauthorized operation of a pharmacy.

(7) “Charges” means a nonpublic record issued by the Board which:

(a) Alleges conduct by a registrant or licensee that the Board believes constitutes a violation under the Maryland Pharmacy Act;

(b) Sets forth sections of the Maryland Pharmacy Act that the Board believes were violated; and

(c) Provides notice to the registrant or licensee of disciplinary proceedings before the Board.

(8) “Complaint” means an allegation received by the Board that a registrant or licensee may have violated the Maryland Pharmacy Act, and which may be grounds for an investigation or disciplinary action by the Board.

(9) “Consent order” means a final order issued by the Board that has been negotiated and agreed to by both the registrant or licensee and the Board to resolve a formal disciplinary action.

(10) “Contested case” means a proceeding conducted under the Administrative Procedure Act.

(11) “Final order” means a public record issued by the Board resolving a formal disciplinary action by consent or after an adjudication, which:

(a) Denies a registration or license;

(b) Sanctions by:

(i) Reprimand;

(ii) Probation;

(iii) Fine; or

(iv) Suspension or revocation of a registration or license;

(c) Summarily suspends a registration or license;

(d) Dismisses charges;

(e) Surrenders a registration or license;

(f) Resolves the contested case by consent of the parties; or

(g) Takes any other action that the Board may take by law.

(12) “Formal disciplinary action” means action taken by the Board that:

(a) Is initiated by:

(i) Charges; or

(ii) A notice of initial denial;

(b) Is resolved by a consent order;

(c) Results in a summary suspension; or

(d) Results in a letter of surrender.

(13) “Informal action” means that the Board closes a case, without formal disciplinary action or issuing a final order, by sending a:

(a) Letter of education;

(b) Letter of admonishment; or

(c) Letter of agreement.

(14) “Letter of admonishment” means an informal action taken by the Board consisting of a nonpublic letter closing the case if the Board believes a registrant or licensee engaged in conduct that violated the Maryland Pharmacy Act and may include a letter of agreement in which a registrant or licensee agrees to satisfy certain conditions instead of the Board issuing charges.

(15) Letter of Education.

(a) “Letter of education” means an informal action consisting of a nonpublic letter:

(i) Issued by the Board, closing the case if the Board does not believe that the registrant's or

licensee's conduct rose to the level of a violation of the Maryland Pharmacy Act; and

(ii) In which the Board educates the registrant or licensee regarding the laws and standards of the practice of pharmacy or operating a pharmacy.

(b) “Letter of education” may include a letter of agreement in which a registrant or licensee agrees to satisfy certain conditions.

(16) Letter of Surrender.

(a) “Letter of surrender” means a public record accepted by the Board in which:

(i) The licensee agrees to surrender the licensee's license or permit; or

(ii) The registrant agrees to surrender the registrant's registration.

(b) “Letter of surrender” may include conditions for the Board's acceptance of the surrender as a resolution of the case.

(17) “Licensee” means the holder of a license or permit issued by the Board.

(18) “Maryland Pharmacy Act” means Health Occupations Article, Title 12, Annotated Code of Maryland.

(19) “Notice of initial denial” means a nonpublic record issued by the Board by which an applicant, registrant, or licensee is notified that the Board intends to:

(a) Change a registration or licensure status;

(b) Deny a registration, license, or permit; or

(c) Deny some other benefit sought by the registrant or licensee.

(20) “Party” means the:

(a) Respondent or person named or admitted as a party, or properly seeking and entitled as a right to be a party in a formal disciplinary proceeding; or

(b) Administrative prosecutor from the Office of the Attorney General presenting a case on behalf of the Board.

(21) “Postdeprivation hearing” means a show cause or an evidentiary hearing scheduled by the Board after the Board has issued an order for summary suspension under State Government Article, §10-226(c)(2), Annotated Code of Maryland, in which the registrant or licensee may challenge the Board's basis for issuing the order of summary suspension.

(22) “Predeprivation hearing” means a show cause hearing in which the registrant or licensee has an opportunity to demonstrate to the Board why the Board should not:

(a) Issue an order for summary suspension under State Government Article, §10-226(c)(2), Annotated Code of Maryland; or

(b) Take some other action that the Board may take.

(23) “Presiding officer” means the president of the Board or, in the president's absence, a Board member designated by the president, who:

(a) Conducts hearings before the Board; and

(b) Issues prehearing orders.

(24) “Probation” means a sanction imposed by the Board in a public final order under which the registrant or licensee is:

(a) Monitored by the Board for a period of time; and

(b) Required to comply with certain conditions in order to avoid further disciplinary action.

(25) “Public record” means a document that the Board is permitted or required to disclose to the public under State Government Article, Title 10, Subtitle 6, Annotated Code of Maryland.

(26) “Recommended decision” means a nonpublic record issued to the Board by an administrative law judge which sets out proposed findings of fact, proposed conclusions of law, a proposed sanction, or any combination of these actions.

(27) “Recusal” means the disqualification of a member of the Board to participate in a proceeding because

of interest, bias, or some other reason that may interfere with the Board member's participation in the case.

(28) “Registrant” means the holder of a pharmacy technician registration issued by the Board.

(29) “Respondent” means a registrant or licensee subject to the jurisdiction of the Board, who has been:

(a) Given formal notice of allegations concerning violations of the Maryland Pharmacy Act; and

(b) Notified as to the possible imposition of sanctions or a summary suspension.

(30) “Revocation” means the removal of a registrant's registration or licensee's license or permit.

(31) “Sanction” means an action by the Board which:

(a) Reprimands;

(b) Places on probation;

(c) Fines; or

(d) Suspends or revokes a registration, license, or permit.

(32) “Show cause hearing” means a nonevidentiary hearing in which the registrant or licensee may demonstrate to the Board why the Board should not issue a proposed order or continue to take an action that the Board may take.

(33) “Summary suspension” means the indefinite suspension of a registration or license under State Government Article, §10-226(c)(2), Annotated Code of Maryland, issued if the Board believes emergency action is necessary to protect the public health, safety, or welfare.

(34) “Suspension” means the temporary denial of the right to use a registration, license, or permit and is usually defined by:

(a) A specified period of time;

(b) Specific dates; or

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(c) Specific conditions.

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.03 Confidentiality of Proceedings.

A. Except as otherwise provided by law, the proceedings of the Board are confidential and that confidentiality may not be waived by the parties.

B. The Office of Administrative Hearings' proceedings involving the adjudication of a Board formal disciplinary action and the administrative law judge's recommended decision are confidential.

C. The respondent may not waive the confidentiality of the:

(1) Proceedings; or

(2) Patients whose medical records or care are reflected in the record of the proceedings.

D. To the extent possible, even after the close of a formal disciplinary action, the parties shall refrain from revealing:

(1) Legal documents;

(2) Oral statements; or

(3) Information that would reveal the identity of patients involved in the matter.

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.04 Representation by Counsel.

A. A respondent may be represented by counsel at any stage of a formal disciplinary action.

B. If a hearing is held on a matter, the respondent shall be represented:

(1) In proper person; or

(2) By an attorney who has been:

(a) Admitted to the Maryland Bar; or

(b) Specially admitted to practice law under Maryland Rules, Rules Governing Admission to the Bar of Maryland, Rule 14, Annotated Code of Maryland.

C. The Board may request the Office of the Attorney General to participate in a hearing to present the case on behalf of the State.

D. The member of the Office of the Attorney General presenting the case on behalf of the State has the same rights as any party with regard to:

(1) Submission of evidence, examination, and cross-examination of witnesses; and

(2) The filing of objections, exceptions, and motions.

E. The Board may request a member of the Office of the Attorney General to act as legal advisor to the Board on questions of:

(1) Procedure;

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(2) Evidence; and

(3) Law.

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.05 Disposition of Complaints.

A. For each complaint, after reviewing any completed investigative information or reports, the Board shall:

(1) Dismiss the complaint;

(2) Close the case with informal action;

(3) Issue a cease and desist order;

(4) Refer the matter for further investigation;

(5) Refer the matter to an administrative prosecutor; or

(6) Vote to:

(a) Charge a registrant or licensee with a violation of the Maryland Pharmacy Act;

(b) Consider the matter as a basis for a summary suspension;

(c) Initially deny a registration, license, or permit or reinstatement of a registration, license, or permit; or

(d) Accept the surrender of a registration, license, or permit subject to conditions acceptable to the Board.

B. The Board may refer a complaint or other disciplinary matter to the administrative prosecutor at any time, whether or not the Board has voted to charge a registrant or licensee with violations of the Maryland Pharmacy Act.

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.06 Notice of Charges or Notice of Initial Denial.

A. If the Board issues charges or a notice of initial denial, the document shall be:

(1) Served on the respondent by certified mail at the address the respondent is required to maintain with the Board; or

(2) Hand delivered in person.

B. Charges or notice of initial denial shall:

(1) Inform the respondent of the statutory basis for the charges or denial of a registration, license, or permit;

(2) Allege sufficient facts that the Board believes constitute a basis for:

(a) Violation of the Maryland Pharmacy Act; or

(b) Denial of a registration, license, or permit; and

(3) Include the notice of hearing.

C. If the Board issues a notice of initial denial to an applicant for a registration or license, the applicant may not withdraw the application without approval from the Board.

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.07 Notice of Hearing.

A. Except for a show cause hearing, written notice of hearings shall be sent by the Executive Director or an officer of the Board to the parties at least 20 days before the hearing.

B. The Board shall serve the notice of hearing by:

(1) Certified mail at the address the respondent is required to maintain with the Board; or

(2) Hand delivery in person.

C. The notice of hearing shall state, if applicable:

(1) The date, time, place, and nature of the hearing;

(2) The right to:

(a) Representation;

(b) Call witnesses;

(c) Submit documents or other relevant evidence;

(d) Request subpoenas for witnesses and evidence and the costs associated with such a request;

(3) That a failure to appear for the scheduled hearing may result in an adverse action against the party; and

(4) That the parties may agree to the evidence and waive their right to appear at the hearing.

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D. The notice of hearing may include:

(1) Deadlines for:

(a) Discovery; and

(b) Motions; and

(2) Dates for the:

(a) Prehearing conference; and

(b) Case resolution conference.

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.08 Prehearing Conferences and Case Resolution Conferences.

A. The Board may set a prehearing conference or a case resolution conference, or both.

B. The prehearing conference may be used to prepare for the hearing by:

(1) Delineating the issues;

(2) Stipulating to:

(a) Facts;

(b) Laws; and

(c) Other matters;

(3) Arranging a schedule for the:

(a) Exchange of documents and witness information; and

(b) Submission of motions and responses to motions; or

(4) Addressing other matters that will promote the orderly and efficient conduct of the hearing.

C. Prehearing Orders.

(1) If a prehearing conference has been held, a prehearing order may be issued by the presiding officer.

(2) The prehearing order shall set forth the actions taken or to be taken with regard to any matter addressed at the prehearing conference.

(3) If a prehearing conference is not held, the presiding officer may issue a prehearing order to regulate the conduct of the proceedings.

(4) Absent an exception from the presiding officer, the prehearing order shall be binding on the parties.

D. The Case Resolution Conference.

(1) Matters admitted, revealed, negotiated, or otherwise discussed are without prejudice and may not be used by the respondent, administrative prosecutor, or the Board in subsequent proceedings, unless the information is otherwise discoverable or available through another source.

(2) The Board is not bound by the recommendations of the case resolution conference committee and may:

(a) Modify the proposed settlement;

(b) Require additional conditions; or

(c) Reject the recommendation and require the respondent to proceed to a hearing.

(3) If the respondent disagrees with the recommendation of the case resolution conference committee, the respondent may elect to proceed to a hearing on the matter, regardless of whether the Board has ratified the recommendation of the case resolution conference committee.

(4) Participation in a case resolution conference is not a basis for recusal of a Board member, Board counsel, or Board prosecutor from further proceedings.

E. Motions.

(1) Unless otherwise set forth in a prehearing order or notice of hearing, motions shall be:

(a) Accompanied by a memorandum of points and authorities; and

(b) Filed with the Board at least 15 working days before the hearing.

(2) A copy of a motion filed with the Board shall be served on the opposing party by the party filing the motion.

(3) A response shall be filed with the Board at least 10 working days before the hearing and a copy served on the opposing party.

(4) The Board may refuse to consider a motion or response that is not timely filed.

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.09 Discovery.

A. Discovery on Request. By written request served on the other party and filed with the Board or the Office of Administrative Hearings, as appropriate, a party may require another party to produce, within 15 days, the following:

(1) A list of witnesses to be called;

(2) Copies of documents intended to be produced at the hearing; or

(3) Both §A(1) and (2) of this regulation.

B. Mandatory Discovery.

(1) Each party shall provide to the other party not later than 15 days before the prehearing conference, if scheduled, or 45 days before the scheduled hearing date, whichever is earlier:

(a) The name and curriculum vitae of any expert witness who will testify at the hearing; and

(b) A detailed written report summarizing the expert's testimony, which includes the:

(i) Opinion offered;

(ii) Factual basis for the opinion; and

(iii) Reasons underlying the opinion.

(2) If the Board or the Office of Administrative Hearings, as appropriate, finds that the report is not sufficiently specific, or otherwise fails to comply with the requirements of §B(1) of this regulation, the Board or the Office of Administrative Hearings, as appropriate, shall exclude from the hearing the testimony of the expert and any report of the expert.

(3) The Board or the Office of Administrative Hearings, as appropriate, shall consider and decide arguments regarding the sufficiency of the report:

(a) At the prehearing conference, if scheduled; or

(b) Immediately before the scheduled hearing.

(4) If an expert adopts a sufficiently specific charging document as the expert's report, that adoption satisfies the requirements set forth in §B(1) of this regulation.

C. Parties are not entitled to discovery of items other than as listed in §§A and B of this regulation.

D. Both parties have a continuing duty to supplement their disclosure of witnesses and documents.

E. Absent unforeseen circumstances that would otherwise impose an extraordinary hardship on a party, witnesses or documents may not be added to the list:

(1) After the prehearing conference, if scheduled; or

(2) Later than 15 days before the hearing, if no prehearing conference is scheduled.

F. The prohibition against adding witnesses does not apply to witnesses or documents to be used for impeachment or rebuttal purposes.

G. Construction.

(1) In hearings conducted by an administrative law judge of the Office of Administrative Hearings, this regulation shall, whenever possible, be construed as supplementing and in harmony with COMAR 28.02.01.

(2) In the event of a conflict between this regulation and COMAR 28.02.01, this regulation applies.

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.10 Evidentiary Hearings.

A. Hearings shall be conducted under the Administrative Procedure Act.

B. The Board may delegate its authority to conduct hearings to the Office of Administrative Hearings.

C. Hearings are not open to the public.

D. Records, including the recommended decision, shall be treated as confidential and sealed.

E. Records.

(1) The Board shall prepare an official record of hearings that shall include all:

(a) Pleadings;

(b) Testimony;

(c) Exhibits; and

(d) Other memoranda or material filed in the proceeding.

(2) Unless waived by all parties, a stenographic record of the proceedings shall be made at the expense of the Board.

(3) The stenographic record may not be transcribed, unless requested by a party or by the Board.

(4) The cost of transcribing all or part of a proceeding, shall be paid by the party requesting the typewritten transcript.

F. Quorum.

(1) A majority of the members serving on the Board is a quorum of the Board.

(2) Hearings shall be held before a quorum of the Board.

G. Presiding Officer.

(1) The presiding officer shall:

(a) Conduct a full, fair, and impartial hearing;

(b) Take action to avoid unnecessary delay in the disposition of the proceedings;

(c) Maintain order; and

(d) Adjourn or recess the hearing from time to time.

(2) The presiding officer may regulate the course of the hearing and the conduct of the parties, including the authority to:

(a) Permit the examination of witnesses;

(b) Rule on offers of proof and admit relevant and material evidence;

(c) Consider and rule on motions;

(d) Grant a continuance or postponement;

(e) Determine the order in which the parties shall present their cases;

(f) Limit unduly repetitious testimony;

(g) Reasonably limit the time for presentation; and

(h) Issue orders necessary to:

(i) Secure procedural simplicity and administrative fairness; and

(ii) Eliminate unjustifiable expense and delay.

H. Examination of Witnesses and Introduction of Evidence.

(1) The rules of evidence in State Government Article, §10-213, Annotated Code of Maryland apply to hearings before the Board.

(2) A party may:

(a) Submit evidence;

(b) Examine and cross-examine witnesses; and

(c) File objections, exceptions, and motions.

(3) If a party is represented by counsel, submission of evidence, examination and cross-examination of witnesses, and filing of objections, exceptions, and motions shall be done and presented solely by the counsel.

(4) The presiding officer, or a person designated by the presiding officer for that purpose, may examine a witness called by a party.

(5) The presiding officer may call as a witness a person necessary to ensure a full and complete record.

(6) Any Board member may examine any witness.

I. Briefs.

(1) A party may submit a brief on the issues of fact and law involved in the hearing.

(2) The presiding officer may designate:

(a) The form of the brief;

(b) The number of copies to be submitted; and

(c) The date and time of submission.

(3) The Board may refuse to consider a brief that is not timely filed or fails to conform to requirements imposed by the presiding officer.

J. If a party who is the respondent in the proceedings fails to appear at a hearing after due notice, the Board may:

(1) Reschedule the hearing; or

(2) In the Board's discretion, proceed upon the investigation, report, documents, witnesses, and records before it.

K. The Board shall take testimony under oath.

L. Decision and Order.

(1) A decision and order rendered by the Board shall:

(a) Be in writing; and

(b) Include the findings of fact and conclusions of law.

(2) A copy of the decision and order and accompanying findings and conclusions shall be delivered or mailed promptly to each party or the party's attorney of record.

(3) The findings of fact, conclusions of law, and order referred to in §L of this regulation shall be retained as a permanent record by the Board.

M. A party aggrieved by a final decision of the Board under Health Occupations Article, §12-313, Annotated Code of Maryland, may seek judicial review of the Board's decision.

N. The review referenced in §M shall be in accordance with State Government Article, §§10-222-10-223, Annotated Code of Maryland.

O. Rehearings.

(1) Within 10 days after service on a party of the decision of the Board, the party may apply to the Board for

rehearing.

(2) The application shall state the grounds for rehearing.

(3) The Board shall grant or deny the application within 20 days of submission to the Board.

(4) Unless otherwise ordered, neither the rehearing nor the application for rehearing shall:

(a) Stay the enforcement of the order; or

(b) Excuse the persons affected by the order for failure to comply with the terms of the order.

(5) At a rehearing, the Board shall only consider facts not presented in the original proceeding, including facts arising after the date of the original proceeding.

(6) By new order, the Board may abrogate, change, or modify its original order.

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.11 Exceptions Hearings.

A. If a case has been delegated to the Office of Administrative Hearings under State Government Article, §10-205, Annotated Code of Maryland, for proposed findings of fact, conclusions of law, and disposition, a party may file exceptions with the Board within 30 days of receipt of the recommended decision.

B. The opposing party to the exceptions shall respond within 15 days of receipt of the exceptions.

C. If a party files exceptions, the Board shall schedule a hearing to be held before a quorum of the Board.

D. The exceptions hearing shall be a nonevidentiary hearing to provide the parties with an opportunity for oral argument on the exceptions to the recommended decision.

E. The Board shall:

(1) Consider:

(a) The exceptions;

(b) Responses to exceptions; and

(c) The record in the case; and

(2) Issue an order containing accepted findings of fact, conclusions of law, and disposition.

F. The presiding officer:

(1) Shall determine procedural issues governed by this regulation; and

(2) May:

(a) Impose reasonable time limitations; and

(b) Make rulings reasonably necessary to facilitate the effective and efficient operation of the exceptions hearing.

G. If the parties do not file timely exceptions, a quorum of the Board shall:

(1) Consider the recommended decision from the Office of Administrative Hearings; and

(2) Issue an order based on the:

(a) Board's accepted findings of fact and conclusions of law; and

(b) The record of the case.

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.12 Summary Suspensions.

A. The Board shall order the summary suspension of a registration, license, or permit if the Board determines that there is a substantial likelihood that a registrant or licensee poses a risk of harm to the public health, safety, or welfare.

B. Based on information gathered in an investigation or otherwise provided to the Board, the Board may vote to issue:

(1) A notice of an intent to summarily suspend a registration, license, or permit; or

(2) An order of summary suspension.

C. If the Board votes to issue a notice of intent to summarily suspend a registration, license, or permit or an order of summary suspension, the Board shall refer the matter to an administrative prosecutor for prosecution.

D. Service of the notice of intent to summarily suspend a registration, license, or permit shall be made by:

(1) Hand delivery in person;

(2) Certified mail to the address the respondent is required to maintain with the Board; or

(3) Other reasonable means to effect service.

E. Notice of Intent to Summarily Suspend.

(1) A notice of intent to summarily suspend a registration, license, or permit shall include:

(a) A proposed order of summary suspension which is unexecuted by the Board and which includes:

(i) The statutory authority on which the action has been taken;

(ii) Allegations of fact which the Board believes demonstrate a substantial likelihood that the registrant or licensee poses a risk of harm to the public health, safety, or welfare; and

(iii) Notice to the respondent of the right to request an evidentiary hearing of the summary suspension if the Board executes the proposed order of summary suspension; and

(b) An order or summons to appear before the Board:

(i) To show cause why the Board should not execute the order of summary suspension; and

(ii) Which notifies the respondent of the consequences of failing to appear.

(2) Predeprivation Hearing.

(a) If the Board issues a notice of intent to summarily suspend a registration, license, or permit, the Board shall offer the respondent the opportunity to appear before the Board to show cause why the respondent's registration, license, or permit should not be summarily suspended.

(b) The show cause hearing shall be a nonevidentiary hearing to provide the parties with an opportunity for oral argument on the proposed summary suspension.

(c) The presiding officer:

(i) Shall determine procedural issues;

(ii) May impose reasonable time limits on each party's oral argument; and

(iii) Shall make rulings reasonably necessary to facilitate the effective and efficient operation of the show cause hearing.

F. Order of Summary Suspension.

(1) The Board may order the summary suspension of a registration, license, or permit without first issuing a notice of intent to summarily suspend or providing a respondent with a predeprivation hearing if the Board determines that the threat to public health, safety, and welfare requires the immediate suspension of the registration, license, or permit.

(2) Postdeprivation Hearing.

(a) The respondent shall be provided with a show cause hearing within a reasonable time after the effective date of the order of summary suspension.

(b) The show cause hearing under §F(2)(a) of this regulation shall:

(i) Be conducted before the Board as provided in §E(2) of this regulation; and

(ii) Provide the respondent with an opportunity to show cause why the Board should lift the summary suspension.

(3) After the show cause hearing, if the Board votes to continue the summary suspension, the respondent may request an evidentiary hearing before the Board.

(4) An evidentiary hearing:

(a) May be consolidated with a hearing on charges issued by the Board that include the facts that form the basis for the summary suspension; and

(b) Shall be conducted under the Administrative Procedure Act.

G. Disposition.

(1) If the Board issues a notice of intent to summarily suspend a registration, license, or permit, the Board may, after the show cause hearing, vote to:

(a) Order a summary suspension;

(b) Deny the summary suspension;

(c) Enter into a consent order; or

(d) Enter into any interim order warranted by the circumstances of the case, including one providing for the stay of the summary suspension subject to certain conditions.

(2) If the Board orders a summary suspension before a show cause hearing, the Board may, at the

conclusion of the show cause hearing, vote to:

(a) Affirm the order of summary suspension;

(b) Rescind the order of summary suspension;

(c) Enter into a consent order; or

(d) Enter into an interim order warranted by the circumstances of the case, including one providing for a stay of the summary suspension subject to certain conditions.

(3) An order for summary suspension or any other order of the Board issued after the initiation of summary suspension proceedings is a:

(a) Final order of the Board; and

(b) Public record.

COMAR **10**. **34**.01.12, MD ADC **10**. **34**.01.12

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MD Health & Men. **10**. **34**.01.13

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 01 Disciplinary Proceedings (Refs & Annos)
.13 Surrender of a Registration, License, or Permit.

A. The Board may:

(1) Accept the surrender of a registration, license, or permit;

(2) Require conditions for surrender of a registration, license, or permit, including:

(a) The admission of a violation of the Maryland Pharmacy Act;

(b) The admission of facts;

(c) A statement of the circumstances under which the surrender was offered or accepted;

(d) Restrictions on future registration, licensing, or permit;

(e) Conditions for reinstatement of the registration, license, or permit; or

(f) An agreement that the respondent may not again apply for a registration, license, or permit.

B. A letter of surrender is a final order of the Board and is a public record.

COMAR **10**. **34**.01.13, MD ADC **10**. **34**.01.13

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.01.14

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 01 Disciplinary Proceedings (Refs & Annos)

.14 Probation and Violation of Probation.

A. If the Board imposes a period of probation as a sanction, the Board may impose conditions of probation that the Board considers appropriate, including:

(1) Re-education or completion of approved courses;

(2) Payment of a fine;

(3) Practicing pharmacy or operating a pharmacy under supervision;

(4) Monitoring by the Board or by an individual or entity approved by the Board with periodic reporting to the Board;

(5) Periodic review of a licensee's practice or operations;

(6) Periodic audits of a licensee's billing practice;

(7) An examination by a physician or other appropriate health care provider;

(8) Limitation of the licensee's practice or operations;

(9) Limitation of the pharmacy technician's scope of duties;

(10) Drug screenings;

(11) Individual or group counseling or therapy;

(12) Obtaining a passing score on an appropriate examination; or

(13) Any other condition the Board considers appropriate for the rehabilitation or retraining of a registrant or a licensee.

B. A term of probation may be defined by a specific period of time or the successful completion of certain conditions or acts by the registrant or licensee.

C. A registrant or licensee seeking release from probation shall do so by petitioning the Board to terminate the probation when the:

(1) Specific period of time has passed; or

(2) Registrant or licensee has successfully completed the conditions or acts required for release.

D. If, at any time, the Board has reason to believe that the registrant or licensee is not in compliance with the conditions of probation, the Board shall:

(1) Charge the registrant or licensee with a violation of probation;

(2) Take an action provided for in the final order in the event of a violation of probation, including suspension of the registration, license, or permit;

(3) Consider a summary suspension of the registration, license, or permit; or

(4) Take any other action the Board considers appropriate and which the Board may take by law.

E. If the Board determines that the respondent has violated probation, the Board shall:

(1) Take an action provided for in the final order in the event of a violation of probation;

(2) Impose additional conditions or probation; or

(3) Impose a sanction or take any other action that the Board considers appropriate and may take by law.

COMAR **10**. **34**.01.14, MD ADC **10**. **34**.01.14

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MD Health & Men. **10**. **34**.01.15

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 01 Disciplinary Proceedings (Refs & Annos)
.15 Reinstatement.

A. A registrant or licensee shall petition the Board for a lifting of the suspension of a registration, license, or permit or a reinstatement following revocation or surrender of a registration, license, or permit.

B. The Board may reinstate a registration, license, or permit in accordance with:

(1) The terms and conditions of the order of revocation or suspension;

(2) A letter of surrender;

(3) An order of reinstatement issued by the Board; or

(4) A final judgment in any proceeding for judicial review.

C. If not otherwise specified in a document under §B of this regulation, the licensee shall meet the requirements of COMAR **10**. **34**.13 to reinstate a license or permit.

C-1. If not otherwise specified in a document under §B of this regulation, the registrant shall meet the requirements of COMAR **10**. **34**.34 to reinstate a registration.

D. If a time period is not specified in the Board's final order, a petition for reinstatement may not be considered by the Board before the expiration of 1 year after the date of the order.

E. The form of a reinstated registration, license, or permit shall:

(1) Be similar in every respect to an original registration, license, or permit; and

(2) Bear the new date of issue.

F. If the Board grants reinstatement of a registration, license, or permit, it may impose any restrictions or conditions on the registration, license, or the licensee's practice that it considers appropriate.

G. The Board may reinstate the license of an individual whose license has been revoked under Criminal Law Article, §5-702, Annotated Code of Maryland, if:

(1) The individual has petitioned the Board for reinstatement;

(2) The petition for reinstatement is made to the Board after the expiration of 5 years after the revocation;

(3) The individual has met the requirements of COMAR **10**. **34**.13 to reinstate a license; and

(4) The individual has made restitution to aggrieved persons that may have resulted from a violation and conviction of Criminal Law Article, §5-702, Annotated Code of Maryland.

COMAR **10**. **34**.01.15, MD ADC **10**. **34**.01.15

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Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 01 Disciplinary Proceedings (Refs & Annos)

ADMINISTRATIVE HISTORY

Effective date: September 1, 1971

Regulation .03A, E, G amended effective February 19, 1990 (17:3 Md. R. 298)

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Regulation .04D, G amended effective October 3, 1980 (7:20 Md. R. 1879)

Regulation .06 amended effective February 19, 1990 (17:3 Md. R. 298)

y(10)6D

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y(10)6D

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MD Health & Men. T. 10, Subt. 34, Ch. 01, Administrative History

Regulation .13A amended effective January 28, 2008 (35:2 Md. R. 127)

Regulation .14 amended effective January 28, 2008 (35:2 Md. R. 127)

Regulation .15 amended effective January 28, 2008 (35:2 Md. R. 127)

y(10)6D

Annotation: COMAR **10**. **34**.01.03G(1) cited in Eichberg v. Board of Pharmacy, 50 Md. App. 189 (1981)

COMAR T. 10, Subt. 34, Ch. 01, Administrative History, MD ADC T. 10, Subt. 34, Ch. 01, Administrative History

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MD Health & Men. **10**. **34**.02.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 02 Examination for Licensure and Professional Experience Programs (Refs & Annos)
.01 Scope.

This chapter applies to:

A. Applicants for licensure as a pharmacist; and

B. Internship programs for student pharmacists for which credit may be allowed toward licensure.

COMAR **10**. **34**.02.01, MD ADC **10**. **34**.02.01

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.02.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 02 Examination for Licensure and Professional Experience Programs (Refs & Annos)
.02 Definitions.

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

B. Terms Defined.

(1) “Board” means the State Board of Pharmacy.

(2) “Licensure examinations” means the Board-administered or Board-approved examinations required of applicants for licensure which include the following:

(a) Exam I:

(i) Part I: NAPLEX, and

(ii) Part II: Pharmacy Law Test;

(b) Exam II:

(i) Prescreening Test of Oral English Competency, or

(ii) Test of Oral English Competency.

COMAR **10**. **34**.02.02, MD ADC **10**. **34**.02.02

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 02 Examination for Licensure and Professional Experience Programs (Refs & Annos)
.03 Licensure Examinations.

A. An applicant may take Exam I upon satisfactory proof that the applicant has graduated, or is expected to graduate at the completion of the immediate semester, from a school or college of pharmacy that has been:

(1) Approved by the Board; or

(2) Accredited by the American Council on Pharmaceutical Education.

B. An applicant may not receive a license until the applicant has provided satisfactory proof to the Board of the applicant's graduation from a college or school of pharmacy approved by the Board or accredited by the American Council on Pharmaceutical Education.

C. Passing Grades-Exam I.

(1) The passing grade for each of the two parts of the Exam I is 75.

(2) If a candidate receives a passing grade on Part I or Part II of Exam I, the candidate is not required to retake that part unless the passing grade was received more than 1 year before the date the candidate successfully completed all of the other examination requirements set forth in this regulation.

D. Passing Grades-Exam II.

(1) Prescreening Test of Oral English Competency.

(a) On completion of a prescreening test application form provided by the Board, an applicant may elect to take a standardized prescreening test of oral English competency given by the Board's agents at times to be determined by the Board.

(b) An agent of the Board possessing post-secondary credentials in an academic discipline acceptable to the Board shall score the prescreening test of oral English competency through the use of a standardized rating

system.

(c) An agent of the Board shall design the rating system of the prescreening test so that a passing score demonstrates that an applicant speaks fluent English as proficiently as typical United States native speakers whose English is easily understood by the average pharmacy patient or customer.

(d) By choosing to take the prescreening test of oral English competency, an applicant is certifying to the Board that the applicant speaks English as proficiently as typical United States native speakers whose English is easily understood by the average pharmacy patient or customer.

(e) By choosing to take the prescreening test to verify this certification, the applicant consents to pay the costs of test administration and shall pay the fee indicated on the Board's prescreening application form directly to the Board's agent.

(f) An applicant who passes the prescreening test passes Exam II, the Test of Oral English Competency required under Regulation .02B(2)(b) of this chapter.

(g) An applicant who fails the prescreening test for oral English competency may take the Test of Oral English Competency required under Regulation .02B(2)(b) of this chapter without prejudice to the applicant's licensure application if the applicant pays all related fees.

(2) Test of Oral English Competency.

(a) In order to obtain a license to practice pharmacy, an applicant shall pass a standardized test of oral English competency approved by the Board or the board of pharmacy of another state with a score acceptable to the Board, based upon the Board's standards and the examination taken.

(b) The Board shall provide the applicant with a list of Board-approved testing services and the passing score for each approved test of oral English competency.

(3) Claims of Speech Impairment.

(a) An applicant who claims to have a speech impairment shall submit documentation of the impairment on forms supplied by the Board and completed by a Board-approved:

(i) Licensed physician; and

(ii) Speech-language pathologist licensed to practice speech pathology in the United States.

(b) The applicant shall submit the documentation with:

(i) The applicant's initial application; or

(ii) Before the applicant's second attempt at passing the test of oral English competency.

(c) After the second examination, the applicant may not submit documentation of impairment unless:

(i) An intervening medical or surgical event caused the impairment;

(ii) The applicant claims the impairment before a third examination; and

(iii) The applicant provides documentation that is approved by the Board.

(d) The Board may accept documentation of a speech impairment as a passing score on Exam II if the applicant also:

(i) Provides documentation from a Board-approved licensed pharmacist or a Board-approved instructor in a school of pharmacy that the applicant can communicate in a professionally competent manner with patients and health care providers; and

(ii) Describes, in a hearing before the Board, the manner in which the applicant would communicate with a licensed prescriber regarding a prescription and would counsel a typical patient on proper drug usage.

(4) The certifying or verifying authority shall send all certificates and verifications directly to the Board for the applicants.

(5) The Board-approved testing services may not accept certificates and verifications sent to or by the applicant.

(6) If any of the documents required under this regulation are in a language other than English, the certifying or verifying authority shall submit a certified translation.

(7) The applicant shall bear the costs of:

(a) Translation by a certified translator;

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(b) Taking the test of oral English competency; and

(c) Obtaining documents required under this regulation.

COMAR **10**. **34**.02.03, MD ADC **10**. **34**.02.03

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MD Health & Men. **10**. **34**.02.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 02 Examination for Licensure and Professional Experience Programs (Refs & Annos)
.04 Internship Program or Training Required.

An applicant shall complete one of the following as a prerequisite to Board licensure:

A. 1,000 hours of a school-supervised professional experience program conducted by a school of pharmacy accredited by the American Council of Pharmaceutical Education; or

B. 1,560 hours of full-time training, under the direct supervision of licensed pharmacists pursuant to Regulation .05 of this chapter.

COMAR **10**. **34**.02.04, MD ADC **10**. **34**.02.04

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.02.05

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 02 Examination for Licensure and Professional Experience Programs (Refs & Annos)
.05 Partial or Non-Pharmacy-School-Supervised Program of Internship.

A. Applicants may complete the requirement for internship training by having at least 1,560 hours of full-time training, under the direct supervision of licensed pharmacists.

B. The licensed pharmacists providing direct supervision shall be approved by the Board.

C. The applicant shall present evidence satisfactory to the Board that the applicant has completed the training under this regulation, validated by the supervising pharmacist or pharmacists.

D. If an approved school or college of pharmacy offers a partial fulfillment of internship requirements as a part of its curriculum, time spent in a program by an applicant may be accepted by the Board on an equivalent basis to replace a portion of the required 1,560-hour internship training under this regulation.

COMAR **10**. **34**.02.05, MD ADC **10**. **34**.02.05

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 03 Inpatient Institutional Pharmacy (Refs & Annos)
.01 Scope.

This chapter applies to:

A. A permit holder that operates a pharmacy that services an inpatient setting; and

B. A person or entity that holds a pharmacy permit and operates a pharmacy in or for an institutional facility.

COMAR **10**. **34**.03.01, MD ADC **10**. **34**.03.01

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 03 Inpatient Institutional Pharmacy (Refs & Annos)
.02 Definitions.

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

B. Terms Defined.

(1) “Director of pharmacy” means a pharmacist who is responsible for the pharmacy services provided by an institutional pharmacy in compliance with appropriate State and federal laws and regulations.

(2) “Dispense” or “dispensing” means the procedure which results in the receipt of a prescription or nonprescription drug or device by a patient or the patient's agent and which entails the:

(a) Interpretation of an authorized prescriber's prescription for a drug or device;

(b) Selection and labeling of the drug or device prescribed pursuant to that prescription; and

(c) Measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

(3) Distribute.

(a) “Distribute” 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, Title 12, Annotated Code of Maryland, prior to administration of the provided drug or device to the patient pursuant to a prescription issued by an authorized prescriber.

(b) “Distribute” does not include the operations of a person who holds a permit issued under Health Occupations Article, §12 6C 03, Annotated Code of Maryland.

(4) “Drug” means a prescription or non-prescription medication or other material used in the diagnosis or treatment of injury, illness, or disease.

(5) “Drug recall” means the recall of a drug by a manufacturer or the U.S. Food and Drug Administration (FDA) in the event that there is a reasonable possibility that the use of or exposure to an affected product may cause either:

(a) Adverse effects on health; or

(b) Death.

(6) “Emergency drug supply” means a process for supplying drugs which:

(a) May be required for the emergency need of a patient; and

(b) Is not available from an authorized source in a timely manner.

(7) “Institutional facility” or “institution” means an entity other than a comprehensive care facility, assisted living facility, developmental disabilities facility, or correctional facility whose primary purpose is to provide a physical environment for patients to obtain inpatient, outpatient, or emergency care, except for urgent care facilities that are not part of an institution.

(8) “Institutional medication protocol” means a course of therapy including drug treatment predetermined and documented by the institution and the generally accepted medical practice for proper completion of a particular therapeutic or diagnostic intervention ordered by an authorized prescriber and which allows the pharmacist to execute the protocol.

(9) “Institutional pharmacy” means a pharmacy which:

(a) Provides services to an acute care, rehabilitation, transitional care, chronic care, or mental health hospital;

(b) Engages in compounding, distributing, or dispensing of drugs;

(c) May provide nondispensing functions as described in Regulation .16 of this chapter; and

(d) Has been issued a pharmacy permit pursuant to Health Occupations Article, §§12-401 and 12-403(c), Annotated Code of Maryland.

(10) “Licensed pharmacist” means an individual who is licensed by the Board to practice pharmacy.

(11) “Medication order” means a patient-specific order entered on the chart or a medical record of a patient by an authorized prescriber or the authorized prescriber's designee for a drug or device that is transmitted in writing, verbally or by electronic means and includes the:

(a) Date ordered;

(b) Drug name;

(c) Dosage;

(d) Dosage form;

(e) Patient name with second identifier such as date of birth or medical record number;

(f) Route of administration;

(g) Administration instructions, if appropriate; and

(h) Signature of an:

(i) Authorized prescriber, as defined in Health Occupations Article, §12-101(b), Annotated Code of Maryland; or

(ii) Individual permitted to practice medicine without a license as defined in Health Occupations Article, §14-302, Annotated Code of Maryland.

(12) “Order-sets” means predefined orders, including medication orders, that are based on an institutionally approved protocol.

(13) Pharmaceutical care.

(a) “Pharmaceutical care” means the provision of a patient's drug regimen for the purpose of:

(i) Achieving definite outcomes related to the cure or prevention of a disease;

(ii) Elimination or reduction of a patient's symptoms; or

(iii) Arresting or slowing of a disease process by identifying, resolving, or preventing actual or potential drug therapy problems.

(b) “Pharmaceutical care” may include patient counseling and providing information to licensed and certified health care providers.

(14) “Prescription Drug.

(a) “Prescription drug” means any drug required by federal law or regulation to be dispensed only by a prescription.

(b) “Prescription drug” includes:

(i) A biological product; and

(ii) Finished dosage forms and bulk drug substances subject to §503(b) of the Federal Food, Drug and Cosmetic Act.

(c) “Prescription drug” does not include blood and blood components intended for transfusion or biological products that are also medical devices.

(15) “Second identifier” means a reliable method to:

(a) Identify a patient for whom service or treatment is intended; and

(b) Match the service or treatment intended to the patient.

(16) “Verbal order” means a medication order from an authorized prescriber which is received by an authorized licensed practitioner using appropriate read back procedures that is subsequently recorded in the patient's chart and countersigned by the prescriber within a time period required by the institution.

(17) “Written order” means a medication order that is recorded as a written document by an authorized prescriber.

COMAR **10**. **34**.03.02, MD ADC **10**. **34**.03.02

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MD Health & Men. **10**. **34**.03.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 03 Inpatient Institutional Pharmacy (Refs & Annos)
.03 Issuance of Permits.

An inpatient institutional pharmacy shall obtain required permits in compliance with State and federal laws.

COMAR **10**. **34**.03.03, MD ADC **10**. **34**.03.03

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.03.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 03 Inpatient Institutional Pharmacy (Refs & Annos)
.04 Policies and Procedures.

A. The director of pharmacy shall establish and operate under a policies and procedures manual which:

(1) Complies with this chapter;

(2) Defines the scope and method of pharmacy services provided to the patients of the institutional facility;

(3) Determines when personnel may have access to the pharmacy area;

(4) Provides for the safe and efficient dispensing and delivery of pharmaceutical products as outlined in this subtitle;

(5) Includes:

(a) Labeling requirements that meet the requirements of this chapter;

(b) Distribution methods for medication that assures that a patient receives the correct dose ordered by the prescriber;

(c) Packaging methods that assure the medication is appropriately identified, designed to maintain stability until expiration and traceable throughout the distribution chain to facilitate recall;

(d) Distribution methods that provide for safe handling of medications that may be manual or computerized employing centralized, decentralized, or remote devices that meet the requirements of COMAR **10**. **34**.28.

(e) Pharmacy security methods that comply with this chapter;

(f) Conditions in which an emergency drug supply may be replenished or prepared, delivered, and stored by the institutional facility;

(g) Duties that may be performed by a licensed pharmacist, registered pharmacy technician and unlicensed personnel; and

(h) Methods for proper disposal of pharmaceuticals as required by State and federal law;

(6) Is provided to:

(a) The personnel of the pharmacy;

(b) The institutional facility; and

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

(7) Is in a form that is:

(a) Written or electronic; and

(b) Readily retrievable;

B. The director of pharmacy shall provide annual training on the policies and procedures manual to the personnel of the pharmacy.

COMAR **10**. **34**.03.04, MD ADC **10**. **34**.03.04

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MD Health & Men. **10**. **34**.03.05

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 03 Inpatient Institutional Pharmacy (Refs & Annos)
.05 Personnel.

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

(1) Be in full and actual charge of the pharmacy and its personnel;

(2) Be 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

(3) Review the policies and procedures of the pharmacy annually and revise them as necessary.

B. Staff.

(1) The pharmacy permit holder shall employ licensed pharmacists, registered pharmacy technicians, and unlicensed personnel as required to competently and safely provide pharmacy services.

(2) The director of pharmacy shall delegate responsibility for the operations of the pharmacy to a designated pharmacist when the director of pharmacy is not available.

COMAR **10**. **34**.03.05, MD ADC **10**. **34**.03.05

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MD Health & Men. **10**. **34**.03.06

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 03 Inpatient Institutional Pharmacy (Refs & Annos)
.06 Security.

A. If a pharmacist is not present within the pharmacy, the pharmacist shall lock and secure the pharmacy and any of its decentralized areas that contain pharmaceuticals before leaving the pharmacy or the decentralized area.

B. The director of pharmacy shall establish policies and procedures for emergency access to the pharmacy or any of its decentralized areas.

C. Security Requirements. Entry into an inpatient institutional pharmacy area where prescription drugs or devices are held shall be limited to authorized personnel under a pharmacist's supervision.

D. An inpatient institutional pharmacy shall be equipped with:

(1) A security system to detect entry after hours, if applicable;

(2) A security system that provides additional protection against theft and diversion;

(3) Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records;

(4) An inventory management and control system designed to protect against, detect, and document instances of theft, diversion, or counterfeiting;

(5) A security system designed to protect the integrity and confidentiality of data and documents;

(6) Video monitoring of entrances and exits, or alternate acceptable security; and

(7) A means to make the data and documentation required under this chapter readily available to:

(a) The Board;

(b) An agent of the Board; or

(c) Federal and State regulatory and law enforcement officials.

COMAR **10**. **34**.03.06, MD ADC **10**. **34**.03.06

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MD Health & Men. **10**. **34**.03.07

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 03 Inpatient Institutional Pharmacy (Refs & Annos)
.07 Physical Requirements and Equipment.

A. The institutional pharmacy shall have floor space, shelving, and equipment to ensure that drugs and supplies within the institutional pharmacy are properly stored and prepared with respect to sanitation, temperature, light, ventilation, moisture control, segregation, and security.

B. The institutional pharmacy shall have professional and technical equipment, supplies, and adequate physical facilities for proper compounding, dispensing, and storage of drugs.

C. The institutional pharmacy shall have reference materials as required by COMAR **10**. **34**.07.03 to enable personnel to prepare and dispense drugs properly and perform pharmaceutical care functions.

D. The institutional pharmacy shall store alcohol and flammables in areas that meet basic local building code requirements for the storage of volatiles and such other laws, ordinances, or regulations as may apply.

E. An institutional pharmacy that provides parenteral preparations shall comply with COMAR **10**. **34**.19.

F. The institutional pharmacy shall dispose of hazardous materials consistent with State and federal laws and regulations;

G. The institutional pharmacy is responsible for the maintenance of the institution's automated medication systems in compliance with COMAR **10**. **34**.28

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.08 Responsibilities of Director of Pharmacy.

The director of pharmacy or designee shall:

A. Be responsible for the safe and efficient dispensing, control, security, and accountability of drugs;

B. Work in cooperation with the other professional staff of the institutional facility with respect to the duties listed in this regulation and in ordering, administering, and controlling drug products and materials, including prescription blanks;

C. Supervise the preparation of parenteral and other medications compounded within the institutional facility;

D. Provide written policies and procedures to hospital professional and technical staff with regard to admixtures prepared within the institution outside of the institutional pharmacy including, but not limited to:

(1) Establishing policies and procedures for preparation and handling of the admixtures; and

(2) Providing incompatibility information with respect to the admixtures;

E. Recommend specifications for procurement, storage and disposal of drugs, chemicals, and biologicals administered to patients to the appropriate committee of the institutional facility as determined by the governing body;

F. Participate in the development of a formulary for the facility;

G. Establish procedures for the development of a standard format and ongoing procedures for checking the accuracy and placement of labels on medications throughout the institution;

H. Maintain and make available an inventory of antidotes and other emergency drugs, both in the pharmacy and in patient care areas, as well as:

(1) Current antidote information;

(2) Telephone numbers of a regional poison information center;

(3) Other emergency assistance organizations; and

(4) Such other materials and information as may be considered necessary by the governing body of the institutional facility;

I. Maintain records of transactions of the institutional pharmacy as may be required by applicable law and as may be necessary to maintain accurate control and accountability for pharmaceuticals;

J. Participate in those aspects of the institutional facility's quality assurance and improvement program which relate to medication safety and pharmaceutical utilization and effectiveness;

K. Participate in teaching or research programs, or both, in the institutional facility as required;

L. Implement the policies, procedures, and decisions of the governing body of the institutional facility;

M. Ensure that a system is in place that provides a safe, secure, and efficient distribution system for pharmaceutical products within the facility;

N. Ensure that the institutional pharmacy meets inspection and other requirements of Health Occupations Article, Title 12, Annotated Code of Maryland, and these regulations;

O. Develop and implement policies and procedures to ensure that discontinued and outdated drugs and drug containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition;

P. Establish policies and procedures for identification, handling, storage, and disposition of medications brought into the institution by the patients;

Q. Conduct an on-going plan for a quality assurance program that will review and evaluate pharmaceutical services and recommend improvements in these services;

R. Establish policies and procedures for identification and handling of investigational drugs that include the provision of pharmacologic and toxicologic information to the medical and nursing staff according to institutional policies ;

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S. Arrange for the inspection of drug storage areas throughout the institution on a monthly basis and maintain written records of these reviews; and

T. Participate in developing and monitoring the policies and procedures pertaining to:

(1) Administration of drugs at an institutional facility to ensure that only authorized individuals administer drugs; and

(2) Self-administration of drugs not on the hospital formulary by patients to ensure that the:

(a) Administration occurs in accordance with procedures established by the appropriate committee of the institution; and

(b) That the self-administration is ordered by an authorized prescriber.

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.09 Medication Packaging -Record Keeping.

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

(1) Accuracy;

(2) Completeness:

(3) Appropriateness; and

(4) Compliance with the U.S. Food and Drug Administration and current United States Pharmacopeia approved packaging.

B. Packaging from the Manufacturer's Original Container. The pharmacy shall use a master log with respect to drugs that are packaged within the pharmacy facility from the original manufacturer's container which includes the:

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

(2) Manufacturer's expiration date;

(3) Manufacturer;

(4) Lot number assigned by the pharmacy;

(5) Quantity packaged;

(6) Expiration date as defined in §C of this regulations;

(7) Generic name of the drug;

(8) Strength;

(9) Date of packaging;

(10) Name of person packaging; and

(11) Initials of verifying licensed pharmacist.

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

(1) Twelve months from the date of 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. The licensed pharmacist shall ensure that labeling of the medication container includes the:

(1) Generic name of the medication;

(2) Brand name of the medication, if appropriate

(3) Strength of the medication, if appropriate;

(4)Lot number of the distributor or manufacturer;

(5) Expiration date of the medication; and

(6) Beyond use date of the medication, if appropriate.

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.10 Labeling for Use Outside the Institutional Facility.

A. The director of pharmacy or designee shall ensure that the labels on drugs dispensed for use outside the facility by an institutional pharmacy to clinics, ambulatory patients, or other patients about to be discharged meet the requirements of Health Occupations Article, §12-505, Annotated Code of Maryland.

B. The director of pharmacy or designee shall ensure that the labels contain other information that may be required by federal or State law or regulations including, but not limited to, cautionary information.

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.11 Drug Dispensing -Emergency Supplies and Procedures.

A. The director of pharmacy shall participate in the development and maintenance of the formulary for emergency drugs and supplies that are maintained throughout the institutional facility.

B. The director of pharmacy or designee shall, in conjunction with the medical staff of the institutional facility, develop and implement written policies and procedures to ensure compliance with the provisions of this regulation.

C. The institutional pharmacy shall furnish emergency drugs and supplies only if:

(1) The emergency drugs and supplies are stored in an environment which:

(a) Maintains the integrity of the drugs; and

(b) Provides accessibility only to authorized personnel;

(2) The institution follows a policy that drugs will be dispensed from the emergency drugs and supplies formulary only upon written or verbal order by an authorized prescriber;

(3) The emergency drugs and supplies are stocked and maintained in a manner that complies with the standards of applicable State law;

(4) The emergency drugs and supplies are:

(a) Stored and secured:

(i) With a tamper evident seal; or

(ii) Via electronic means; and

(b) Kept in a secure area;

(5) The emergency drugs and supplies are labeled as follows:

(a) Clearly indicating that the emergency drugs and supplies are for use in emergencies only;

(b) Listing the expiration dates of the emergency drugs and supplies;

(c) Listing the name or initials of the pharmacist who checked the emergency drugs and supplies; and

(d) Highlighting the expiration date of the medication with the shortest expiration date;

(6) When the emergency drugs and supplies are contained within an emergency cart, the pharmacist checking the emergency cart shall ensure that the exterior of the cart is labeled with the:

(a) Contents of the emergency cart; and

(b) Name or initials of the pharmacist; and

(7) The director of pharmacy or designee shall ensure that repackaged drugs contained in emergency drugs and supplies are labeled:

(a) In accordance with Regulation .10 of this chapter; and

(b) With other information as may be required by the medical staff.

D. Upon notification that emergency drugs and supplies have been opened, a pharmacist or registered pharmacy technician shall:

(1) Restock the emergency drugs and supplies; or

(2) Provide a replacement supply.

E. The director of pharmacy or designee shall ensure:

(1) That the expiration date of emergency drugs and supplies is the earliest date of expiration of any drug supplied; and

(2) Before the expiration date, the pharmacist or designee shall replace the expired drug and relabel the emergency drugs and supplies as provided in §C(5) of this regulation.

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.12 Drug Dispensing -Prescribers' Orders.

A. Drugs may be dispensed from the institutional pharmacy only in response to medication orders issued by prescribers who have been authorized to do so by law and by the governing body of the institution.

B. Documentation.

(1) Institutional Medication Protocols.

(a) The pharmacist may dispense, or make available, drugs for an approved institutional medication protocol if conditions designated by the institution are met.

(b) The director of pharmacy or designee shall assist in establishing institutional policies and procedures governing the development of order-sets for each individual situation for which institutional medication protocol orders exist.

(c) The appropriate committee of the institution shall approve any order-sets before the pharmacist may provide the medications based on the institutional medication protocol.

(2) A pharmacist may provide medications based on orders which do not contain unapproved abbreviations as published by the appropriate committee of the institutional facility.

(3) The director of pharmacy or designee shall ensure that authorized personnel have access to patient information necessary for drug monitoring including the patient's:

(a) Sex;

(b) Age;

(c) Weight;

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(d) Height;

(e) Diagnosis;

(f) Medication and food allergies;

(g) Pregnancy and lactation status; and

(h) Vaccination status.

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.13 Controlled Dangerous Substances.

A. Drug Accountability.

(1) The director of pharmacy is responsible for establishing procedures and maintaining adequate written or electronic records regarding dispensing and accountability of controlled dangerous substances which specify at least the following:

(a) Name and strength of the drug;

(b) Dose;

(c) Dosage form;

(d) Prescriber;

(e) Patient name with second identifier;

(f) Date and time of administration; and

(g) Individual administering the drug;

(2) The director of pharmacy shall be responsible for establishing and maintaining adequate procedures for documentation of:

(a) Recording of receipt of delivery to the pharmacy;

(b) Entering into pharmacy inventory;

(c) Receiving into Schedule II inventory; and

(d) Dispensing of controlled dangerous substances, Schedule II -Schedule V.

(3) The director of pharmacy or designee shall be responsible for establishing and maintaining adequate procedures for documenting partially administered controlled dangerous substances:

(a) For disposal by hospital policy; and

(b) Return of unused drugs to the pharmacy.

(4) The director of pharmacy or designee shall establish procedures to ensure that controlled dangerous substance records include the handwritten or electronic signature of the individual authorized:

(a) By the institution to dispose of drugs or to return them to the pharmacy; and

(b) To witness the disposal, as defined by the institution's policies and procedures.

B. Storage and Security in the Institutional pharmacy.

(1) On at least a monthly basis, a pharmacist or registered pharmacy technician shall perform a physical count of each Schedule II controlled dangerous substance in the pharmacy and shall then compare that count with the perpetual inventory maintained by the pharmacy with reference to each drug;

(2) On at least a monthly basis, the director of pharmacy or designee shall:

(a) Investigate discrepancies within the pharmacy;

(b) Report losses as required by law; and

(c) Take appropriate action; and

(3) The director of pharmacy or designee shall establish a procedure by which previously dispensed controlled dangerous substances that are no longer necessary for medical reasons are returned to the pharmacy.

C. Storage and Security in the Institution. The director of pharmacy shall develop policies that only permit the dispensing of controlled dangerous substances when the following security precautions exist in the institution and the pharmacy:

(1) Access to controlled dangerous substances outside the pharmacy is restricted to authorized personnel approved by institutional policy;

(2) Controlled dangerous substances stored outside the pharmacy are accounted for at least at the change of each shift by licensed personnel authorized by the institution, unless a controlled access automated dispensing system provides an on-demand report of a perpetual inventory; and

(3) A pharmacist reviews the discrepancies in counts of controlled dangerous substances previously reported by other professional personnel.

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.14 Drug Recalls.

A. The director of pharmacy or designee shall develop and implement a drug recall procedure that can be readily activated to assure that drugs which have been recalled are returned to the pharmacy for proper disposition.

B. If a recall has been initiated for a drug that has been purchased by the institution, the director of pharmacy or designee shall issue a notice in a timely manner informing affected departments of the institution that the drug shall be returned to the pharmacy for proper return or disposal.

C. The institutional pharmacy is responsible for the timely retrieval of affected drugs.

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.15 Adverse Drug Events.

A. The director of pharmacy or designee shall participate in the appropriate committee or committees to establish procedures to report and record adverse drug events including medication errors and adverse drug reactions.

B. The director of pharmacy or designee shall immediately report adverse drug events to the prescriber, or the prescriber's designee, and make a written or electronic report to the appropriate committee or committees, as determined by the governing body of the institutional facility.

C. The director of pharmacy shall participate in the deliberations of the institutional committee charged with the development of the programmatic and operational changes that result from the analysis of medication errors or other adverse events.

D. The director of pharmacy, in collaboration with the medical staff and other appropriate departments and services, shall develop and maintain a process for training staff regarding detecting and reporting medication errors to prevent future occurrences.

E. The director of pharmacy or designee shall make further reports of adverse reactions as required by federal or State law.

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.16 Pharmaceutical Care Functions of the Pharmacist.

The pharmacist shall be available as necessary to provide pharmaceutical care to individual patients including, but not limited to:

A. Participating in decisions about medication use for patients including decisions not to use medication therapy as well as judgments about:

(1) Medication selection;

(2) Dosages;

(3) Routes and methods of administration;

(4) Medication therapy monitoring; and

(5) The provision of medication-related information and counseling to individual patients;

B. Cooperating directly with health care professionals and the patient in designing, implementing, and monitoring a therapeutic outcome.

C. Providing care directly to the patient to improve a patient's quality of life through achieving definite and predefined, medication-related therapeutic outcomes such as:

(1) Curing the disease;

(2) Eliminating or reducing a symptomatology;

(3) Arresting or slowing a disease process;

(4) Preventing a disease or symptomatology; and

(5) Improving patient's quality of life.

D. Identifying potential and actual medication-related problems, resolving actual medication-related problems, and preventing potential medication-related problems caused by:

(1) Untreated indications;

(2) Improper drug selection;

(3) Sub-therapeutic dosage;

(4) Failure to received medication;

(5) Over dosage;

(6) Adverse drug reactions;

(7) Drug interactions, including drug-drug, drug-food, drug-laboratory test interactions; and

(8) Medication use without appropriate indication.

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Chapter 04 Transfer and Outsourcing of Prescriptions and Prescription Orders (Refs & Annos)
.01 Scope.

This chapter governs the:

A. Transfer of prescriptions between pharmacies;

B. Filling of prescriptions at one pharmacy pursuant to the request of staff of a second pharmacy; and

C. Preparation of medication for stock and investigational use.

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Chapter 04 Transfer and Outsourcing of Prescriptions and Prescription Orders (Refs & Annos)
.02 Definitions.

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

B. Terms Defined.

(1) “Outsourcing” means the transmitting of a prescription order from a primary pharmacy to a secondary pharmacy that prepares the prescription.

(2) “Patient specific” means a prescription order prepared and labeled for a specific individual.

(3) “Preparation” means compounding or packaging of medication.

(4) “Primary pharmacy” means the pharmacy that initially receives a prescription order.

(5) “Secondary pharmacy” means the pharmacy to which a prescription order is transmitted for subsequent dispensing to a patient.

(6) “Stock medication” means medication that is not labeled for, or intended for, use by a specific patient when it leaves the pharmacy, but is intended to be stored and ultimately administered by a licensed health care professional in accordance with applicable laws and regulations.

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Chapter 04 Transfer and Outsourcing of Prescriptions and Prescription Orders (Refs & Annos)
.03 Permanent Transfer of a Prescription Between Pharmacies.

A pharmacist from a primary pharmacy may permanently transfer a prescription order to a secondary pharmacy to be dispensed to a specific patient if:

A. The prescription is lawfully refillable;

B. The prescription is not for a Schedule II controlled dangerous substance noted in Criminal Law Article, Title 5, Subtitle 4, Annotated Code of Maryland;

C. The pharmacist transferring the prescription from the primary pharmacy indicates on the prescription, within the prescription computer database and within any appropriate other records used for dispensing:

(1) That the prescription has been permanently transferred;

(2) The name of the secondary pharmacy;

(3) The name of the pharmacist who transferred the prescription to the secondary pharmacy;

(4) The name of the pharmacist at the secondary pharmacy to whom the prescription was transferred if the transfer occurred in an oral manner; and

(5) The date on which the prescription was transferred to the secondary pharmacy.

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.04 Refilling of Permanently Transferred Prescriptions.

A. A pharmacist at the primary pharmacy may not refill a prescription that has been permanently transferred to a secondary pharmacy.

B. The use of unified prescription records by more than one pharmacy through a computerized prescription database does not constitute a permanent transfer of a prescription order.

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➡➡ .05 Documentation by the Secondary Pharmacy Receiving a Permanent Prescription Transfer.

The pharmacist at the secondary pharmacy who receives a permanently transferred prescription document is responsible for maintaining documentation in a readily retrievable and identifiable manner which includes:

A. That the prescription was transferred from another pharmacy;

B. The name and information identifying the specific location of the primary pharmacy;

C. The name of the pharmacist who transferred the prescription to the secondary pharmacy;

D. The name of the pharmacist at the secondary pharmacy who accepted the transferred prescription;

E. The date of issuance of the original prescription order;

F. The date on which the prescription order was first filled;

G. The date of the last refill;

H. The number of remaining refills;

I. The original prescription number; and

J. The date on which the prescription was transferred to the secondary pharmacy.

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.06 Outsourcing of a Prescription Order.

A pharmacist from a primary pharmacy may transmit a prescription order to a secondary pharmacy for preparation and final dispensing to a specific patient or for return to the primary pharmacy for final dispensing to a specific patient if:

A. The label contains the name, address, and phone number of the primary pharmacy;

B. The patient is informed in writing of the name and address of the secondary pharmacy;

C. The patient is informed in writing that the prescription order was prepared at a secondary pharmacy;

D. The original prescription order is filed as a prescription order at the primary pharmacy;

E. The pharmacist from the primary pharmacy documents in a readily retrievable and identifiable manner:

(1) That the prescription order was prepared by a secondary pharmacy;

(2) The name of the secondary pharmacy;

(3) The name of the pharmacist who transmitted the prescription order to the secondary pharmacy;

(4) The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner;

(5) The date on which the prescription was transmitted to the secondary pharmacy; and

(6) The date on which the medication was sent to the primary pharmacy;

F. Both the primary and secondary pharmacies are licensed in this State, or operated by the federal government;

and

G. The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy.

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.07 Documentation by the Secondary Pharmacy when a Prescription Order is Outsourced.

The permit holder at the secondary pharmacy is responsible for maintaining documentation in a readily retrievable and identifiable manner, which includes:

A. That the prescription order was transmitted from another pharmacy;

B. The name and information identifying the specific location of the primary pharmacy;

C. The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner;

D. The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order;

E. The name of the pharmacist at the secondary pharmacy who prepared the prescription order;

F. The date on which the prescription order was received at the secondary pharmacy; and

G. The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

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Title 10 Department of Health and Mental Hygiene
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Chapter 04 Transfer and Outsourcing of Prescriptions and Prescription Orders (Refs & Annos)
.08 Preparation of Stock and Investigational Medications.

A. A pharmacist may provide medication for use as stock medication for a licensed health care facility in accordance with applicable laws, if the pharmacy providing the medication also serves as the primary provider of patient specific medication for the facility.

B. A pharmacist may provide medication for use as stock medication for final dispensing or administration by an authorized prescriber who is permitted by law to administer or dispense medication if the pharmacist receives a written stock medication order from the authorized prescriber for each delivery of medication to the authorized prescriber.

C. A pharmacist may prepare, package, and label investigational drugs not destined for a specific individual at the time of preparation, packaging, and labeling if:

(1) The study for which medications are prepared, packaged, and labeled is approved by an institutional review board as defined in federal law; and

(2) The pharmacy permit holder ensures that records disclosing the identity of the subject who eventually receives the medication are:

(a) Received by a pharmacist on duty at the pharmacy within 30 days after being provided to a patient; and

(b) Maintained in the pharmacy.

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.09 Permit and Quality Assurance.

A. The permit holder of a pharmacy which prepares patient specific prescriptions as a secondary pharmacy such that these prescriptions account for 5 percent or more of the pharmacy's total number of prescriptions filled shall submit to the Board of Pharmacy, for approval by the Board or a designee of the Board, a plan detailing the steps it has taken to ensure the safety and quality of prescriptions filled as a secondary pharmacy.

B. The plan under §A of this regulation shall include:

(1) Measures to be taken to comply with State and federal laws;

(2) The method by which each pharmacist responsible for each prescription is identified in the records;

(3) Measures taken to maintain the security, integrity, and confidentiality of patient records; and

(4) The establishment and maintenance of a quality assurance program.

C. Except as provided in Regulation .06 of this chapter, a permit holder of a pharmacy shall obtain manufacturing and distribution permits in order to compound or package medication that is not prepared as a prescription destined for a specific patient, but is forwarded to another pharmacy, authorized prescriber, licensed distributor, or other person or entity.

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Subtitle 34 Board of Pharmacy
Chapter 05 Pharmacy Security (Refs & Annos)
.01 Definitions.

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

B. Terms Defined.

(1) “Emergency” means an event such as a fire, water leak, electrical failure, public disaster, or catastrophe which may impact the prescription area.

(2) “Means of access” means the manner of entry into the secure prescription area.

(3) “Prescription area” means the portion of an establishment for which a pharmacy permit has been issued which contains:

(a) Patient records;

(b) Prescription devices; and

(c) Prescription drugs.

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Chapter 05 Pharmacy Security (Refs & Annos)

.02 Prescription Area.

A. The pharmacy permit holder shall:

(1) Ensure that the prescription area:

(a) Maintains temperature and ventilation at levels that do not affect the prescription drugs or devices stored in the area; and

(b) Permits reasonable communication between the pharmacist and the public when the pharmacy is open;

(2) Provide a means of securing the prescription area;

(3) Prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services;

(4) Monitor unauthorized or emergency entry after the prescription area has been secured by the pharmacist; and

(5) Prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open.

B. The pharmacist shall:

(1) Secure the prescription area and its contents in order that the pharmacy permit holder or the pharmacy permit holder's agent may:

(a) Monitor unauthorized or emergency entry after the prescription area has been secured by the pharmacist; and

(b) Prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open;

(2) Have sole possession of a means of access to the pharmacy, except in emergencies; and

(3) Establish a means of access for use in an emergency when the pharmacist is not available to access the prescription area.

C. Security.

(1) A pharmacy shall be secure from unauthorized entry as follows:

(a) Access from outside the premises shall be:

(i) Kept to a minimum; and

(ii) Well controlled;

(b) The outside perimeter of the premises shall be well lit; and

(c) Entry into areas where prescription drugs or devices and patient records are stored shall be limited to authorized personnel.

(2) A pharmacy shall be equipped with:

(a) An alarm system to detect entry after hours;

(b) A security system that provides protection against theft and diversion;

(c) Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records;

(d) An inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting;

(e) A security system to protect the integrity and confidentiality of data and documents limited to authorized personnel; and

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(f) A means to make the data and documentation required under this section readily available to the Board, an agent of the Board, the Division of Drug Control, or federal and other State law enforcement officials.

COMAR **10**. **34**.05.02, MD ADC **10**. **34**.05.02

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.05.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 05 Pharmacy Security (Refs & Annos)
.03 Pharmacy Operation.

A. A pharmacist shall be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation.

B. If the prescription area is not open the same hours as the establishment, the pharmacy permit holder shall prominently display signs indicating the business hours of the prescription area.

COMAR **10**. **34**.05.03, MD ADC **10**. **34**.05.03

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MD Health & Men. **10**. **34**.05.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 05 Pharmacy Security (Refs & Annos)
.04 Records.

A. A pharmacy permit holder shall:

(1) Prevent unauthorized disclosure or loss by securing all patient records;

(2) Designate personnel with authorized access to computerized patient records; and

(3) Maintain current computerized records in a manner which permits reconstruction within 48 hours, except:

(a) In an emergency as defined in Regulation .01 of this chapter, or

(b) With the prior approval of the Board.

B. A pharmacy permit holder may store patient records away from the prescription area in a manner that prevents unauthorized disclosure or loss.

COMAR **10**. **34**.05.04, MD ADC **10**. **34**.05.04

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.05.05

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 05 Pharmacy Security (Refs & Annos)
.05 Security Responsibility.

The pharmacy permit holder is responsible for assuring that pharmacists, employees, and others who enter the pharmacy:

A. Know and abide by the requirements of this chapter;

B. Maintain those measures necessary to ensure this chapters' enforcement; and

C. Report thefts of prescription drugs or devices to the:

(1) Board;

(2) Local police;

(3) Division of Drug Control; and

(4) U.S. Drug Enforcement Administration.

COMAR **10**. **34**.05.05, MD ADC **10**. **34**.05.05

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.06.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 06 Reporting Pharmacist's and Pharmacy Technician's Mailing Address and Location of Employment (Refs & Annos)

.01 Scope.

These regulations apply to each pharmacist and pharmacy technician licensed or registered by the Maryland Board of Pharmacy.

COMAR **10**. **34**.06.01, MD ADC **10**. **34**.06.01

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.06.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 06 Reporting Pharmacist's and Pharmacy Technician's Mailing Address and Location of Employment (Refs & Annos)
.02 Definitions.

A. In these regulations, the following terms have the meanings indicated.

B. Terms Defined.

(1) “Board” means the State Board of Pharmacy.

(2) “Mailing address” means the address the pharmacist or pharmacy technician specifies that the Board use when communicating with the pharmacist or pharmacy technician.

(3) “Primary employment location” means the establishment where the pharmacist or pharmacy technician is employed on a regular basis or works most often.

COMAR **10**. **34**.06.02, MD ADC **10**. **34**.06.02

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.06.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 06 Reporting Pharmacist's and Pharmacy Technician's Mailing Address and Location of Employment (Refs & Annos)
.03 Mailing Address.

A. Each licensed pharmacist and registered pharmacy technician shall report to the Board the pharmacist's or pharmacy technician's current mailing address on the pharmacist's or pharmacy technician's biennial license or registration renewal form. The mailing address may be the pharmacist's residence address or shall be the pharmacy technician's residence address.

B. Within 30 days of the date a pharmacist or pharmacy technician changes the pharmacist's or pharmacy technician's mailing address, the pharmacist or pharmacy technician shall notify the Board in writing of any change in the information in §A of this regulation.

COMAR **10**. **34**.06.03, MD ADC **10**. **34**.06.03

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.06.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 06 Reporting Pharmacist's and Pharmacy Technician's Mailing Address and Location of Employment (Refs & Annos)
.04 Place of Employment.

A. This regulation applies only to pharmacists and pharmacy technician's employed in Maryland.

B. Each licensed pharmacist and registered pharmacy technician shall report to the Board the pharmacist's or pharmacy technician's place of employment on the pharmacist's or pharmacy technician's biennial license or registration renewal form. A pharmacist or pharmacy technician employed at more than one location shall report the primary employment location at the time the renewal form is submitted to the Board.

C. Within 30 days of a change in the pharmacist's or pharmacy technician's primary employment location, the pharmacist or pharmacy technician shall notify the Board in writing of any change in the information required by this regulation. If the pharmacist's or pharmacy technician's primary employment location changes and the pharmacist's or pharmacy technician's new primary employment location is owned by the same corporation, partnership, or individual owner, the pharmacist or pharmacy technician is not required to report the change except when completing a biennial license or registration renewal form.

COMAR **10**. **34**.06.04, MD ADC **10**. **34**.06.04

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MD Health & Men. **10**. **34**.06.05

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 06 Reporting Pharmacist's and Pharmacy Technician's Mailing Address and Location of Employment (Refs & Annos)

.05 Grounds for Disciplinary Action.

A. A pharmacist's failure to report the information required in Regulations .03 and .04 of this chapter or failure to provide the Board with complete, up-to-date, and accurate information shall constitute grounds for action under Health Occupations Article, §12-313(b)(24), Annotated Code of Maryland, and may, in appropriate cases, constitute grounds for action under Health Occupations Article, §12-313(b)(1), (6), or (7), Annotated Code of Maryland.

B. A pharmacy technician's failure to report the information required in Regulations .03 and .04 of this chapter or failure to provide the Board with complete, up-to-date, and accurate information shall constitute grounds for action under Health Occupations Article, §12-6B-09(23), Annotated Code of Maryland, and may, in appropriate cases, constitute grounds for action under Health Occupations Article, §12-6B-09(2), (6), or (7), Annotated Code of Maryland.

COMAR **10**. **34**.06.05, MD ADC **10**. **34**.06.05

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.07.01

C

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 07 Pharmacy Equipment (Refs & Annos)
.01 Definitions.

A. In this chapter, the following term has the meaning indicated.

B. Term Defined. “Material safety data sheets” means a list of hazardous chemicals that provides detailed information on each hazardous chemical, including its potential hazardous effects, its physical and chemical characteristics and recommendations for appropriate protective measures.

COMAR **10**. **34**.07.01, MD ADC **10**. **34**.07.01

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MD Health & Men. **10**. **34**.07.01-1

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 07 Pharmacy Equipment (Refs & Annos)
.01-1 Equipment.

A pharmacy shall have the following equipment to carry out the practice of pharmacy in Maryland:

A. If applicable, a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity to a Class A prescription balance;

B. A refrigerator, solely for the storage of drugs requiring refrigeration, with a thermometer or a temperature monitoring device; and

C. A freezer, if applicable.

COMAR **10**. **34**.07.01-1, MD ADC **10**. **34**.07.01-1

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MD Health & Men. **10**. **34**.07.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 07 Pharmacy Equipment (Refs & Annos)
.02 Additional Equipment.

The pharmacy shall maintain additional equipment to enable it to prepare and dispense prescriptions properly consistent with its scope of practice.

COMAR **10**. **34**.07.02, MD ADC **10**. **34**.07.02

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 07 Pharmacy Equipment (Refs & Annos)
.03 Reference Libraries.

A. A pharmacy permit holder shall maintain an adequate reference library to enable it to prepare and dispense prescriptions properly, consistent with its scope of practice.

B. A pharmacy permit holder shall maintain a library of reference sources appropriate to the type of pharmacy practice at that particular location. A pharmacy permit holder shall include in the pharmacy's library current material regarding the technical, clinical, and professional aspects of practice with emphasis in the area in which the pharmacy specializes.

B-1. A pharmacy permit holder may utilize websites and electronic references created by established medical publishers which are recognized as standard for a particular type of pharmacy practice as a supplement to its printed library.

C. A pharmacy permit holder shall maintain a library containing reference sources that:

(1) Enable the pharmacist to compound medications in a safe and effective manner;

(2) List the possible drug interactions and possible adverse effects of medications dispensed by the pharmacy;

(3) List the therapeutic usage and dosages of medications dispensed by the pharmacy;

(4) List the therapeutic equivalents for medications; and

(5) Provide guidelines for the counseling of patients.

D. A pharmacy permit holder that specializes in nuclear or parenteral prescriptions may limit the library it maintains pursuant to §B of this regulation to the pharmacy permit holder's area of specialization.

E. A pharmacy permit holder shall maintain material safety data sheets, if applicable.

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 08 Information Required on Prescriptions or Patient Drug Profiles (Refs & Annos)

.01 Information Required on All Original and Refill Prescriptions or Patient Drug Profiles or Computerized Patient Drug Records.

In addition to the information required by law on every prescription, patient drug profile, or computerized patient drug record, the following information shall be legibly entered on all original and refill prescriptions or patient drug profiles or computerized patient drug records:

A. The date of filling or refilling;

B. The initials of, or other identifying symbol for:

(1) The pharmacist responsible for filling or refilling the prescription; and

(2) The data-entry pharmacy technician involved in the dispensing process.

COMAR **10**. **34**.08.01, MD ADC **10**. **34**.08.01

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 08 Information Required on Prescriptions or Patient Drug Profiles (Refs & Annos)
.02 Access to Records.

The information required in Regulation .01 of this chapter shall be readily retrievable for inspection during business hours by authorized personnel.

COMAR **10**. **34**.08.02, MD ADC **10**. **34**.08.02

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 09 Fees (Refs & Annos)
.01 Scope.

This chapter governs all licensees, permit holders, or applicants for licenses or permits issued by the Board.

COMAR **10**. **34**.09.01, MD ADC **10**. **34**.09.01

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 09 Fees (Refs & Annos)
.02 Fees.

The following fees are established by the Board:

A. Pharmacist Fees.

(1) Pharmacist examination fee -$150;

(2) Pharmacist reciprocity fee -$300;

(3) Pharmacist renewal fee -$225;

(4) Pharmacist reinstatement fee for up to 2 years after license expiration, payable in addition to renewal fee -$300; and

(5) Pharmacist reinstatement fee for more than 2 years after license expiration, payable in addition to renewal fee -$315.

B. Pharmacy Fees.

(1) Pharmacy initial fee -$700;

(2) Pharmacy renewal fee -$600;

(3) Pharmacy -late fee (payable if renewal fee is received between December 2 and January 31) -$200; and

(4) Pharmacy reinstatement fee .(payable if renewal fee is received after January 31) -$550.

C. Distributor Fees.

(1) Distributor initial fee -1,750;

(2) Distributor renewal fee -$1,750; and

(3) Distributor reinstatement fee after December 31 -$1,500.

D. Pharmacy Technician Fees.

(1) Pharmacy technician registration fee -$45;

(2) Pharmacy technician renewal fee -$45;

(3) Pharmacy technician reinstatement fee -$45;

(4) Pharmacy student -pharmacy technician administration fee for exemption -$45; and

(5) Review of pharmacy technician training programs submitted to the Board for approval -$200.

E. Miscellaneous Fees.

(1) Duplicate registration fee -$10;

(2) Duplicate license or duplicate permit fee -$30;

(3) Written verification of good standing fee -$25;

(4) Returned check fee -$35;

(5) Roster printed on labels fee -$150; and

(6) Failure to maintain current address fee -$25.

COMAR **10**. **34**.09.02, MD ADC **10**. **34**.09.02

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 09 Fees (Refs & Annos)
.03 Change of Fees.

Fees are subject to change by action of the Board of Pharmacy. Licensees and applicants shall be notified of the change.

COMAR **10**. **34**.09.03, MD ADC **10**. **34**.09.03

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 10 Pharmacist and Pharmacy Technician Code of Conduct (Refs & Annos)

.01 Patient Safety and Welfare.

A. A pharmacist shall:

(1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:

(a) United States Code, Title 21,

(b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,

(c) Health Occupations Article, Title 12, Annotated Code of Maryland,

(d) Criminal Law Article, Title 5, Annotated Code of Maryland, and

(e) COMAR 10.19.03;

(2) Verify the accuracy of the prescription before dispensing the drug or device if the pharmacist has reason to believe that the prescription contains an error; and

(3) Maintain proper sanitation, hygiene, biohazard precautions, and infection control when performing tasks in the prescription process.

B. A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;

(2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or

(3) Engage in unprofessional conduct.

C. Therapeutic Interchange.

(1) A pharmacist may not perform a therapeutic interchange without the prior approval of the authorized prescriber except as provided in §C(2) of this regulation.

(2) A pharmacist who provides a pharmacy service to a patient of a hospital, as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a resident of a comprehensive care or extended care facility, as defined in COMAR 10.07.02.01B, may perform a therapeutic interchange without the prior approval of the authorized prescriber if the governing body of the hospital, comprehensive care facility, or extended care facility has established procedures for therapeutic interchange.

(3) This section does not permit any act not otherwise authorized by Health Occupations Article, Title 12, Annotated Code of Maryland.

COMAR **10**. **34**.10.01, MD ADC **10**. **34**.10.01

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 10 Pharmacist and Pharmacy Technician Code of Conduct (Refs & Annos)
.02 Compensation.

A pharmacy technician or a pharmacist may not fraudulently seek or accept compensation for a pharmacy product or service not provided.

COMAR **10**. **34**.10.02, MD ADC **10**. **34**.10.02

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 10 Pharmacist and Pharmacy Technician Code of Conduct (Refs & Annos)
.03 Patient Privacy.

A. The pharmacy technician, the pharmacist, and the pharmacy permit holder shall ensure confidentiality in creating, storing, accessing, transferring, and disposing of a patient record.

B. A pharmacy technician or a pharmacist may not disclose identifiable information contained in a patient's medical record:

(1) Without the patient's consent;

(2) Without order or direction of a court; or

(3) Unless the disclosure is authorized pursuant to Health-General Article, §§4-301-4-307, Annotated Code of Maryland.

COMAR **10**. **34**.10.03, MD ADC **10**. **34**.10.03

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MD Health & Men. **10**. **34**.10.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 10 Pharmacist and Pharmacy Technician Code of Conduct (Refs & Annos)
.04 Competence.

A pharmacy technician or a pharmacist shall:

A. Maintain knowledge of the current pharmacy and drug laws and health and sanitation laws relevant to the practice of pharmacy; and

B. Provide a pharmaceutical service only within the scope of the pharmacy technician's or pharmacist's training and education.

COMAR **10**. **34**.10.04, MD ADC **10**. **34**.10.04

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MD Health & Men. **10**. **34**.10.05

C

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 10 Pharmacist and Pharmacy Technician Code of Conduct (Refs & Annos)
.05 Duty to Report.

A. Except when the conduct in question includes drug or alcohol abuse or dependency, a pharmacy technician or a pharmacist shall report to the Board:

(1) Conduct which violates a statute or regulation pertaining to the practice of pharmacy;

(2) Conduct by a pharmacy technician or a pharmacist that deceives, defrauds, or harms the public; and

(3) The unauthorized practice of pharmacy.

B. A pharmacy technician or a pharmacist shall report to the pharmacist rehabilitation committee, as defined in Health Occupations Article, §12-317, Annotated Code of Maryland, conduct by a pharmacist technician or a pharmacist that involves drug or alcohol abuse or dependency.

COMAR **10**. **34**.10.05, MD ADC **10**. **34**.10.05

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MD Health & Men. **10**. **34**.10.06

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 10 Pharmacist and Pharmacy Technician Code of Conduct (Refs & Annos)

.06 Discrimination, Harassment, and Sexual Misconduct.

A. In the practice of pharmacy, a pharmacy technician or a pharmacist may not:

(1) Discriminate based on age, gender, race, ethnicity, national origin, religion, sexual orientation, disability, socioeconomic status, or other basis as proscribed by law; or

(2) Sexually harass a patient, coworker, employee, or supervisee, which includes but is not limited to an unwanted, deliberate, or repeated comment, gesture, or physical contact of a sexual nature.

B. Sexual Misconduct. A pharmacy technician or a pharmacist may not:

(1) Dispense or offer to dispense a prescription drug or device in exchange for:

(a) A sexual act such as anal intercourse, analingus, cunnilingus, fellatio, or vaginal intercourse as specified in Criminal Law Article, §3-301(e) and (g), Annotated Code of Maryland, or

(b) Sexual contact such as the intentional touching of an intimate part of an individual's body, whether clothed or unclothed, for the purpose of sexual arousal, gratification, abuse of either party, or penetration as specified in Criminal Law Article, §3-301(f), Annotated Code of Maryland; or

(2) Engage in sexual behavior including but not limited to a sexual act or sexual contact as specified in §B(1)(a) of this regulation, with a client or patient:

(a) In the context of a professional evaluation, treatment, procedure, or other service to the client or patient, regardless of the setting in which the professional service is provided, or

(b) Under the pretense of diagnostic or therapeutic intent or benefit.

C. Sexual contact does not include an act commonly expressive of familial or friendly affection.

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COMAR **10**. **34**.10.06, MD ADC **10**. **34**.10.06

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MD Health & Men. **10**. **34**.10.07

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 10 Pharmacist and Pharmacy Technician Code of Conduct (Refs & Annos)

.07 Disposition and Return of a Prescription Drug or Device.

A. A pharmacist may accept the return of a properly labeled and properly sealed manufacturer's package or an individual unit dose of a drug or a device that the pharmacist determines to have 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.

B. A pharmacist may not:

(1) Return to the pharmacy's stock or offer for sale a prescribed drug or device that has been previously sold and has left the pharmacy's possession except as provided in §A of this regulation; or

(2) Sell, give away, or otherwise dispose of a drug, drug accessory, chemical, or device if the pharmacist knows or should know that the drug, drug accessory, chemical, or device is to be used in an illegal activity.

C. A pharmacy technician may not accept the return of prescription drugs or devices from a patient.

COMAR **10**. **34**.10.07, MD ADC **10**. **34**.10.07

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MD Health & Men. **10**. **34**.10.08

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 10 Pharmacist and Pharmacy Technician Code of Conduct (Refs & Annos)
.08 Refusing to Dispense a Controlled Substance.

A. If, based on generally accepted professional standards for the practice of pharmacy, a pharmacist has reason to believe, or should have reason to believe, that a prescription for a controlled dangerous substance was not issued for a legitimate medical purpose in the usual course of the prescriber's practice, the pharmacist may not dispense the controlled dangerous substance until the pharmacist:

(1) Consults with the prescriber; and

(2) Verifies the medical legitimacy of the prescription.

B. If, after consulting with the prescriber, and based on generally accepted professional standards for the practice of pharmacy, a pharmacist has reason to believe that the prescription for a controlled dangerous substance was not issued for a legitimate medical purpose in the usual course of the prescriber's practice, the pharmacist shall:

(1) Refuse to dispense the drug; and

(2) Report the incident to the regulatory board that licenses the prescriber.

COMAR **10**. **34**.10.08, MD ADC **10**. **34**.10.08

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MD Health & Men. **10**. **34**.10.09

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 10 Pharmacist and Pharmacy Technician Code of Conduct (Refs & Annos)
.09 Sanctions.

A. The Board may take action to reprimand a licensee, place the licensee on probation, or suspend or revoke the licensee's license if the licensee commits a violation of this chapter.

B. The Board may take action to reprimand a registrant, place the registrant on probation, or suspend or revoke the registrant's registration if the registrant commits a violation of this chapter.

C. The Board may impose a monetary penalty as authorized under Health Occupations Article, §§12-314, 12-410, and 12-6B-10, Annotated Code of Maryland.

COMAR **10**. **34**.10.09, MD ADC **10**. **34**.10.09

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 11 Disciplinary Sanctions, Monetary Penalties, and Civil Fines (Refs & Annos)
.01 Scope.

This chapter establishes standards for the imposition of disciplinary sanctions, monetary penalties, and civil fines for violations of Health Occupations Article, Title 12, Annotated Code of Maryland.

COMAR **10**. **34**.11.01, MD ADC **10**. **34**.11.01

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C

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 11 Disciplinary Sanctions, Monetary Penalties, and Civil Fines (Refs & Annos)
.02 Definitions.

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

B. Terms Defined.

(1) “Act” means Health Occupations Article, Title 12, Annotated Code of Maryland.

(2) “Board” means the State Board of Pharmacy.

(3) “Civil fine” means a fine assessed by the Board against a person for practicing without an active license, pharmacy permit, registration, or wholesale distributor permit.

(4) “License” means, unless the context requires otherwise, a license issued by the Board to practice pharmacy.

(5) “Penalty” means monetary penalty.

(6) “Pharmacy permit” means a permit issued by the Board to establish and operate a pharmacy.

(7) “Registration” means, unless the context requires otherwise, a registration issued by the Board to perform delegated pharmacy acts under the direct supervision of a licensed pharmacist.

(8) “Sanction” means a disciplinary action reprimanding, restricting, suspending, or revoking a license, pharmacy permit, registration, or wholesale distributor permit.

(9) “Wholesale distributor permit” means a permit issued by the Board to establish and operate a wholesale distributor as defined in the Health Occupations Article, §12-6C-01(v), Annotated Code of Maryland.

COMAR **10**. **34**.11.02, MD ADC **10**. **34**.11.02

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Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 11 Disciplinary Sanctions, Monetary Penalties, and Civil Fines (Refs & Annos)

.03 Imposition of Disciplinary Sanctions or Monetary Penalties Generally.

A. After a hearing pursuant to Health Occupations Article, §12-315, 12-601, or 12-6B-09, Annotated Code of Maryland, the Board may impose a penalty against a pharmacy technician, pharmacist, or wholesale distributor permit holder pursuant to Health Occupations Article, §12-314, 12-6B-10, or 12-6C-11, Annotated Code of Maryland, instead of or in addition to:

(1) Reprimanding the registrant, licensee, or wholesale distributor permit holder;

(2) Placing the registrant, licensee, or wholesale distributor permit holder on probation;

(3) Suspending a registration, license, or wholesale distributor permit; or

(4) Revoking a registration, license, or wholesale distributor permit.

B. After a hearing pursuant to Health Occupations Article, §12-411, Annotated Code of Maryland, the Board may impose a penalty against a pharmacy permit holder pursuant to Health Occupations Article, §12-410, Annotated Code of Maryland:

(1) Instead of or in addition to suspending the pharmacy permit; or

(2) In addition to revoking the pharmacy permit.

C. Notwithstanding the guidelines set forth in this chapter, in order to resolve a pending disciplinary action, the Board and the registrant, licensee, pharmacy permit holder, or wholesale distributor permit holder may agree to a surrender of a registration, license, pharmacy permit, or wholesale distributor permit or a consent order with terms, sanction, and penalty agreed to by the Board and the registrant, licensee, pharmacy permit holder, or wholesale distributor permit holder.

D. Nothing in this chapter prohibits the Board from staying any period of nonactive suspension.

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 11 Disciplinary Sanctions, Monetary Penalties, and Civil Fines (Refs & Annos)
.04 Guidelines for Imposition of Disciplinary Sanctions or Monetary Penalties on Pharmacists.

A. Subject to the provisions of this chapter, the Board may impose the following sanctions and, if appropriate, penalties for violations of the Act and its regulations according to the minimum and maximum sanctions and penalties set forth in the following categories:

Violation	Minimum Sanction	Maximum Sanction	Minimum Penalty	Maximum Penalty	
(1)	Fraudulently or deceptively obtaining or attempting to obtain a license	Probation for 1 year	Denial of license application or revocation	$500	$10,000
(2)	Fraudulently or deceptively using a license	Suspension for 30 days	Revocation	$1,000	$10,000
(3)	Aiding an unauthorized individual to practice pharmacy	Reprimand	Revocation	$250	$10,000
(4)	Failure to provide supervision	Reprimand	Probation for 3 years	$250	$5,000
(5)	Delegating a pharmacy act to an unauthorized individual	Reprimand	Revocation	$250	$10,000
(6)	Providing professional services while under the influence of alcohol or drugs	Probation for 6 months	Revocation	$500	$10,000
(7)	Submitting a false statement to	Reprimand	Revocation	$250	$10,000

	collect a fee				
(8)	Record keeping violation	Probation for 1 year	Active suspension for 5 years	$500	$10,000
(9)	Adulteration or misbranding	Probation for 1 year	Revocation	$500	$10,000
(10)	Providing or causing to provide any prescription form that bears the name, address, or other means of identification of a pharmacist or pharmacy to any authorized prescriber	Reprimand	Probation for 5 years	$250	$2,500
(11)	Providing remuneration to an authorized prescriber for referring an individual to a pharmacist or pharmacy for a product or service	Probation for 1 year	Active suspension for 5 years	$1,000	$10,000
(12)	Knowingly associating as a partner, co-owner, or employee of a pharmacy that is owned wholly or substantially by an authorized prescriber or group of authorized prescribers	Probation for 2 years	Active suspension for 5 years	$1,000	$10,000
(13)	Dispensing any drug, device, or diagnostic for which a prescription is required without a prescription	Reprimand	Revocation	$250	$10,000

(14)	Convicted of, or pled guilty to, a felony or crime of moral turpitude	Probation for 2 years	Revocation	$500	$10,000
(15)	Reciprocal discipline	Reprimand	Revocation	$250	$10,000
(16)	Failure to cooperate in an investigation of the Board or its agent	Probation for 1 year	Revocation	$500	$10,000
(17)	Physical or mental incompetence	Probation for 2 years	Revocation	N/A	N/A
(18)	Confidentiality violation	Reprimand	Revocation	$250	$10,000
(19)	Diversion	Active suspension for 1 year	Revocation	$1,000	$10,000
(20)	Standard of care violation	Reprimand	Revocation	$500	$10,000
(21)	Sexual misconduct	Active suspension for 1 year	Revocation	$2,500	$10,000
(22)	Failure to comply with an order of the Board	Probation for 1 year	Revocation	$500	$10,000
(23)	Other violation of the Act not specifically enumerated in this chapter	Reprimand	Revocation	$250	$10,000

B. If a licensee is found in violation of more than one category enumerated in this regulation, the category or categories containing the highest maximum sanction and penalty shall control.

C. A departure from the guidelines set forth in this regulation, on its own, is not grounds for any hearing or appeal of a Board action.

D. The Board may not consider a petition for reinstatement of a license that has been revoked until at least 5 years have passed from the date of revocation.

COMAR **10**. **34**.11.04, MD ADC **10**. **34**.11.04

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.05 Guidelines for Imposition of Disciplinary Sanctions or Monetary Penalties on Pharmacy Technicians.

A. Subject to the provisions of this chapter, the Board may impose the following sanctions and, if appropriate, penalties for violations of the Act and its regulations according to the minimum and maximum sanctions and penalties set forth in the following categories:

Violation	Minimum Sanction	Maximum Sanction	Minimum Penalty	Maximum Penalty	
(1)	False application and registration	Probation for 1 year	Denial of registration application or revocation	$50	$2,500
(2)	Performing acts outside of permissible scope	Probation for 1 year	Revocation	$50	$2,500
(3)	Convicted of, or pled guilty to, a felony or crime of moral turpitude	Probation for 1 year	Denial of registration application or revocation	$500	$2,500
(4)	Physical or mental incompetence	Active suspension for 1 year	Denial of registration application or revocation	N/A	N/A
(5)	Diversion	Active suspension for 1 year	Revocation	$1,000	$2,500
(6)	Reciprocal discipline	Reprimand	Denial of registration application or revocation	$250	$2,500
(7)	Lack of good	Probation for 1	Denial of	N/A	N/A

	moral character	year	registration application or revocation		
(8)	Sexual misconduct	Active suspension for 1 year	Revocation	$1,000	$2,500
(9)	Professional incompetence	Probation for 1 year	Revocation	$100	$2,500
(10)	Confidentiality violation	Probation for 1 year	Revocation	$1,000	$2,500
(11)	Failure to cooperate in Board or Division of Drug Control investigation	Reprimand	Denial of registration application or revocation	$1,000	$2,500
(12)	Other violation of the Act not specifically enumerated in this chapter	Reprimand	Revocation	$50	$2,500

B. If a registrant is found in violation of more than one category enumerated in this regulation, the category or categories containing the highest maximum sanction and penalty shall control.

C. A departure from the guidelines set forth in this regulation, on its own, is not grounds for any hearing or appeal of a Board action.

D. The Board may not consider a petition for reinstatement of a registration that has been revoked until at least 5 years have passed from the date of revocation.

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.06 Guidelines for Imposition of Disciplinary Sanctions or Monetary Penalties on Pharmacy Permit Holder.

A. Subject to the provisions of this chapter, the Board may impose the following sanctions and, if appropriate, penalties for violations of the Act and its regulations according to the minimum and maximum sanctions and penalties set forth in the following categories:

Violation	Minimum Sanction	Maximum Sanction	Minimum Penalty	Maximum Penalty	
(1)	False application and registration	Suspension for 30 days	Denial of permit application or revocation	$500	$5,000
(2)	Misrepresenting a permit	Active suspension for 1 year	Revocation	$250	$10,000
(3)	Failure to notify the Board of closing	N/A	N/A	$500	$10,000
(4)	Failure to notify the Board of a change in ownership	Suspension for 30 days	Revocation	$750	$10,000
(5)	Failure to maintain necessary equipment and appliances	Suspension for 30 days	Revocation	$250	$10,000
(6)	Failure to keep pharmacy clean and orderly	Suspension for 30 days	Active suspension for 6 months	$250	$5,000
(7)	Failure to maintain proper security	Suspension for 30 days	Revocation	$250	$10,000
(8)	Employing unlicensed or	Suspension for 30 days	Revocation	$1,000	$10,000

	unregistered personnel				
(9)	Reciprocal discipline	Suspension for 30 days	Revocation	$1,000	$10,000
(10)	Failure to cooperate in Board or Division of Drug Control investigation	Suspension for 30 days	Revocation	$250	$10,000
(11)	Failure to store drugs or devices in accordance with Board regulations	Suspension for 30 days	Revocation	$1,000	$10,000
(12)	Failure to have a pharmacist on the premises at all times the pharmacy is operational	Suspension for 30 days	Revocation	$2,500	$10,000
(13)	Record keeping violation	Suspension for 30 days	Active suspension for 1 year	$500	$5,000
(14)	Standard of practice violation	Suspension for 30 days	Revocation	$500	$10,000
(15)	Purchasing prescription drugs from an unlicensed wholesale distributor	Suspension for 30 days	Revocation	$2,500	$10,000
(16)	Other violation of the Act not specifically enumerated in this chapter	Suspension for 30 days	Revocation	$50	$10,000

B. If a pharmacy permit holder is found in violation of more than one category enumerated in this regulation, the category or categories containing the highest maximum sanction and penalty shall control.

C. A departure from the guidelines set forth in this regulation, on its own, is not grounds for any hearing or appeal of a Board action.

D. The Board may not consider a petition for reinstatement of a pharmacy permit that has been revoked until at least 5 years have passed from the date of revocation.

COMAR **10**. **34**.11.06, MD ADC **10**. **34**.11.06

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.07 Guidelines for Imposition of Disciplinary Sanctions or Monetary Penalties on Wholesale Distributor Permit Holder.

A. Subject to the provisions of this chapter, the Board may impose the following sanctions and, if appropriate, penalties for violations of the Act and its regulations according to the minimum and maximum sanctions and penalties set forth in the following categories:

Violation	Minimum Sanction	Maximum Sanction	Minimum Penalty	Maximum Penalty	
(1)	False application and registration	Probation for 1 year	Denial of permit application or revocation	$1,000	$10,000
(2)	Operating without a necessary permit	Probation for 1 year	Revocation	$1,000	$500,000
(3)	Record keeping violation	Reprimand	Active suspension for 5 years	$500	$50,000
(4)	Failure to cooperate in an inspection or investigation by the Board or its agent	Reprimand	Revocation	$2,500	$500,000
(5)	Receiving, creating, or distributing altered, misbranded, or counterfeit drugs or devices	Reprimand	Revocation	$1,000	$500,000
(6)	Pedigree violation	Probation for 1 year	Revocation	$10,000	$500,000

(7)	Purchasing, receiving, selling, or transferring prescription drugs or devices to or from and unlicensed source	Probation for 1 year	Revocation	$1,000	$500,000
(8)	Providing false or fraudulent documents or statements to the Board	Active suspension for 1 year	Revocation	$25,000	$500,000
(9)	Distributing or receiving drugs or devices that were purchased by a public or private hospital or other health care entity	Probation for 2 years	Revocation	$2,500	$500,000
(10)	Distributing or receiving drugs or devices that were stolen or obtained by fraud or deceit	Probation for 3 years	Revocation	$50,000	$500,000
(11)	Convicted of, or pled guilty to, a felony or crime of moral turpitude	Probation for 2 years	Denial of permit application or revocation	$5,000	$500,000
(12)	Convicted of, or pled guilty to, a violation of federal, state, or local drug or device law or regulation	Reprimand	Denial of permit application or revocation	$2,500	$500,000
(13)	Distributing a prescription drug or device that was	Active suspension for 2 years	Revocation	$50,000	$500,000

	previously dispensed by a pharmacy or distributed by a practitioner				
(14)	Failure to report prohibited acts	Reprimand	Revocation	$500	$500,000
(15)	Reciprocal discipline	Reprimand	Revocation	$500	$500,000
(16)	Failure to comply with conditions of probation	Probation for 1 year	Revocation	$10,000	$500,000
(17)	Other violation of the Act not specifically enumerated in this chapter	Reprimand	Revocation	$500	$500,000

B. If a wholesale distributor permit holder is found in violation of more than one category enumerated in this regulation, the category or categories containing the highest maximum sanction and penalty shall control.

C. A departure from the guidelines set forth in this regulation, on its own, is not grounds for any hearing or appeal of a Board action.

D. The Board may not consider a petition for reinstatement of a wholesale distributor permit that has been revoked until at least 5 years have passed from the date of revocation.

COMAR **10**. **34**.11.07, MD ADC **10**. **34**.11.07

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Chapter 11 Disciplinary Sanctions, Monetary Penalties, and Civil Fines (Refs & Annos)

➡➡ .08 Mitigating and Aggravating Factors to Be Considered in the Assessment of the Sanction and Penalty.

A. Depending upon the facts and circumstances of each case, and to the extent that they apply, the Board may consider the following mitigating and aggravating factors in determining whether the sanction in a particular case should fall outside the range of sanctions established by the guidelines. These factors may include, but are not limited to, the following:

(1) Mitigating Factors:

(a) The licensee's, registrant's, or permit holder's lack of a prior disciplinary record;

(b) The licensee, registrant, or permit holder self-reported the violation to the Board;

(c) The licensee's, registrant's, or permit holder's full and voluntary admission of misconduct to the Board and cooperation during Board proceedings;

(d) The licensee, registrant, or permit holder implemented remedial measures to correct or mitigate harm arising from the misconduct;

(e) The licensee, registrant, or permit holder made a timely good-faith effort to make restitution or to rectify the consequences of the misconduct;

(f) Evidence of rehabilitation or rehabilitative potential;

(g) Absence of premeditation to commit the misconduct;

(h) Absence of potential harm to public or adverse impact; and

(i) The licensee's, registrant's, or permit holder's conduct was an isolated incident and not likely to recur; and

(2) Aggravating Factors:

(a) The licensee, registrant, or permit holder has a previous criminal or administrative disciplinary history;

(b) The violation was committed deliberately or with gross negligence or recklessness;

(c) The violation had the potential for, or caused, serious patient harm;

(d) The violation was part of a pattern of detrimental conduct;

(e) The licensee, registrant, or permit holder was motivated to perform the violation for financial gain;

(f) The vulnerability of the patient or customer;

(g) The licensee, registrant, or permit holder attempted to hide error or misconduct from patients or others;

(h) Previous attempts at rehabilitation of the licensee, registrant, or permit holder were unsuccessful; and

(i) The licensee, registrant, or permit holder committed the violation under the guise of treatment.

B. The existence of one or more of these factors does not impose on the Board or an Administrative Law Judge any requirement to articulate its reasoning for not exercising its discretion to impose a sanction outside of the range of sanctions set forth in this chapter.

C. Nothing in this regulation requires the Board or an Administrative Law Judge to make findings of fact with respect to any of these factors.

COMAR **10**. **34**.11.08, MD ADC **10**. **34**.11.08

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.09 Civil Fines to Pharmacists, Pharmacy Technicians, and Pharmacy Permit Holders.

A. Practicing on an Expired License. The Board may assess a civil fine against a pharmacist who practices on an expired license in the amount of $1,000 per month of practice past the expiration date of the license, up to a maximum fine of $50,000.

B. Working on an Expired Registration. The Board may assess a civil fine against a pharmacy technician who works on an expired registration in the amount of $25 per month of practice past the expiration date of the registration, up to a maximum fine of $250.

C. Operating a Pharmacy on an Expired Permit. The Board may assess a civil fine against a permit holder that operates a pharmacy on an expired permit in the amount of $5,000 per month of operation past the expiration date of the permit, up to a maximum fine of $50,000.

D. Practicing or Operating Without a License, Registration, or Pharmacy Permit.

(1) The Board may assess a civil fine of no less than $5,000 and no more than $50,000 against:

(a) An individual who practices pharmacy without a license; or

(b) An individual or entity that operates a pharmacy without a permit.

(2) The Board may assess a civil fine of no less than $250 and no more than $50,000 against an individual who works as an unregistered pharmacy technician.

(3) Factors in determining the amount of a fine include, but are not limited to, the following:

(a) The extent to which the individual or entity derived any financial benefit from the unauthorized practice or operation;

(b) The willfulness of the unauthorized practice or operation;

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(c) Actual or potential public harm caused by the unauthorized practice or operation; and

(d) The length of time in which the individual or entity engaged in the unauthorized practice or operation.

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Chapter 11 Disciplinary Sanctions, Monetary Penalties, and Civil Fines (Refs & Annos)
.10 Civil Fines to Wholesale Distributor Permit Holders.

A. Operating on an Expired Wholesale Distributor Permit. The Board may assess a civil fine against a permit holder that operates on an expired wholesale distributor permit in the following amount:

(1) A maximum of $10,000 per month of operation past the expiration date of the permit, if the annual gross receipts in Maryland of the permit holder for the previous tax year were less than $10,000,000, up to a maximum fine of $500,000; or

(2) A maximum of $25,000 per month of operation past the expiration date of the permit, if the annual gross receipts in Maryland of the permit holder for the previous tax year were $10,000,000 or more, up to a maximum fine of $500,000.

B. Practicing Without a License.

(1) The Board may assess a civil fine of no less than $10,000 and no more than $500,000 against an individual or entity that operates a wholesale distributor without a license.

(2) Factors in determining the amount of a fine include, but are not limited to, the following:

(a) The size of the wholesale distributor;

(b) The gravity of the violation for which the fine is to be imposed;

(c) The good faith of the wholesale distributor;

(d) Any previous violations by the wholesale distributor;

(e) Actual or potential public harm caused by the unauthorized operation; and

(f) The length of time in which the entity engaged in the unauthorized operation.

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Chapter 11 Disciplinary Sanctions, Monetary Penalties, and Civil Fines (Refs & Annos)
.11 Payment of a Penalty.

A. A licensee, registrant, or permit holder shall pay to the Board a penalty imposed under this chapter within 30 days of the date the Board's order is issued, unless the Board's order specifies otherwise.

B. Filing an appeal under State Government Article, §10-222, Annotated Code of Maryland, or Health Occupations Article, §12-316, 12-412, or 12-601, Annotated Code of Maryland, does not automatically stay payment of a penalty imposed by the Board pursuant to this chapter.

C. If a licensee, registrant, or permit holder fails to pay, in whole or in part, a penalty imposed by the Board pursuant to this chapter, the Board may not restore, reinstate, or renew a license, registration, or permit until the penalty has been paid in full.

D. In its discretion, the Board may refer cases of delinquent payment to the Central Collection Unit of the Department of Budget and Management to institute and maintain proceedings to ensure prompt payment.

E. Deposit of Monies.

(1) The Board shall pay monies collected pursuant to this chapter, except for civil fines collected under Regulation .09 of this chapter, into the State's General Fund.

(2) Civil Fines.

(a) The Board shall pay civil fines collected under Regulation .09 of this chapter into the State Board of Pharmacy Fund, in accordance with Health Occupations Article, §12-707(e)(2), Annotated Code of Maryland.

(b) The Board shall pay civil fines collected under Regulation .10 of this chapter into the State's General Fund.

COMAR **10**. **34**.11.11, MD ADC **10**. **34**.11.11

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Chapter 12 Removal of Expired Medications (Refs & Annos)
.01 Manufacturer's Expiration Date.

A. A wholesale distributor, pharmacist, or pharmacy shall distribute or hold for sale medications bearing a manufacturer's expiration date pursuant to 21 C.F.R. §211.137.

B. A wholesale distributor, pharmacist, or pharmacy shall have adequate and credible provisions for return of outdated drugs, including but not limited to partials, through its wholesaler distributor or reverse distributor.

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Title 10 Department of Health and Mental Hygiene
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Chapter 13 Reinstatement of Expired Licenses for Pharmacists (Refs & Annos)
.01 Definitions.

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

B. Terms Defined.

(1) “Board” means the State Board of Pharmacy.

(2) “MPJE” means the Multistate Pharmacy Jurisprudence Examination.

(3) “NAPLEX” means the North American Pharmacist Licensure Examination.

(4) “Reinstatement” means renewal of a license after the license has expired.

(5) “Renewal” means renewing a license before the date of expiration.

COMAR **10**. **34**.13.01, MD ADC **10**. **34**.13.01

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Chapter 13 Reinstatement of Expired Licenses for Pharmacists (Refs & Annos)
.02 Reinstatement Fee.

The reinstatement fee authorized by Health Occupations Article, §12-310(a)(2), Annotated Code of Maryland, shall be as determined in COMAR **10**. **34**.09.

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Chapter 13 Reinstatement of Expired Licenses for Pharmacists (Refs & Annos)
.03 Reinstatement Requirements.

A. General Requirements. A pharmacist who wishes to reinstate an expired license to practice pharmacy shall:

(1) Provide evidence of the completed amount of approved continuing education required by the Board in COMAR **10**. **34**.18 in conjunction with the reinstatement application;

(2) Provide evidence of good standing in any other state in which the pharmacist has been licensed, if applicable; and

(3) Pay to the Board the reinstatement fee established by the Board in COMAR **10**. **34**.09.

B. Specific Requirements.

(1) The Board:

(a) May reinstate the license of a pharmacist who has actively engaged in the practice of pharmacy in Maryland after the expiration of the pharmacist's license if the pharmacist:

(i) Meets the requirements of §A of this regulation; and

(ii) Pays the pharmacist reinstatement fee established in COMAR **10**. **34**.09.02;

(b) May bring charges against a pharmacist who has practiced without a license; and

(c) When determining sanctions for practicing pharmacy without a license under §B(1) of this regulation, shall consider:

(i) The length of time during which the pharmacist practiced without a license; and

(ii) Any violations of Health Occupations Article, Title 12, Annotated Code of Maryland, committed by the pharmacist during the period of unlicensed practice.

(2) A pharmacist not actively engaged in the practice of pharmacy, whose Maryland license expired less than 2 years before applying for reinstatement, shall meet the requirements of §A of this regulation.

(3) A pharmacist licensed in another state and actively engaged in the practice of pharmacy in that state, whose Maryland license expired less than 2 years before applying for license reinstatement, shall meet the requirements of §A of this regulation.

(4) A pharmacist licensed in another state and actively engaged in the practice of pharmacy in that state, whose Maryland license expired 2 years but less than 5 years before applying for license reinstatement, shall:

(a) Meet the requirements of §A of this regulation;

(b) Submit evidence satisfactory to the Board which documents the applicant's pharmacy experience during the 2 years immediately preceding the date of the applicant's reinstatement application; and

(c) Pass the MPJE.

(5) A pharmacist not actively engaged in the practice of pharmacy, whose Maryland license expired more than 2 years but less than 5 years before applying for reinstatement, shall:

(a) Meet the requirements of §A of this regulation; and

(b) Pass the MPJE.

(6) A pharmacist not actively engaged in the practice of pharmacy in another state, whose Maryland license expired more than 5 years but less than 10 years before applying for reinstatement, shall:

(a) Meet the requirements of §A of this regulation;

(b) Pass the MPJE; and

(c) Submit evidence satisfactory to the Board of having performed 1,000 hours of service in a pharmacy with a valid pharmacy permit under the supervision of a licensed pharmacist.

(7) A pharmacist not actively engaged in the practice of pharmacy, whose Maryland license expired 10 or more years before applying for reinstatement, shall:

(a) Meet the requirements of §A(2) and (3) of this regulation;

(b) Pass the MPJE;

(c) Submit evidence satisfactory to the Board of having performed 1,000 hours of service in a pharmacy with a valid pharmacy permit under the supervision of a licensed pharmacist; and

(d) Pass the NAPLEX.

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Chapter 13 Reinstatement of Expired Licenses for Pharmacists (Refs & Annos)
.04 Waiver.

The Board may waive any of the requirements set forth in Regulation .03 of this chapter in reinstating a pharmacist's expired license.

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ADMINISTRATIVE HISTORY

Effective date: April 9, 1984 (11:7 Md. R. 625)

Recodified from COMAR **10**. **34**.15 to **10**. **34**.13

Regulation .01 amended effective September 5, 1988 (15:18 Md. R. 2152)

Regulation .01B amended effective October 24, 1994 (21:21 Md. R. 1814); November 1, 1999 (26:22 Md. R. 1693); February 17, 2003 (30:3 Md. R. 180); July 1, 2010 (37:10 Md. R. 722)

Regulation .02 amended effective October 24, 1994 (21:21 Md. R. 1814)

Regulation .03 amended effective February 19, 1990 (17:3 Md. R. 299); October 24, 1994 (21:21 Md. R. 1814)

Regulation .03B, C amended effective September 5, 1988 (15:18 Md. R. 2152)

Regulation .03 repealed and new Regulation .03 adopted effective November 1, 1999 (26:22 Md. R. 1693)

Regulation .03 amended effective July 1, 2010 (37:10 Md. R. 722)

Regulation .03B amended effective October 14, 2002 (29:20 Md. R. 1589); February 17, 2003 (30:3 Md. R. 180)

Regulation .04 adopted effective February 19, 1990 (17:3 Md. R. 299)

Regulation .04 amended effective July 1, 2010 (37:10 Md. R. 722)

COMAR T. 10, Subt. 34, Ch. 13, Administrative History, MD ADC T. 10, Subt. 34, Ch. 13, Administrative History

MD Health & Men. T. 10, Subt. 34, Ch. 13, Administrative History

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.14.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 14 Opening and Closing of Pharmacies (Refs & Annos)
.01 Definitions.

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

B. Terms Defined.

(1) “Cease to operate” means the date on which the last prescription is filled or refilled by a licensed pharmacist.

(2) “Closing” means the date on which the pharmacy permit holder provides to the Board information and documentation required by Regulations .04 and .05 of this chapter.

(3) “Operational pharmacy” means a pharmacy that is actively compounding, dispensing, or distributing prescription or nonprescription drugs or devices in accordance with Health Occupations Article, §12-101(p), Annotated Code of Maryland.

COMAR **10**. **34**.14.01, MD ADC **10**. **34**.14.01

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.14.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 14 Opening and Closing of Pharmacies (Refs & Annos)
.02 Opening a Pharmacy.

A. To apply for a pharmacy permit, an applicant shall:

(1) Submit an application to the Board on the form that the Board requires;

(2) Pay to the Board an application fee set by the Board in COMAR **10**. **34**.09; and

(3) Submit to an opening inspection, at which time the applicant shall have, at a minimum, the following:

(a) If applicable, a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity;

(b) A refrigerator, solely for the storage of medications requiring refrigeration, with a thermometer or a temperature monitoring device;

(c) Additional equipment to enable the pharmacy to prepare and dispense prescriptions properly consistent with the pharmacy's scope of practice;

(d) Hot and cold running water;

(e) A library of current reference sources, consistent with the pharmacy's scope of practice, that is accessible to appropriate personnel;

(f) A current edition of Maryland Pharmacy Laws;

(g) A security system in accordance with COMAR **10**. **34**.05.02; and

(h) A pharmacist on the premises during the opening inspection, if prescription drugs are present.

B. A pharmacy may not be located in a residence.

C. A permit holder who has been issued a pharmacy permit by the Board shall, within 60 days following the initial issuance of the pharmacy permit, have and maintain an operational pharmacy.

D. The Board shall inspect a pharmacy after the initial issuance of a pharmacy permit to ensure that the pharmacy is an operational pharmacy.

E. If a pharmacy is not an operational pharmacy within 60 days following the initial issuance of a pharmacy permit, the Board shall notify the permit holder of the Board's intent to rescind the pharmacy permit.

F. A permit holder who has been notified of the Board's intent to rescind the pharmacy permit under this regulation shall return the permit to the Board within 10 days of notification, unless the permit holder submits documentation satisfactory to the Board to show that the pharmacy is an operational pharmacy.

G. If a pharmacy permit has been rescinded under this regulation, the permit holder may reapply if application requirements are met.

H. The Board may waive any of the requirements set forth in this regulation.

COMAR **10**. **34**.14.02, MD ADC **10**. **34**.14.02

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.14.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 14 Opening and Closing of Pharmacies (Refs & Annos)
.03 Information to be Included in Notification of Closing.

A. At least 14 days before a location's anticipated date of ceasing to operate as a licensed pharmacy, the pharmacy permit holder shall:

(1) Notify the:

(a) Board in writing by certified mail, return receipt requested, or hand delivered to the Board's office of the day on which the licensed pharmacy will cease to operate as a pharmacy; and

(b) Division of Drug Control by certified mail, return receipt requested, of the day on which the licensed pharmacy will cease to operate as a pharmacy; and

(2) Request a closing inspection date.

B. Upon notification by a pharmacy permit holder of the proposed date on which a licensed pharmacy will cease to operate, the Board shall notify the Board's agent to schedule the closing inspection in conjunction with the Board's agent, if necessary.

C. The Board, or the Board's agent, shall perform the closing inspection within 72 hours of the pharmacy ceasing to operate.

COMAR **10**. **34**.14.03, MD ADC **10**. **34**.14.03

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.14.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 14 Opening and Closing of Pharmacies (Refs & Annos)
.04 Required Information and Procedure.

A. At the closing inspection of a licensed pharmacy, the pharmacy permit holder shall provide to the Board, or the Board's agent, information and documentation required by Regulation .05 of this chapter.

B. The pharmacy permit holder shall remove or completely cover indications that the premises was a pharmacy within 30 days after the date the licensed pharmacy ceases to operate as a pharmacy.

C. The pharmacy permit holder shall notify prescription drug suppliers to the pharmacy, before ceasing to operate as a pharmacy, of the date that the location will cease to operate as a pharmacy.

D. The pharmacy permit holder shall notify the public of the date that the pharmacy will cease to operate as a pharmacy by that date.

E. The pharmacy permit holder shall notify the public of the location to which the patients' records have been transferred, by the date the pharmacy ceases to operate.

F. If patient records are not transferred, the pharmacy permit holder shall notify the public of the:

(1) Location of the patient records;

(2) Method by which the patient records shall be maintained; and

(3) Procedure by which patients and other authorized individuals or entities may access the patient records.

G. The pharmacy permit holder shall comply with all federal and State laws and regulations.

H. If the Board's agent performs the closing inspection, the Board's agent shall obtain information and documentation required by Regulation .05 of this chapter.

COMAR **10**. **34**.14.04, MD ADC **10**. **34**.14.04

MD Health & Men. **10**. **34**.14.04

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.14.05

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 14 Opening and Closing of Pharmacies (Refs & Annos)

.05 Information and Documentation Due at the Closing Inspection.

Information and documentation due at the closing inspection shall include:

A. The exact date on which the pharmacy ceased to operate as a pharmacy;

B. A copy of the inventory required by the Drug Enforcement Administration;

C. The pharmacy permit and State Department of Health and Mental Hygiene controlled dangerous substance registration for cancellation;

D. The names, address, telephone numbers, and Drug Enforcement Administration registration numbers of the persons or business entities to whom any prescription drugs in stock were returned or transferred under Regulation .05 of this chapter and for any prescription files or patient records transferred;

E. If prescription drugs are destroyed pursuant to Regulation .06 of this chapter, and Regulation .07 of this chapter does not apply to the prescription drugs, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating the:

(1) Date, place and manner in which the prescription drugs were destroyed;

(2) Names, addresses, and telephone numbers of the persons responsible for destroying the prescription drugs; and

(3) Name, dosage unit, and quantity of each type of prescription drug destroyed;

F. If any patient records which are not required to be maintained by law, or other documents containing patient information are destroyed, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating:

(1) That the documents were destroyed;

(2) The date of the destruction of the documents;

(3) The name and address of the person who destroyed the documents;

(4) That the records or other documents were destroyed in a manner so as to avoid breaches of patients' confidentiality; and

(5) The identity of the records destroyed; and

G. If any patient records or other documents containing patient information are transferred, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating:

(1) The date, time, place to which and manner in which the records or other documents were transferred;

(2) The names, addresses, and telephone numbers of the persons responsible for transferring the records or other documents;

(3) That the records or other documents were transferred in a manner so as to avoid breaches of patients' confidentiality; and

(4) The identity of the records transferred.

COMAR **10**. **34**.14.05, MD ADC **10**. **34**.14.05

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.14.06

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 14 Opening and Closing of Pharmacies (Refs & Annos)
.06 Disposition of Prescription Drugs Other than Controlled Dangerous Substances.

With the exception of controlled dangerous substances, prescription drugs in stock shall be disposed of by one or more of the following means:

A. Returning them to a distributor or manufacturer; or

B. Transferring them to another licensed pharmacy, authorized prescriber, or other person or entity approved by the Board or the Division of Drug Control.

COMAR **10**. **34**.14.06, MD ADC **10**. **34**.14.06

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.14.07

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 14 Opening and Closing of Pharmacies (Refs & Annos)
.07 Disposition of Controlled Dangerous Substances.

The pharmacy permit holder shall comply with the procedures set forth in this chapter in addition to those set forth in COMAR 10.19.03.10C-E governing the disposal of controlled dangerous substances.

COMAR **10**. **34**.14.07, MD ADC **10**. **34**.14.07

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.15.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 15 Licensure by Reciprocity (Refs & Annos)
.01 Requirements.

A. An individual applying for licensure as a pharmacist by reciprocity shall:

(1) Submit to the Board an application on a form provided by the Board;

(2) Pay to the Board the fee as specified in COMAR **10**. **34**.09;

(3) Submit to the Board evidence of completion of at least 520 hours of pharmacy experience after graduation from a school or college of pharmacy approved by the Board or accredited by the American Council on Pharmaceutical Education;

(4) Pass the MPJE; and

(5) Pass the exam of oral English competency described in COMAR **10**. **34**.02.

B. The Board shall waive the requirements of §A(5) of this regulation if the candidate for licensure by reciprocity submits to the Board written documentation that the candidate has passed an equivalent oral English competency exam in another state that was required by the other state's licensing procedures.

COMAR **10**. **34**.15.01, MD ADC **10**. **34**.15.01

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. T. 10, Subt. 34, Ch. 15, Administrative History

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 15 Licensure by Reciprocity (Refs & Annos)

ADMINISTRATIVE HISTORY

Effective date: December 3, 1984 (11:24 Md. R. 2069)

Chapter recodified from COMAR **10**. **34**.18 to **10**. **34**.15

Regulation .01 amended effective April 16, 1990 (17:7 Md. R. 849)

Regulation .01 repealed and new Regulation .01 adopted effective April 6, 1998 (25:7 Md. R. 527)

Regulation .01A amended effective July 1, 2010 (37:10 Md. R. 722)

COMAR T. 10, Subt. 34, Ch. 15, Administrative History, MD ADC T. 10, Subt. 34, Ch. 15, Administrative History

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.16.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 16 Portable Drug Kits for Licensed Home Health Agencies, Hospices, and Home Infusion Providers Licensed as Residential Services Agencies (Refs & Annos)
.01 Definitions.

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

B. Terms Defined.

(1) “Committee” means, in this chapter, a joint committee of representatives from the Board of Pharmacy and the Board of Nursing.

(2) “Portable drug kit” means a container comprising prescription drugs and other emergency medical supplies or drugs for use in licensed home health and licensed hospice settings, and by home infusion providers licensed as residential services agencies.

(3) “Prescription protocol” means an order for a portable drug kit signed by the medical director of a licensed home health agency, licensed general hospice, or a home infusion provider licensed as a residential services agency.

COMAR **10**. **34**.16.01, MD ADC **10**. **34**.16.01

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.16.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 16 Portable Drug Kits for Licensed Home Health Agencies, Hospices, and Home Infusion Providers Licensed as Residential Services Agencies (Refs & Annos)

.02 Requirements for Prescription Protocol.

Before distributing a portable drug kit, the pharmacist shall ensure that the prescription protocol includes:

A. The name, strength, and quantity of a drug to be included in the portable drug kit;

B. The name of the receiving agency or designated agent;

C. The directions for use;

D. Conditions for use;

E. Contraindications for use; and

F. The signature, printed name, and telephone number of the physician authorizing the kit.

COMAR **10**. **34**.16.02, MD ADC **10**. **34**.16.02

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.16.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 16 Portable Drug Kits for Licensed Home Health Agencies, Hospices, and Home Infusion Providers Licensed as Residential Services Agencies (Refs & Annos)
.03 Records.

A pharmacist shall:

A. File the prescription protocol in a readily retrievable manner;

B. Document the:

(1) Date of distribution of the portable drug kit,

(2) Name of the person or agency to whom the kit is delivered, and

(3) Date of delivery for each kit distributed;

C. File an administration record for all drugs administered from a kit upon return of the kit to the pharmacy; and

D. Notify the Board of Pharmacy before distributing portable drug kits under this chapter.

COMAR **10**. **34**.16.03, MD ADC **10**. **34**.16.03

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.16.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 16 Portable Drug Kits for Licensed Home Health Agencies, Hospices, and Home Infusion Providers Licensed as Residential Services Agencies (Refs & Annos)

.04 Requirements of the Portable Drug Kit.

A. The pharmacist shall ensure that the portable drug kit:

(1) Is sealed with a tamper evident tag or other means for detecting entry to the kit;

(2) Displays on the outside of the kit:

(a) A serial number unique to the kit;

(b) An expiration date which reflects the earliest expiration date of any item contained in the kit;

(c) The contents of the kit;

(d) That the contents are or are not sterile;

(e) The legend “To be returned to the pharmacy within 5 days of breaking seal, with a completed administration record or prescription enclosed”; and

(f) Storage requirements for the contents;

(3) Contains:

(a) Only prescription drugs and nonprescription items approved for the kit by a committee as defined in Regulation .01B(1) of this chapter;

(b) A temperature monitor to indicate maintenance of proper storage conditions; and

(c) A written administration record to be completed by the licensed health care provider using the kit, which

includes the administration record indicating:

(i) The name of the patient,

(ii) The name of the prescriber,

(iii) Drug name, form, and dosage,

(iv) Date the drug was used or wasted,

(v) The reason for administration or wastage of the drug, and

(vi) The name of the licensed health care provider utilizing the kit;

(4) Displays or includes written information inside the kit listing contraindications to use of the kit; and

(5) Does not contain a controlled dangerous substance.

B. A pharmacist shall only distribute a portable drug kit which complies with the requirements of this chapter.

COMAR **10**. **34**.16.04, MD ADC **10**. **34**.16.04

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.16.05

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 16 Portable Drug Kits for Licensed Home Health Agencies, Hospices, and Home Infusion Providers Licensed as Residential Services Agencies (Refs & Annos)
.05 Contents of Portable Drug Kit.

The committee shall review annually the approved prescription drugs and nonprescription items to ensure that the contents of a portable drug kit are appropriate.

COMAR **10**. **34**.16.05, MD ADC **10**. **34**.16.05

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.16.06

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 16 Portable Drug Kits for Licensed Home Health Agencies, Hospices, and Home Infusion Providers Licensed as Residential Services Agencies (Refs & Annos)

➡➡ .06 Distribution of Portable Drug Kits.

Portable drug kits may only be distributed to licensed health care providers who are authorized by law to administer the contents of a portable drug kit.

COMAR **10**. **34**.16.06, MD ADC **10**. **34**.16.06

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties (Refs & Annos)

.01 Definitions.

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

B. Terms Defined.

(1) “Board” means the State Board of Pharmacy.

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

(3) “Continuing care in a retirement community” means providing shelter and providing either medical and nursing or other health related services or making the services readily accessible through the provider or an affiliate of the provider, whether or not the services are specifically offered in the written agreement for shelter:

(a) To an individual who is 60 years old or older and not related by blood or marriage to the provider;

(b) For the life of the individual or for a period exceeding 1 year; and

(c) Under one or more written agreements that require a transfer of assets or an entrance fee notwithstanding periodic charges.

(4) “Full service pharmacy” means a pharmacy that provides complete pharmaceutical services to the general public and does not restrict or limit its services to any group of individuals.

(5) Pharmaceutical Specialty.

(a) “Pharmaceutical specialty” means a limited pharmaceutical service provided by a pharmacy that:

(i) Is in or makes use of a specialized setting by virtue of certain equipment, systems, location, or physical structure; and

(ii) Restricts or limits its services to a group or groups of individuals requiring such specialty services.

(b) “Pharmaceutical specialty” includes the following services:

(i) Assisted living facilities;

(ii) Comprehensive care facilities;

(iii) Developmental disabilities facilities;

(iv) Home infusion;

(v) Inpatient hospital;

(vi) Nonsterile compounding;

(vii) Nuclear pharmaceutical;

(viii) Research;

(ix) Sterile compounding;

(x) Veterinary care;

(xi) Provision of pharmaceutical services across all settings of care within a continuing care in a retirement community; and

(xii) Other services approved by the Board.

(6) “Waiver pharmacy” means a pharmacy that has been issued a waiver permit by the Board.

COMAR **10**. **34**.17.01, MD ADC **10**. **34**.17.01

MD Health & Men. **10**. **34**.17.01

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.17.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties (Refs & Annos)

.02 Pharmaceutical Specialty.

A. The Board may recognize as a pharmaceutical specialty not listed under Regulation .01B(4) of this chapter, upon written application and supporting documentation to the Board by an applicant for a waiver permit.

B. When evaluating an application for a waiver pharmacy, the Board shall consider whether:

(1) The pharmaceutical specialty service is necessary to meet a specific therapeutic need;

(2) The location is accessible without endangering public health and safety;

(3) The pharmacy is properly equipped to perform the pharmaceutical specialty;

(4) The applicant has provided a full and detailed description of the pharmaceutical specialty that clearly substantiates the basis for the request of a waiver permit; and

(5) A policy and procedure manual is included with the application which sets forth a detailed description of the pharmacy operation.

C. No one criterion or combination of criteria listed in §B of this regulation shall be binding upon the Board.

D. The Board's determination of whether a limited practice or setting constitutes a pharmaceutical specialty is final.

COMAR **10**. **34**.17.02, MD ADC **10**. **34**.17.02

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.17.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties (Refs & Annos)

.03 Requirements of a Waiver Pharmacy.

A. The Board shall issue a waiver permit to an applicant that:

(1) Meets the requirements of this chapter; and

(2) Performs pharmaceutical specialty services:

(a) Listed in Regulation .01B(4) of this chapter; or

(b) Approved by the Board.

B. The applicant shall:

(1) Submit an application form approved by the Board;

(2) Pay a fee as set forth in COMAR **10**. **34**.09;

(3) Submit any other documentation as required by the Board;

(4) Employ at least one pharmacist at the applicant's proposed facility who has received education or training in the pharmaceutical specialty in addition to that required for licensure; and

(5) Notify the Board in writing within 30 days of any change in the information given on the initial or renewal waiver pharmacy application.

COMAR **10**. **34**.17.03, MD ADC **10**. **34**.17.03

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

MD Health & Men. **10**. **34**.17.03

END OF DOCUMENT

MD Health & Men. **10**. **34**.17.04

C

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 17 Waiver of Full Service Requirements for Recognized Pharmaceutical Specialties (Refs & Annos)
.04 Restricted Practice.

A. A waiver pharmacy is restricted to the pharmaceutical specialty services approved by the Board in the waiver permit.

B. A waiver pharmacy may not perform functions of a full service pharmacy.

C. A full service pharmacy may perform pharmaceutical specialty services as long as the full service pharmacy is able to demonstrate competency in performing the pharmaceutical specialty.

D. A full service pharmacy and a waiver pharmacy may operate on the same premises provided that the full service pharmacy and the waiver pharmacy:

(1) Obtain separate permits from the Board;

(2) Are supervised by separate licensed pharmacists who are responsible for the operations of their respective pharmacies at all times the pharmacies are in operation; and

(3) Maintain separate inventory and record keeping for each pharmacy permit.

COMAR **10**. **34**.17.04, MD ADC **10**. **34**.17.04

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.18.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 18 Continuing Education for Pharmacists (Refs & Annos)
.01 Scope.

These regulations govern any person who desires to renew a license to practice pharmacy in Maryland.

COMAR **10**. **34**.18.01, MD ADC **10**. **34**.18.01

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.18.01-1

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 18 Continuing Education for Pharmacists (Refs & Annos)
.01-1 Definitions.

A. In this chapter, the following term has the meaning indicated.

B. Live Instruction.

(1) “Live instruction” means a course offering the ability for the participant to have real-time interaction with the presenter.

(2) “Live instruction” includes programs approved by the American Council on Pharmaceutical Education (ACPE) that are designated by the letter “L” in the course identification number.

COMAR **10**. **34**.18.01-1, MD ADC **10**. **34**.18.01-1

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.18.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 18 Continuing Education for Pharmacists (Refs & Annos)
.02 Exceptions.

A. This chapter does not apply to pharmacists applying for renewal for the first renewal period following the issuance of the original license, if the pharmacist obtains a license within 1 year of the completion of the pharmacist's pharmaceutical education.

B. The Board may grant an exception from the continuing education requirements if the pharmacist presents evidence that failure to comply was due to circumstances beyond the pharmacist's control.

COMAR **10**. **34**.18.02, MD ADC **10**. **34**.18.02

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 18 Continuing Education for Pharmacists (Refs & Annos)
.03 Requirements for Pharmacists Practicing in Maryland.

A. A pharmacist license expires on the last day of the pharmacist's birth month every other year.

B. Before the expiration date of the pharmacist's license, the pharmacist shall:

(1) File a renewal application;

(2) Pay any applicable fees; and

(3) Earn continuing pharmaceutical education (CE) credits required by this chapter.

C. CE Requirements.

(1) A pharmacist licensed to practice in Maryland applying for renewal shall:

(a) Earn 30 hours of approved CE within the 2-year period immediately preceding the license expiration date that include:

(i) 1 hour on the topic of preventing medication errors; and

(ii) 2 hours of CE obtained through live instruction;

(b) Attest to the fact that the pharmacist has completed the CE requirement on a Board approved form; and

(c) Retain supporting documents for inspection by the Board for 4 years after the date of renewal for which the CE credits were used.

(2) A pharmacist certified to administer vaccinations in Maryland applying for renewal shall:

(a) As part of the 30 hours of approved CE requirement, complete 4 hours of CE credits related to vaccinations; or

(b) If registered to administer vaccines before October 1, 2008 for the first renewal of the registration after that date, demonstrate that 4 CE credits taken include education about the herpes zoster and pneumococcal pneumonia vaccines.

COMAR **10**. **34**.18.03, MD ADC **10**. **34**.18.03

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.18.04

C

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 18 Continuing Education for Pharmacists (Refs & Annos)
.04 Requirements for Pharmacists Not Practicing in Maryland.

A licensed pharmacist not practicing in Maryland shall fulfill the continuing education requirements of Maryland.

COMAR **10**. **34**.18.04, MD ADC **10**. **34**.18.04

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

END OF DOCUMENT

MD Health & Men. **10**. **34**.18.05

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
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Chapter 18 Continuing Education for Pharmacists (Refs & Annos)
.05 Requirements for Pharmacists who are Authorized Prescribers.

A pharmacist who is also an authorized prescriber licensed by a board (in Maryland or another state) may use the continuing education (CE) credits applied toward that board toward the Board of Pharmacy's CE requirements.

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.06 Accredited Continuing Education Programs.

A. The Board and the following providers are approved for any programs they offer which otherwise qualify for continuing education (CE) credit:

(1) American Council on Pharmaceutical Education (ACPE);

(2) Schools of pharmacy accredited by ACPE;

(3) Food and Drug Administration (FDA);

(4) Drug Enforcement Administration (DEA); and

(5) Additional providers of programs approved by the Board.

B. Procedures for Approval of Additional Programs.

(1) An additional provider shall request approval for an individual program by submitting a Board application at least 60 days before the date of offering of their individual program.

(2) An approval request shall fulfill the program requirements set forth in Health Occupations Article, §12-309(g), Annotated Code of Maryland.

(3) An approval request shall include a description of course work including:

(a) Measurable learning objectives;

(b) A course outline; and

(c) Self-assessment questions.

(4) The Board's decision to approve or disapprove a program is final.

C. Record Keeping for Providers of Approved Programs.

(1) Providers of approved programs shall maintain program records for 3 years from the date of presentation of the program.

(2) Providers of approved programs of CE shall furnish a certificate of completion to participants who qualify. The provider shall include the:

(a) Name of the participant;

(b) Name of the provider;

(c) Title of the course;

(d) Number of CE hours;

(e) Date of completion; and

(f) A program identification number or provider number on the certificate.

D. The Board may rescind approval of a CE program if it determines that the program no longer meets the requirements of Health Occupations Article, §12-309, Annotated Code of Maryland.

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.07 Acceptance of Previously Unapproved Continuing Education Programs.

A. A pharmacist who completes a program of continuing education that is not previously approved by the Board may request in writing that the Board approve the program for credit.

B. The pharmacist making a request for Board approval under §A of this regulation shall make the request at least 90 days before licensed expiration.

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.08 Miscellaneous.

A. Credits may not be carried over from one licensing renewal period to another.

B. Falsifying continuing education CE records is grounds for disciplinary action.

C. The pharmacist shall use a Board approved form to supply the pharmacist's CE information to the Board.

D. CE requirements imposed by the Board upon a pharmacist as part of an informal action, consent order, or final order, as defined in COMAR **10**. **34**.01.02, shall be in addition to the requirements of this chapter.

E. Pharmacists may receive 2 CE credits for attending a public Board meeting in its entirety.

(1) The Board shall issue a certificate of proof of attendance at a public Board meeting.

(2) A pharmacist may not earn more than 4 CE credits per renewal period for attendance of a public Board meeting.

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Chapter 19 Sterile Pharmaceutical Compounding (Refs & Annos)
.01 Scope.

This chapter applies to a licensed pharmacy in Maryland engaging in:

A. Compounding or mixing sterile prescription solutions or suspensions to be administered parenterally or by irrigation, inhalation, or intraocular routes; and

B. Compounding of radiopharmaceuticals, except where U.S. Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding-Sterile Preparations addresses radiopharmaceuticals, U.S. Pharmacopeia (USP) Chapter 821 Radioactivity, and U.S. Pharmacopeia (USP) Chapter 823 Radiopharmaceuticals for Positron Emission Tomography-Compounding would apply.

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.02 Incorporation by Reference.

In this chapter, the following documents are incorporated by reference:

A. U.S. Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding-Sterile Preparations (USP 797 Standards), which has been incorporated by reference in 21 U.S.C. §351(b) (as amended).

B. U.S. Pharmacopeia (USP) General Chapter 795 Pharmaceutical Compounding-Non-Sterile Preparations (USP 795 Standards), which has been incorporated by reference in 21 U.S.C. §351(b) (as amended).

C. U.S. Pharmacopeia (USP) Chapter 821 Radioactivity, which has been incorporated by reference in 21 U.S.C. §351(b) (as amended).

D. U.S. Pharmacopeia (USP) Chapter 823 Radiopharmaceuticals for Positron Emission Tomography-Compounding, which has been incorporated by reference in 21 U.S.C. §351(b) (as amended).

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.03 Definitions.

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

B. Terms Defined.

(1) “Antineoplastic” means an agent that prevents the development, growth, or proliferation of malignant cells.

(2) “Anteroom” means the area, room, or rooms where personnel perform hand hygiene and garbing immediately adjacent to the designated clean room where the compounding of sterile preparations is performed.

(3) Batch.

(a) “Batch” means a preparation compounded in advance of receipt of a prescription, or a preparation compounded in a supply that will be used on more than one dispensing to a patient or patients or any preparation compounded in excess of the filling of an individual prescription.

(b) “Batch” includes a limited quantity of identical preparations compounded in a single, discrete process, by the same individuals, carried out during one limited time period.

(4) “Biological safety cabinet” means a containment unit:

(a) Suitable for work involving agents that pose higher risk of exposure to operators during compounding; and

(b) Used when there is a need for protection of the preparation, personnel, and environment.

(5) “Clean room” means an International Standards Organization (ISO) Class 7 environment that meets USP 797 Standards, inside which compounding occurs within an ISO Class 5 engineering control device such as

a laminar airflow workstation or a biological safety cabinet.

(5-1) “Closed system vial transfer device (CSTD)” means a closed system drug transfer device that mechanically, not by means of vents or filters, prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug aerosols or vapors into the environment.

(6) “Compounded sterile preparation” means sterile medication preparations, such as intravenous, epidural, and intraocular medications, compounded in the pharmacy using currently accepted aseptic compounding techniques under acceptable compounding conditions.

(7) “Compounding aseptic isolator” means an enclosed positive or negative pressure environment especially designed for sterile preparation compounding that maintains a physical barrier between the workspace and the operator.

(8) “Controlled environment” means a designated area for compounding sterile preparations that consists of a clean room and an anteroom.

(9) “Cytotoxic” means drug entities that are damaging or debilitating to cells, tissues, or organs.

(10) “Laminar air flow workstation” means an ISO Class 5 (“Class 100”) laminar airflow hood inside which sterile compounding occurs.

(11) “Media fill verification” means a process of practical examination to verify the aseptic technique of personnel or an aseptic process by manual manipulation of microbiological growth media which simulates compounding processes and techniques used in actual compounding procedures.

(12) “Parenteral” means routes of drug administration or fluid administration other than via the gastrointestinal tract.

(13) “Pharmacist” means an individual who is licensed to practice pharmacy regardless of the location where the activities of practice are performed.

(14) “Pharmacy” means an establishment in which prescription or nonprescription drugs or devices are compounded, dispensed, or distributed.

(15) “Pyrogen testing” means an analysis of sterile preparations for the presence of cell material from microbiological organisms in sufficient quantity to elicit a febrile reaction.

(16) “Sterile” means free from living microorganisms or any other contaminants.

(17) “Total parenteral nutrition” means providing caloric needs by the parenteral route for a patient who is unable to ingest sufficient calories.

(18) “USP 795 Standards” means standards set forth in the US Pharmacopeia (USP) General Chapter 795 Pharmaceutical Compounding-Non-Sterile Preparations.

(19) “USP 797 Standards” means standards set forth in the U.S. Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding-Sterile Preparations.

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.04 Pharmacy Environment.

The compounding, preparation, and dispensing of compounded sterile preparations shall be accomplished in a pharmacy environment subject to State and federal laws, regulations, and standards.

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.05 General Requirements.

A licensed pharmacist who has appropriate practical and didactic training in compounding sterile preparations, clean room technology, laminar flow technology, quality assurance techniques, and clinical application of intravenous drug therapy shall control and supervise the section of the pharmacy that prepares compounded sterile preparations and is responsible for, at a minimum, the following:

A. Preparation of compounded sterile preparations within the pharmacy or pharmacy satellite;

B. Storage of materials pertinent to the preparation of compounded sterile preparations, including drugs, chemicals, and biologicals, and the establishment of specifications for procurement of the materials;

C. Labeling of containers of compounded sterile preparations compounded within the pharmacy;

D. Recording of transactions of the pharmacy as may be applicable to State and federal laws and regulations, as may be necessary to maintain accurate control over, and accountability for, pharmaceutical materials; and

E. Ensuring that licensed pharmacists meeting the requirements of §A of this regulation, or registered pharmacy technicians under direct supervision of a licensed pharmacist meeting the requirements of §A of this regulation, prepare, compound, and dispense compounded sterile preparations.

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.06 Special Handling, Packaging, Labeling, and Beyond Use Dating.

A. The pharmacy shall make available special handling and packaging materials to maintain container integrity and drug stability of the prepared prescription orders, including antineoplastic or other hazardous sterile preparations, during delivery to the patient including:

(1) A reasonable effort to provide tamper-evident packaging if appropriate to setting;

(2) Delivery from the pharmacy to the patient within a reasonable time; and

(3) Proper in-transit storage consistent with preparation labeling.

B. The dispensed container for any compounded sterile preparation shall include labeling according to Maryland law and regulations, in addition to the following information that is required by federal law:

(1) The date of preparation unless otherwise readily retrievable from prescription records;

(2) Time prepared, if applicable;

(3) The pertinent requirements for proper storage;

(4) The name of the prescriber, unless in an inpatient hospital setting;

(5) The name of the patient;

(6) Directions for use;

(7) The name of the base solution for infusion preparations;

(8) The name and concentration or amount of active drugs contained in the final sterile preparation;

(9) The name or identifying initials of the pharmacist who checked or prepared the compounded sterile preparation unless otherwise readily retrievable from prescription records;

(10) The name, address, and telephone number of the pharmacy unless in an inpatient hospital facility;

(11) The beyond-use/expiration dating and time of the compounded sterile preparation, and if no time is stated, the time is presumed to be at 11:59 p.m. of the stated beyond use date;

(12) Any ancillary and cautionary instructions as needed; and

(13) A pertinent warning consistent with applicable federal and State law that cytotoxic preparations are biohazardous, when applicable.

C. A pharmacy compounding sterile infusion preparations shall provide a 24-hour telephone number to allow its patients or other health care providers who may be administering its prescriptions to contact its pharmacists.

D. Expiration or Beyond-Use Dating. In the absence of direct testing evidence, as detailed in the Stability Criteria and Beyond Use Dating section of USP 795 Standards, the pharmacist shall use “beyond-use dating” as determined by USP 797 Standards and reference materials as cited in Regulation .16 of this chapter.

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.07 Record-Keeping Requirements.

A. Patient Prescription Records.

(1) The pharmacy shall maintain records of patient prescriptions.

(2) Patient prescription records shall contain:

(a) Available medical information consistent with prevailing pharmacy standards; and

(b) The complete record of the formulations of the solutions that were compounded.

(3) The pharmacy shall keep completed patient prescription records in a retrievable manner for at least 5 years.

B. Compounded Sterile Preparations Records.

(1) For a pharmacy preparing compounded sterile preparations, the following records shall be maintained for at least 5 years:

(a) The training and competency evaluation of employees in sterile preparation procedures;

(b) Refrigerator and freezer temperatures;

(c) Certification of the sterile compounding environment, including ISO 5 workstations and the clean and anterooms;

(d) Other facility quality control logs specific to the pharmacy's policies and procedures, for example, cleaning logs for facilities and equipment;

(e) Records documenting inspection for expired or recalled pharmaceutical preparations or raw ingredients;

(f) Preparation records including compounding work sheets, and records of the registered pharmacy technicians' checking/sign-off process; and

(g) Preparation records including compounding work sheets and records of the pharmacists' checking/ sign-off process.

(2) In addition to the records requirement in §B(1) of this regulation, for batch compounded sterile preparations, a pharmacy compounding sterile batch preparations for future use shall have records indicating the:

(a) Drug and ingredient names;

(b) Lot numbers;

(c) Expiration dates;

(d) Drug/diluent amounts; and

(e) Date on which the compounded sterile batch preparations were prepared.

(3) A pharmacy shall maintain records of media fill verification results for 5 years.

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.08 Batch Preparation.

A. A pharmacist may prepare batched sterile preparations for future use in limited quantities supported by prior valid prescriptions or physician orders before receiving a valid written prescription or medication order.

B. Batch preparation of specific compounded sterile preparations is acceptable if the:

(1) Pharmacist can document a history of valid prescriptions or physician orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship; and

(2) Pharmacy maintains the prescription on file for such preparations dispensed.

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.09 Minimum Facility Requirements.

A. Controlled Environment.

(1) The pharmacy shall have a controlled environment.

(2) A pharmacist shall ensure that the controlled environment is:

(a) Accessible only to designated personnel; and

(b) Used only for the preparation of compounded sterile preparations, or such other tasks that require a controlled environment.

(3) The permit holder shall ensure that the controlled environment is:

(a) Structurally isolated from other areas within the pharmacy by means of restricted entry or access; and

(b) Air conditioned to maintain a temperature of the controlled environment according to USP 797 standards.

B. Controlled Environment-Clean Room. The permit holder shall ensure that the clean room in the controlled environment:

(1) Meets USP 797 Standards for design and USP 797 performance criteria quality standards for clean rooms;

(2) Contains no sinks or floor drains;

(3) Contains work surfaces constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that the work surfaces may be readily cleaned and sanitized;

(4) If cytotoxic agents are routinely used in compounding preparations, contains room or rooms equipped with special pressurization requirements consistent with USP 797 Standards and the National Institute for Occupational Safety and Health (NIOSH) standards;

(5) Has in place appropriate environmental engineering control devices capable of maintaining USP 797 air-quality standards during normal compounding activity; and

(6) Contains the following equipment:

(a) A laminar airflow workstation or other suitable International Standards Organization (ISO) Class 5 compounding environment;

(b) Waste containers that are approved by Occupational Safety and Health Administration (OSHA) for used needles and syringes, and for chemotherapy waste; and

(c) Ancillary supplies required for proper compounding.

C. Controlled Environment-Anteroom. The permit holder shall ensure that the anteroom in the controlled environment:

(1) Meets USP 797 Standards for design and USP 797 performance criteria quality standards for anterooms; and

(2) Contains the following equipment:

(a) A sink with hot and cold running water;

(b) Waste containers for personal protective equipment;

(c) An eyewash station or sink design suitable for flushing an eye injury; and

(d) A hazardous waste spill kit, if applicable.

D. The requirements specified in §§B(1) and C(1) of this regulation are not applicable if a compounding aseptic isolator is used to compound sterile preparations in accordance with the:

(1) Compounding aseptic isolator conditions set forth in USP 797 Standards; and

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(2) Isolator vendor or manufacturer specifications.

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.10 Minimum Requirements for Equipment.

A. The permit holder shall provide at least the following equipment that is maintained in working order:

(1) Adequate refrigerator and freezer space (if applicable);

(2) A sink and wash area in the anteroom;

(3) Appropriate waste containers for:

(a) Used needles and syringes; and

(b) Cytotoxic waste including disposable apparel used in its preparation, if applicable;

(4) Laminar air flow workstation or compounding aseptic isolator that meets USP 797 Standards, dedicated for products other than antineoplastics;

(5) If applicable to types of preparations compounded, biological safety cabinet, or compounding aseptic isolator that meets USP 797 Standards, dedicated for use with antineoplastics or other hazardous sterile preparations;

(6) Appropriate filters and filtration equipment; and

(7) A device for light/dark field examination.

B. If used, the permit holder shall provide the following equipment that is maintained in working order, calibrated, or certified where appropriate:

(1) Autoclave;

(2) Automated compounding devices (for example, total parenteral nutrition compounding pumps);

(3) Electronic balance;

(4) Convection oven;

(5) Thermometers or other temperature device; and

(6) Incubator.

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.11 Minimum Requirements for Supplies.

A pharmacy engaging in compounding sterile preparations shall maintain adequate stock levels of the following supplies according to USP 797 Standards, including but not limited to:

A. Personal protective equipment:

(1) Sterile gloves;

(2) Masks;

(3) Non-shedding gowns;

(4) Shoe covers;

(5) Hair covers;

(6) Beard covers; and

(7) Other personal protective equipment;

B. Disposable syringes and needles in necessary sizes;

C. Disinfectant cleaning agents as specified in USP 797 Standards, including 70 percent sterile isopropyl alcohol;

D. Disposable lint free towels;

E. Hand washing materials, including antimicrobial skin cleanser;

F. Adequate equipment and materials for antineoplastic or cytotoxic agent spills;

G. Supplies necessary for the aseptic preparation of compounded sterile preparations; and

H. Closed system vial transfer devices (CSTD), as required for cytotoxic compounding, if applicable.

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.12 Minimum Requirements for Policies and Procedures.

A. The permit holder shall ensure that the pharmacist or the pharmacist's designee shall maintain a policy and procedure manual, reviewed annually, that sets forth in detail the permit holder's standard operating procedures with regard to compounding sterile preparations.

B. The permit holder shall insure that the policy and procedure manual that sets forth the standard operating procedures with regard to compounding sterile preparations is implemented and adhered to.

C. The policy and procedure manual shall include policies and procedures governing the following:

(1) A risk-management program which includes documentation of outcomes including, but not limited to:

(a) An incident reporting system;

(b) An adverse drug reaction reporting system; and

(c) A preparation contamination reporting system;

(2) Security measures ensuring that the premises where sterile compounded preparations are stored and prepared are secured, to prevent access by unauthorized personnel;

(3) Equipment including, but not limited to:

(a) Procedures for use;

(b) Documentation of appropriate certifications; and

(c) Documentation of appropriate calibration and preventive maintenance if applicable;

(4) Sanitation standards and procedures including monitoring for bacterial microorganisms to demonstrate effectiveness of cleaning activities;

(5) Reference materials as set forth in Regulation .16 of this chapter;

(6) Information concerning drug:

(a) Preparation;

(b) Storage and handling;

(c) Dispensing;

(d) Labeling;

(e) Beyond-use/expiration dating;

(f) Delivery;

(g) Destruction;

(h) Recalls; and

(i) Returns;

(7) Patient record keeping as set forth in Regulation .07 of this chapter;

(8) Handling, dispensing, and documentation of investigational drugs;

(9) A quality assurance program;

(10) Verification of training and competency guidelines;

(11) Compounding process media fill verification procedures;

(12) Description of appropriate garb;

(13) Conduct guidelines for personnel in the controlled areas;

(14) Personnel responsibilities;

(15) Patient education, if appropriate;

(16) Protocol and procedures to maintain the integrity of the interior work area of the laminar air flow workstations;

(17) Written procedures as applicable for handling antineoplastic agents and other hazardous substances including:

(a) Utilizing the proper equipment and supplies;

(b) A statement that compounding shall be conducted within a properly certified biological safety cabinet or negative pressure compounding aseptic isolator;

(c) Proper use of protective attire; and

(d) Proper techniques to prevent both contamination of the preparation and chemical exposure of the individual preparing the prescription;

(18) Written procedures as applicable for the disposal of infectious materials or materials containing cytotoxic residues, or hazardous waste;

(19) Written documentation of policy and procedure changes based on data gathered from quality assurance evaluations; and

(20) Written documentation of policies and procedures assuring the sterility and stability of compounded sterile preparations.

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.13 Attire.

A. When compounding sterile preparations, individuals shall comply with the following standards:

(1) Sequencing of garbing that complies with USP 797 Standards;

(2) Thorough hand-washing before gowning;

(3) Wearing clean room garb inside the designated area at all times, which consists of:

(a) A non-shedding coverall or gown;

(b) Head and facial hair covers;

(c) A face mask; and

(d) Shoe covers;

(4) Clean room garb, with the exception of sterile gloves, shall be donned and removed outside the designated clean room area;

(5) All jewelry shall be removed;

(6) Sterile gloves are required; and

(7) Make-up may not be worn in the clean room.

B. The requirements of this regulation are not applicable if a compounding aseptic isolator is used to compound sterile preparations in accordance with USP 797 Standards and isolator vendor/manufacturer specifications.

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.14 Training of Staff, Patient, and Caregiver.

A. The pharmacist shall make counseling available to the patient or primary caregiver, or both, concerning proper use of compounded sterile preparations and related supplies furnished by the pharmacy.

B. The permit holder shall ensure that pharmacy personnel engaging in compounding sterile preparations are trained and demonstrate competence in the safe handling and compounding of compounded sterile preparations and parenteral solutions, including cytotoxic agents if applicable.

C. The permit holder shall maintain records of training and demonstrated competence for individual employees for 5 years.

D. The permit holder shall ensure the continuing competence of pharmacy personnel engaged in compounding sterile preparations.

E. A pharmacy that compounds sterile preparations shall comply with the following training requirements:

(1) The pharmacy shall establish and follow a written program of training and performance evaluation designed to ensure that individuals working in the designated area have the knowledge and skills necessary to perform the assigned tasks properly and include at least the following:

(a) Aseptic technique with media fill verification at a frequency defined by risk level as described in USP 797 Standards:

(i) 12 months for low and medium risk; and

(ii) 6 months for high risk;

(b) Pharmaceutical calculations and terminology;

(c) Compounding sterile preparation documentation process;

(d) Quality assurance procedures;

(e) Aseptic preparation procedures;

(f) Proper cleansing, gowning, and gloving techniques;

(g) General conduct in the controlled area;

(h) Cleaning, sanitizing, and maintaining equipment used in the controlled area;

(i) Sterilization techniques for high risk preparations; and

(j) Container, equipment, and closure system selection.

(2) Individuals assigned to the controlled area shall successfully complete practical skills training in aseptic technique and aseptic area practices.

(3) Evaluations shall include:

(a) Written testing;

(b) Observation for adherence to aseptic technique and aseptic area policies and procedures; and

(c) Media fill verification as set forth in §E(1)(a) of this regulation.

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.15 Quality Assurance.

The permit holder shall ensure that the compounded sterile preparation retains its potency and sterility throughout the assigned "beyond use" dating period through a written quality assurance program that includes:

A. A reasonable effort by the pharmacist to assure that compounded sterile preparations shall be kept under appropriate controlled conditions before dispensing, during transport, and at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration, as set forth by the product manufacturer and established standards and literature, with each compounded sterile preparation dispensed;

B. The phases of compounded sterile preparation, distribution, storage, administration, and directions for use for each type of preparation dispensed;

C. Environmental sampling for microbial organisms in laminar air flow workstations and clean rooms is performed according to methods and schedules specified by USP 797 Standards and if microbial contamination is suspected, for example, in the event of positive media fill verification results;

D. Laminar air flow workstations, biological safety cabinets, and compounding aseptic isolators certified by a trained and qualified operator;

E. Clean room and anteroom certification by a trained and qualified operator according to USP 797 Standards;

F. The proper disposal in accordance with accepted professional standards and applicable State and federal laws of unused drugs and materials used in the preparation of compounded sterile preparations, including antineoplastic agents and hazardous materials;

G. A formal written review process to report and evaluate compliance with this chapter; and

H. A process that complies with applicable USP 797 Standards for performing sterility checks or pyrogen testing, or both, for applicable compounded sterile preparations.

MD Health & Men. **10**. **34**.19.15

COMAR **10**. **34**.19.15, MD ADC **10**. **34**.19.15

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MD Health & Men. **10**. **34**.19.16

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 19 Sterile Pharmaceutical Compounding (Refs & Annos)
.16 Reference Library.

Minimum reference materials in a pharmacy shall include:

A. U.S. Pharmaceutical, General Chapter 797, Pharmaceutical Compounding-Sterile Preparations and other applicable reference materials in order to perform sterile compounding;

B. Reference materials containing drug stability and compatibility data; and

C. Reference materials concerning drug interactions and incompatibility.

COMAR **10**. **34**.19.16, MD ADC **10**. **34**.19.16

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.20.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 20 Format of Prescription Transmission (Refs & Annos)
.01 Scope.

This chapter applies to the conveyance or transmission of prescription orders from authorized prescribers to pharmacies in the State.

COMAR **10**. **34**.20.01, MD ADC **10**. **34**.20.01

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 20 Format of Prescription Transmission (Refs & Annos)

.02 Requirements for Prescription Validity.

A. A valid prescription shall be:

(1) Valid in the professional judgment of the pharmacist responsible for filling the prescription; and

(2) Conveyed:

(a) In a manner that contains the handwritten, pen-to-paper signature of the prescriber;

(b) In a manner that is transmitted to the pharmacy electronically, provided that the prescription is:

(i) Transmitted via electronic intermediaries that are certified by the Maryland Health Care Commission;

(ii) Received by the permit holder's computer, facsimile machine, or other electronic device; and

(iii) Maintained by the permit holder in accordance with Regulation .03 of this chapter; or

(c) In an oral manner where:

(i) Only a pharmacist may take an original oral prescription by a voice messaging system or by phone with the pharmacist reading back the prescription to the prescriber or the prescriber's agent; and

(ii) The pharmacist promptly reduces the oral prescription to writing.

B. The requirement of §A(2)(b)(i) of this regulation does not apply to prescriptions transmitted electronically within:

(1) A closed system of a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland; or

(2) Any other closed system that does not utilize an intermediary for transmission of prescriptions.

COMAR **10**. **34**.20.02, MD ADC **10**. **34**.20.02

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MD Health & Men. **10**. **34**.20.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 20 Format of Prescription Transmission (Refs & Annos)
.03 Prescription Records.

The pharmacy permit holder shall maintain prescription records in a form that:

A. Is readily and accurately retrievable;

B. Is maintained for at least 5 years from the date of dispensing; and

C. Protects the confidentiality and security of the prescription information.

COMAR **10**. **34**.20.03, MD ADC **10**. **34**.20.03

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.20.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 20 Format of Prescription Transmission (Refs & Annos)
.04 Controlled Dangerous Substances.

Transmission and dispensing of controlled dangerous substances shall be in accordance with applicable State and federal statutes and regulations.

COMAR **10**. **34**.20.04, MD ADC **10**. **34**.20.04

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.21.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 21 Standard of Practice for Unlicensed Personnel (Refs & Annos)
.01 Scope.

This chapter establishes standards of practice and the responsibilities of licensed pharmacists and pharmacy permit holders when using unlicensed personnel in the prescription area of a pharmacy.

COMAR **10**. **34**.21.01, MD ADC **10**. **34**.21.01

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 21 Standard of Practice for Unlicensed Personnel (Refs & Annos)
.02 Definitions.

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

B. Terms Defined.

(1) “Board” means the State Board of Pharmacy.

(2) “Operational support” means tasks performed by:

(a) An administrative clerk;

(b) A billing clerk;

(c) A cashier;

(d) Delivery personnel;

(e) A file clerk;

(f) An inventory control clerk; or

(g) An individual engaged in janitorial services.

(3) “Permit holder” means a person or corporation or other legal entity holding a permit issued by the Board to establish and operate a pharmacy.

(4) “Pharmacy” means an establishment holding a permit under Health Occupations Article, §12-401, Annotated Code of Maryland.

(5) “Prescription area” means that portion of an establishment to which a pharmacy permit has been issued, which contains:

(a) Prescription drugs;

(b) Prescription devices; and

(c) Patient records.

(6) “Supervision” means the on-site provision of management, direction, oversight, and review of tasks assigned to personnel.

(7) “Unlicensed personnel” means individuals employed by the permit holder who provide operational support in the prescription area under the supervision of a licensed pharmacist.

COMAR **10**. **34**.21.02, MD ADC **10**. **34**.21.02

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MD Health & Men. **10**. **34**.21.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 21 Standard of Practice for Unlicensed Personnel (Refs & Annos)
.03 Duties of the Permit Holder.

The permit holder shall:

A. Determine which operational support tasks the pharmacist may assign unlicensed personnel to perform in the prescription area;

B. Ensure that unlicensed personnel:

(1) Receive appropriate training for the tasks that the pharmacist assigns unlicensed personnel to perform in the prescription area;

(2) Receive training that will enable unlicensed personnel to understand how the provisions of Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland, apply to:

(a) Prescription records, and

(b) The requirements for confidentiality of patient specific information; and

(3) When performing tasks in the prescription area, maintain proper:

(a) Sanitation;

(b) Hygiene;

(c) Biohazard precautions; and

(d) Infection control; and

C. Ensure that unlicensed personnel are clearly identified to the consumer.

MD Health & Men. **10**. **34**.21.03

COMAR **10**. **34**.21.03, MD ADC **10**. **34**.21.03

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MD Health & Men. **10**. **34**.21.04

C

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 21 Standard of Practice for Unlicensed Personnel (Refs & Annos)
.04 Duties of the Pharmacist.

A. The pharmacist shall provide supervision to unlicensed personnel.

B. The pharmacist may not delegate any pharmacy acts to unlicensed personnel.

COMAR **10**. **34**.21.04, MD ADC **10**. **34**.21.04

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.21.05

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 21 Standard of Practice for Unlicensed Personnel (Refs & Annos)
.05 Duties of Unlicensed Personnel.

A. Unlicensed personnel under the supervision of a pharmacist may perform operational support which the unlicensed personnel have been trained to adequately perform in the prescription area.

B. Unlicensed personnel who perform duties in the prescription area shall maintain the confidentiality of patient specific data in accordance with Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland.

COMAR **10**. **34**.21.05, MD ADC **10**. **34**.21.05

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MD Health & Men. **10**. **34**.21.06

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 21 Standard of Practice for Unlicensed Personnel (Refs & Annos)
.06 Grounds for Discipline.

A. A pharmacist licensee may be subject to discipline if the pharmacist licensee violates any provision of Regulation .04 of this chapter.

B. A permit holder may be subject to disciplinary action if:

(1) The permit holder fails to take reasonable safeguards to ensure compliance with the regulations of the Board; or

(2) The permit holder otherwise violates any of the provisions of Regulation .03 of this chapter.

COMAR **10**. **34**.21.06, MD ADC **10**. **34**.21.06

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MD Health & Men. **10**. **34**.22.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 22 Licensing of Wholesale Prescription Drug or Device Distributors (Refs & Annos)
.01 Scope.

This chapter applies to any person engaged in the wholesale distribution of prescription drugs or devices in Maryland.

COMAR **10**. **34**.22.01, MD ADC **10**. **34**.22.01

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MD Health & Men. **10**. **34**.22.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 22 Licensing of Wholesale Prescription Drug or Device Distributors (Refs & Annos)
.02 Definitions.

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

B. Terms Defined.

(1) “Authenticate” means to affirmatively verify, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree for the prescription drug has occurred.

(2) “Authorized distributor of record” means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug.

(3) “Blood” means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(4) “Blood component” means that part of blood separated by physical or mechanical means.

(5) “Board” means the State Board of Pharmacy.

(6) “Co-licensed partner” means a person in a relationship in which two or more persons have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the U.S. Food and Drug Administration's implementation of the Federal Prescription Drug Marketing Act.

(7) “DEA” means the U. S. Drug Enforcement Administration.

(8) “Designated representative” means an individual who:

(a) Is designated by the wholesale distributor;

(b) Serves as the primary contact of the wholesale distributor with the Board; and

(c) Is actively involved in, and aware of, the daily operation of the wholesale distributor.

(9) “Drop shipment” means the sale of a prescription drug:

(a) To a wholesale distributor by:

(i) The manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third-party logistics provider, or manufacturer's exclusive distributor; and

(b) Through which:

(i) The wholesale distributor or a pharmacy warehouse takes title to, but not physical possession of, the prescription drug;

(ii) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the prescription drug to a patient; and

(iii) The pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor.

(10) “FDA” means the U. S. Food and Drug Administration.

(11) “Gross receipts” means gross receipts from sales of prescription drugs and devices in the State.

(12) Health Care Entity.

(a) “Health care entity” means a person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care.

(b) “Health care entity” does not include a community pharmacy or a wholesale distributor.

(c) “Health care entity” may not simultaneously be a health care entity and a community pharmacy or wholesale distributor.

(13) “Manufacturer” means a person licensed or approved by the U.S. Food and Drug Administration to engage in the manufacture of prescription drugs or prescription devices, consistent with the definition of “Manufacturer” under the U.S. Food and Drug Administration's regulations and guidelines implementing the Prescription Drug Marketing Act.

(14) “Manufacturer's exclusive distributor” means a person who:

(a) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; and

(b) Takes title to the manufacturer's prescription drug, but does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug.

(15) “Normal distribution channel” means a chain of custody for a prescription drug that, directly or by drop shipment, goes:

(a) From:

(i) A manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third-party logistics provider, or manufacturer's exclusive distributor; and

(b) To:

(i) A pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(ii) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iii) A wholesale distributor to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iv) A pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy, or other designated person authorized by law to dispense or administer the prescription drug to a patient; or

(v) An authorized distributor of record to another authorized distributor of record solely for distribution to an office-based health care practitioner authorized by law to dispense or administer the prescription drug to a patient.

(16) “Pedigree” means a document or electronic file containing information that records each wholesale distribution of a prescription drug.

(17) “Prescription device” means any device required by federal law or regulation to be dispensed only by a prescription.

(18) Prescription Drug.

(a) “Prescription drug” means any drug required by federal law or regulation to be dispensed only by a prescription.

(b) “Prescription drug” includes:

(i) A biological product; and

(ii) Finished dosage forms and bulk drug substances subject to §503(b) of the Federal Food, Drug and Cosmetic Act.

(c) “Prescription drug” does not include blood and blood components intended for transfusion or biological products that are also medical devices.

(19) Repackage.

(a) “Repackage” means to repackage or otherwise change the container, wrapper, or labeling of a prescription drug to further the distribution of the prescription drug.

(b) “Repackage” does not include changes to a container, wrapper, or labeling of a prescription drug completed by the pharmacist responsible for dispensing the prescription drug to a patient.

(20) “Repackager” means a person who repackages prescription drugs.

(21) “Third-party logistics provider” means a person who:

(a) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on

behalf of the manufacturer; and

(b) Does not take title to the prescription drug, or have general responsibility to direct the prescription drug's sale or disposition.

(22) Wholesale Distribution.

(a) “Wholesale distribution” means the distribution of prescription drugs or prescription devices to persons other than a consumer or patient.

(b) “Wholesale distribution” does not include:

(i) Intra-company sales;

(ii) The sale, purchase, distribution, trade, or transfer of a prescription drug or an offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons which include transfers of prescription drugs or devices by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(iii) The distribution of samples of a prescription drug by a manufacturer's representative;

(iv) Prescription drug returns conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR §203.23, as amended;

(v) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed health care practitioners for office use;

(vi) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug in accordance with a prescription;

(vii) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy to or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;

(viii) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record, if the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug, and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(ix) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; or

(x) The sale or transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, or to a third-party returns processor.

(23) Wholesale Distributor.

(a) “Wholesale distributor” means a person that is engaged in the wholesale distribution of prescription drugs or prescription devices.

(b) “Wholesale distributor” includes:

(i) A manufacturer;

(ii) A repackager;

(iii) An own-label distributor;

(iv) A private-label distributor;

(v) A jobber;

(vi) A broker;

(vii) A warehouse, including a manufacturer's or distributor's warehouse;

(viii) A manufacturer's exclusive distributor, or an authorized distributor of record;

(ix) A drug wholesaler or distributor;

(x) An independent wholesale drug trader;

(xi) A third-party logistics provider;

(xii) A retail pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5 percent of the retail pharmacy's annual sales; and

(xiii) A pharmacy warehouse that conducts wholesale distribution.

COMAR **10**. **34**.22.02, MD ADC **10**. **34**.22.02

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MD Health & Men. **10**. **34**.22.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 22 Licensing of Wholesale Prescription Drug or Device Distributors (Refs & Annos)

.03 Minimum Application Requirements for Applicant.

A. The Board shall require the following minimum information from a wholesale distributor as part of an application for a permit and as part of a renewal of a permit:

(1) The type of business form under which the applicant operates, such as partnership, corporation, or sole proprietorship;

(2) The full name or names of the owner and the operator of the wholesale distributor applying for or renewing a permit, including:

(a) For an individual, the:

(i) Full name of the individual;

(ii) Telephone number of the individual;

(iii) Business address of the individual; and

(iv) Date of birth of the individual;

(b) For a partnership, the:

(i) Full name of each partner;

(ii) Telephone number of the partnership;

(iii) Address of each partner;

(iv) Date of birth of each partner;

(v) Business address of the partnership; and

(vi) Federal employer identification number of the partnership;

(c) For a publicly traded corporation, the:

(i) Full name and title of each corporate officer and director;

(ii) Telephone number of the publicly traded corporation;

(iii) Business address of the corporation;

(iv) Federal employer identification number of the corporation;

(v) Name of parent company or companies if applicable;

(vi) Corporate names;

(vii) Name of the state of incorporation; and

(viii) Name and address of the resident agent of the corporation;

(d) For a nonpublicly traded corporation, the:

(i) Full name and title of each corporate officer and director;

(ii) The telephone number of the nonpublicly traded corporation;

(iii) Business address of the corporation;

(iv) Federal employer identification number of the corporation;

(v) Name of parent company or companies if applicable;

(vi) Corporate names;

(vii) Full name and business address of shareholders of more than 10 percent of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange;

(viii) Name of the state of incorporation; and

(ix) Name and address of the resident agent of the corporation;

(e) For a sole proprietorship, the:

(i) Full name of the sole proprietor;

(ii) The telephone number of the sole proprietor;

(iii) Full name of the business entity;

(iv) Business address; and

(v) Date of birth of the sole proprietor;

(f) For a limited liability company, the:

(i) Full name and business address of the limited liability company;

(ii) Telephone number of the limited liability company;

(iii) Full name of each member;

(iv) Full name of each manager;

(v) Federal employer identification number of the limited liability company;

(vi) Name of the state in which the limited liability company was organized; and

(vii) Name and address of the resident agent of the company;

(3) Addresses, telephone numbers, and the names of contact persons for the facility used by the applicant for

the storage, handling, and distribution of prescription drugs;

(4) All trade or business names used by the permit holder which may not be identical to the name used by another unrelated applicant in the State;

(5) A list of federal and state licenses, registrations, or permits, including the license, registration, or permit numbers issued to the wholesale distributor by federal authority or another state that authorizes the wholesale distributor to purchase, possess, and distribute prescription drugs or devices;

(6) A list of disciplinary actions by federal or state agencies against the wholesale distributor as well as any such actions against principals, owners, directors, or officers;

(7) For the designated representative and the immediate supervisor of the designated representative at the applicant's place of business the following information:

(a) Names;

(b) Places of residence for the past 7 years;

(c) Dates and places of birth;

(d) The name and address of each business where the individual was employed during the past 7 years, and the individual's job title or office held at each business;

(e) A statement of whether, during the past 7 years, the individual has been the subject of any proceeding for the revocation of any professional or business license or any criminal violation and, if so, the nature and disposition of the proceeding;

(f) A statement of whether, during the past 7 years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning the event;

(g) A description of any involvement, including any investments other than the ownership of stock in a publicly traded company or mutual fund, by the individual during the past 7 years, with any business that manufactures, administers, prescribes, distributes, or stores prescription drugs, and any lawsuits in which the business was named as a party;

(h) A description of any misdemeanor or felony offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of the guilt was withheld or whether the individual pled guilty or

nolo contendere;

(i) If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal, within 15 days after the disposition of the appeal, a copy of the final written order of disposition; and

(j) A photograph of the individual taken in the previous 180 days;

(8) A full description of the facility and warehouse including:

(a) Square footage;

(b) Security and alarm system descriptions;

(c) Terms of lease or ownership;

(d) Address; and

(e) Description of temperature and humidity controls;

(9) Written evidence that the wholesale distributor has obtained general and product liability insurance;

(10) A description of the wholesale distributor's import and export activities; and

(11) Other relevant information that the Board may require.

B. The Board shall require the following information from the designated representative and the immediate supervisor of the designated representative at the applicant's place of business as part of the initial application for a permit:

(1) Two complete sets of legible fingerprints taken on forms approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigation;

(2) The fee authorized under the Criminal Procedure Article, §10-221(b)(7), Annotated Code of Maryland, for access to State criminal history records; and

(3) The processing fee required by the Federal Bureau of Investigation for a national criminal history

records check.

C. The information required under §A of this regulation shall be provided under oath.

D. The Board may not issue an initial or renewal wholesale distributor permit to an applicant unless the Board or its designee:

(1) Conducts a physical inspection of the applicant's place of business, including any facility of the applicant;

(2) Finds that the place of business and facility, if any, meets the Board's requirements;

(3) Determines that the designated representative of the applicant meets the following qualifications:

(a) Is 21 years old or older;

(b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;

(c) Is employed by the applicant full time in a managerial level position;

(d) Is actively involved in, and aware of, the daily operation of the wholesale distributor;

(e) Is physically present, except for an authorized absence such as sick leave or vacation leave, at the facility of the applicant during regular business hours;

(f) Is serving as a designated representative for only one applicant at a time, or for two or more wholesale distributors who are located in the same facility and are members of an affiliated group, as defined in §1504 of the Internal Revenue Code;

(g) Does not have any convictions for a violation of any federal, State, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(h) Does not have any convictions for a felony under federal, State, or local laws; and

(4) Determines that the immediate supervisor of the designated representative of the applicant meets the following qualifications:

(a) Is 21 years old or older;

(b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;

(c) Is employed by the applicant full time in a managerial level position;

(d) Is actively involved in, and aware of, the daily operation of the wholesale distributor;

(e) Does not have any convictions for a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution, or distribution of controlled substances; and

(f) Does not have any convictions for a felony under federal, state, or local laws.

E. Surety Bond.

(1) An applicant for a wholesale distributor permit shall submit a surety bond or other equivalent means of security acceptable to the State such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the State Board of Pharmacy to be deposited into an account established by the State under Health Occupations Article, §12-6C-05(f)(7), Annotated Code of Maryland.

(2) The surety bond, or other security, shall be in the amount of:

(a) $100,000, if the annual gross receipts of the applicant for the previous tax year are $10,000,000 or more; or

(b) $50,000, if the annual gross receipts of the applicant for the previous tax year are less than $10,000,000.

(3) The applicant shall submit the following documentation to verify the applicant's annual gross receipts in the State are less than $10,000,000 for the previous tax year:

(a) A federal tax return, if the applicant's total annual gross receipts within or without the State are less than $10,000,000; or

(b) An annual sales report specifying the sales of prescription drugs and devices in the State audited by a certified public accountant, if the applicant's total annual gross receipts within or without the State are $10,000,000 or more.

(4) A surety bond is not required for a pharmacy warehouse that is not engaged in wholesale distribution.

(5) A single surety bond shall cover all facilities operated by the applicant in the State.

F. If a wholesale distributor distributes prescription drugs or prescription devices from more than one facility, the wholesale distributor shall obtain a permit for each facility.

G. The Board shall notify the applicant of the Board's acceptance or rejection of the application within 30 days after the date the Board receives a completed application, including the results of all required criminal history records checks.

H. The applicant shall pay to the Board an application fee set forth in COMAR **10**. **34**.09.02.

I. The wholesale distributor shall provide changes in information provided pursuant to Regulation .03 of this chapter to the Board within 30 days of the effective date of the change.

COMAR **10**. **34**.22.03, MD ADC **10**. **34**.22.03

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 22 Licensing of Wholesale Prescription Drug or Device Distributors (Refs & Annos)
.04 Personnel.

A. The permit holder shall affirm in the initial application and subsequent renewal applications that personnel employed in wholesale distribution have appropriate education and experience to assume responsibilities related to compliance with State licensing requirements.

B. Registered Agent.

(1) Each licensed wholesale distributor located outside of this State that wholesale distributes prescription drugs or devices in this State shall designate a registered agent in this State for service of process.

(2) If any wholesale distributor is not licensed in this State, service on the Director of the State Department of Assessments and Taxation only shall be sufficient service.

C. Requirements and Responsibilities of the Designated Representative.

(1) The designated representative shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor, including applicable State and federal laws.

(2) The designated representative shall have documented training sufficient to ensure that operations of the wholesale distributor are in compliance with applicable State and federal laws and are provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance with all applicable State and federal laws and regulations.

(3) The designated representative shall maintain current working knowledge of the requirements for wholesale distributor and assure ongoing training for personnel to ensure compliance.

(4) The designated representative shall be responsible for all record keeping requirements and make all records available for inspection.

COMAR **10**. **34**.22.04, MD ADC **10**. **34**.22.04

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.05 Violations and Penalties.

A. After a hearing held under Health Occupations Article, §12-601, Annotated Code of Maryland, the Board may deny, suspend, revoke, or place on probation a permit holder, reprimand a permit holder, or impose a fine if the permit holder:

(1) Is convicted of, or pleads guilty or nolo contendere to, violations of federal, State, or local drug or device laws or regulations;

(2) Is convicted of, or pleads guilty or nolo contendere to, a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;

(3) Commits any of the following acts:

(a) Obtains or attempts to obtain a permit by:

(i) Providing false information to the Board; or

(ii) Other fraudulent or deceptive means;

(b) Fails to:

(i) Establish or maintain inventories, records, or written policies and procedures as required by Regulation .07 of this chapter;

(ii) Register with the Maryland Division of Drug Control, and with the U.S. Drug Enforcement Agency, as required by Regulation .07D of this chapter; or

(iii) Permit the Board, the Maryland Division of Drug Control, the U.S. Drug Enforcement Agency, or other authorized federal, State, or local law enforcement officials showing proper identification, to enter, inspect, copy records, or audit as required by Regulation .07D of this chapter;

(c) Willfully makes or maintains false inventories or records;

(d) Violates a provision of, or regulation promulgated under, Health Occupations Article, Title 12, Annotated Code of Maryland;

(e) Manufactures, repackages, sells, delivers, or holds or offers for sale any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution or wholesale distribution;

(f) Adulterates, misbrands, or counterfeits prescription drugs or devices;

(g) Receives prescription drugs or devices that are adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, or delivers or proffers delivery of such prescription drug or device for pay or otherwise;

(h) Alters, mutilates, destroys, obliterates, or removes the whole or any part of the product labeling of a prescription drug or device, or commits any other act with respect to a prescription drug or device that results in the prescription drug or device being misbranded;

(i) Forges, counterfeits, simulates, or falsely represents prescription drugs or devices without the authority of the manufacturer, or uses any mark, stamp, tag, label, or other identification device without the authorization of the manufacturer;

(j) Purchases or receives a prescription drug or device from a person who is not licensed to wholesale distribute prescription drugs or devices to that purchaser or recipient;

(k) Sells or transfers a prescription drug or device to a person who is not legally authorized to receive a prescription drug or device;

(l) Provides the Board, its representatives, or federal or State officials with false or fraudulent records, or makes false or fraudulent statements regarding any matter within the provisions of these regulations;

(m) Wholesale distributes prescription drugs or devices that were:

(i) Purchased by a public or private hospital, or other health care entity;

(ii) Donated or supplied at a reduced price to a charitable organization;

(iii) Stolen or obtained by fraud or deceit; or

(iv) Donated to a drop-off site or repository under the Prescription Drug Repository Program set forth in Health-General Article, Title 15, Subtitle 6, Annotated Code of Maryland;

(n) Fails to obtain a license, or operates without a valid license when a license is required;

(o) Obtains, or attempts to obtain, a prescription drug or device by fraud, deceit, misrepresentation, or engages in misrepresentation or fraud in the distribution or wholesale distribution of a prescription drug or device;

(p) Distributes a prescription drug or device to the patient without a prescription or prescription order from a practitioner licensed by law to use or prescribe the prescription drug or device;

(q) Fails to obtain, authenticate, or pass on a pedigree when required under these regulations;

(r) Receives a prescription drug pursuant to a wholesale distribution without first receiving a pedigree, when required, that was attested to as accurate and complete by the wholesale distributor;

(s) Distributes or wholesale distributes a prescription drug or device that was previously dispensed by a pharmacy or distributed by a practitioner;

(t) Fails to report prohibited acts as listed in these regulations;

(u) Fails to exercise due diligence as provided in Regulation .08 of this chapter;

(v) Otherwise conducts the wholesale distribution of prescription drugs or devices in a manner not in accordance with the law;

(w) Accepts payment or credit for the sale of prescription drugs in violation of Health Occupations Article, §12-6C-09(d), Annotated Code of Maryland; or

(x) If the requirements of Health Occupations Article, §12-6C-09(a), Annotated Code of Maryland, are applicable and are not met, the purchasing or otherwise receiving a prescription drug from a pharmacy; or

(4) Is disciplined by a licensing or disciplinary authority of any state or country, or disciplined by a court of any state or country, for an act that would constitute a ground for Board action against a wholesale distributor permit holder under §A or B of this regulation.

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B. Acts prohibited under this regulation do not include a prescription drug manufacturer, or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

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.06 Minimum Requirements for the Storage and Handling of Prescription Drugs or Devices.

A. Facilities. Facilities at which prescription drugs or devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate:

(a) Cleaning;

(b) Maintenance; and

(c) Proper operations;

(2) Have storage areas designed to provide adequate:

(a) Equipment;

(b) Humidity control;

(c) Lighting;

(d) Sanitation;

(e) Security conditions;

(f) Space;

(g) Temperature; and

(h) Ventilation;

(3) Have a quarantine area for storage of prescription drugs or devices that are:

(a) Adulterated;

(b) Damaged;

(c) Deteriorated;

(d) In immediate or sealed secondary containers that have been opened;

(e) Misbranded; or

(f) Outdated;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin.

B. Security. A facility:

(1) Used for wholesale distribution shall be secure from unauthorized entry as follows:

(a) Access from outside the premises shall be:

(i) Kept to a minimum; and

(ii) Well controlled;

(b) The outside perimeter of the premises shall be well lit; and

(c) Entry into areas where prescription drugs or devices are held shall be limited to authorized personnel;

(2) Shall be equipped with:

(a) An alarm system to detect entry after hours;

(b) A security system that provides protection against theft and diversion;

(c) Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records;

(d) An inventory management and control system that protects against, detects, and documents any instances of theft, diversion, or counterfeiting;

(e) A security system to protect the integrity and confidentiality of data and documents;

(f) Video monitoring of all entrances and exits, or alternate acceptable security; and

(g) A means to make the data and documentation required under this section readily available to the Board, an agent of the Board, or federal and other State law enforcement officials.

C. Storage.

(1) A wholesale distributor shall store a prescription drug or device at appropriate temperatures and under appropriate conditions in accordance with requirements:

(a) If any, of the labeling of the drug or device; or

(b) Set forth in the current edition of an official compendium, such as the United States Pharmacopeia/ National Formulary (USP/NF), under 21 CFR §205.50(c), as amended.

(2) If no storage requirements are established for a prescription drug or device, the drug or device shall be held at a controlled room temperature, as defined in an official compendium as set forth in §C(1)(b) of this regulation to help assure that its identity, strength, quality, and purity are not adversely affected.

(3) A wholesale distributor shall use appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of prescription drugs or devices.

(4) A wholesale distributor shall follow the record-keeping requirements in Regulation .07 of this chapter for stored prescription drugs or devices.

D. Examination of Materials.

(1) Upon receipt, a wholesale distributor shall visually examine each outside shipping container for identity and to prevent the acceptance of:

(a) Contaminated prescription drugs or devices; or

(b) Prescription drugs or devices that are otherwise unfit for distribution.

(2) The examination required under §D(1) of this regulation shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(3) A wholesale distributor shall carefully inspect each outgoing shipment:

(a) For identity of the prescription drug or device product; and

(b) To ensure that there is no delivery of a prescription drug or device that has been damaged in storage or held under improper conditions.

(4) A wholesale distributor shall follow the record-keeping requirements in Regulation .07 of this chapter for incoming and outgoing prescription drugs or devices.

E. Returned, Damaged, and Outdated Prescription Drugs or Devices.

(1) A wholesale distributor shall quarantine and physically separate prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated from other prescription drugs or devices until the quarantined and separated drugs or devices are destroyed or returned to their supplier for proper disposal.

(2) The wholesale distributor shall identify, mark, quarantine, and physically separate from other prescription drugs or devices those prescription drugs or devices whose immediate or sealed outer or sealed secondary containers have been opened or used, until the drugs or devices are either destroyed or returned to their supplier for proper disposal.

(3) Prescription Drugs.

(a) If the conditions under which a prescription drug has been returned cast doubt on the prescription drug's safety, identity, strength, quality, or purity, then the wholesale distributor shall destroy or return the

prescription drug to the supplier, unless examination, testing, or other investigation proves that the prescription drug meets appropriate standards of safety, identity, strength, quality, and purity.

(b) In determining whether the conditions under which a prescription drug has been returned cast doubt on the prescription drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, at a minimum, the:

(i) Conditions under which the prescription drug has been held, stored, or shipped before or during its return; and

(ii) Condition of the prescription drug and its container, carton, or labeling, as a result of storage or shipping.

(4) Prescription Devices.

(a) If the conditions under which a prescription device has been returned cast doubt on the prescription device's safety, identity, or quality, then the wholesale distributor shall destroy or return the prescription device to the supplier, unless examination, testing, or other investigation proves that the prescription device meets appropriate standards of safety, identity, strength, and quality.

(b) In determining whether the conditions under which a prescription device has been returned cast doubt on the prescription device's safety, identity, or quality, the wholesale distributor shall consider, among other things, the:

(i) Conditions under which the prescription device has been held, stored, or shipped before or during its return; and

(ii) Condition of the prescription device and its container, carton, or labeling, as a result of storage or shipping.

(5) A wholesale distributor shall follow the record-keeping requirements in Regulation .07 of this chapter for outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs or devices.

COMAR **10**. **34**.22.06, MD ADC **10**. **34**.22.06

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.07 Minimum Requirements for Maintenance of Prescription Drug or Device Distribution Records.

A. Record Keeping.

(1) A wholesale distributor shall establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of prescription drugs or devices.

(2) The records required under §A(1) of this regulation shall include the following information:

(a) The source of the prescription drugs or devices, including the:

(i) Name and principal address of the seller or transferor; and

(ii) Address of the location from which the prescription drugs or devices were shipped;

(b) The identity and quantity of the prescription drugs or devices received and distributed or disposed of;

(c) The dates of receipt and distribution or other disposition of the prescription drugs or devices; and

(d) The pedigrees, if required by Health Occupations Article, §12-6C-10, Annotated Code of Maryland, for prescription drugs that are wholesale distributed outside the normal distribution channel.

(3) The wholesale distributor shall make available inventories and records for inspection and copying by authorized federal, State, or local law enforcement agency officials for a period of 3 years after their date of creation.

(4) The wholesale distributor shall keep the records described in this regulation readily available for inspection by authorized federal, State, or local law enforcement agency officials during the retention period, either:

(a) At the inspection site; or

(b) So as to be immediately retrievable by computer or other electronic means.

(5) Within 5 working days of a request by an authorized official of a federal, State, or local law enforcement agency, the wholesale distributor shall make available for inspection records kept at a central location apart from the inspection site and not electronically retrievable.

(6) Facilities shall establish and maintain procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting and contraband or suspected counterfeiting and contraband activities to the Board and the FDA.

(7) Wholesale distributors shall maintain a system for the mandatory reporting of significant inventory losses of prescription drugs and devices where it is known or suspected that diversion is occurring to the Board, the FDA, and, where applicable, to the DEA.

(8) Wholesale distributors shall consider the following factors when determining if there has been a significant inventory loss:

(a) The schedule of the missing items;

(b) The abuse or misuse potential of the missing items;

(c) The abuse or misuse potential in the wholesale distributor's area of the missing substance;

(d) The quantity missing in relation to the total quantity purchased (one tablet vs. one bottle or container);

(e) Whether this is the first time a potentially significant inventory loss has occurred;

(f) Whether this loss was reported to local law enforcement authorities; and

(g) Whether there is a significant resale value of the missing items.

B. Written Policies and Procedures.

(1) A wholesale distributor shall establish, maintain, and adhere to written policies and procedures which shall be followed for:

(a) The receipt, security, storage, inventory, and distribution of prescription drugs or devices;

(b) Identifying, recording, and reporting losses or thefts; and

(c) Correcting errors and inaccuracies in inventories.

(2) A wholesale distributor shall include in the written policies and procedures the following:

(a) A procedure by which the oldest approved and unexpired stock of a prescription drug or device is distributed first;

(b) Procedures to be followed for adequate handling of a recall and withdrawal of a prescription drug or device due to:

(i) An action initiated at the request of the United States Food and Drug Administration or other federal, State, or local law enforcement or other government agency, including the Maryland Division of Drug Control;

(ii) A voluntary action by the manufacturer to remove a defective or potentially defective drug or device from the market; and

(iii) An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(c) A procedure to ensure that the wholesale distributor is prepared for, protected against, and is able to handle a crisis that affects security or operation of a facility if any of the following situations occurs:

(i) Strike;

(ii) Fire;

(iii) Flood;

(iv) Catastrophic health emergency as defined in Public Safety Article, §14-3A-01, Annotated Code of Maryland;

(v) Terrorist activities;

(vi) Other natural disaster; or

(vii) Other situations of local, State, or national emergency;

(d) A procedure to ensure that an outdated prescription drug or device is segregated from other drugs or devices and either returned to the manufacturer or destroyed;

(e) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of 3 years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with applicable federal and State requirements; and

(f) A procedure for identifying, segregating, investigating, and reporting prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within 5 business days to the Board and appropriate federal or State agency upon discovery of such discrepancies.

(3) If deviation is appropriate, a wholesale distributor may temporarily deviate from the requirement in §B(2)(a) of this regulation that the oldest approved and unexpired stock be distributed first.

(4) The wholesale distributor shall maintain documentation of the disposition of outdated prescription drugs or devices for 2 years after the disposition of the outdated prescription drugs or devices pursuant to procedures under §B(2)(d) of this regulation.

C. Responsible Individuals. A wholesale distributor shall establish and maintain a list of officers, directors, managers, the designated representative, and others in charge of wholesale distribution, storage, and handling, including:

(1) A description of their duties; and

(2) A summary of their qualifications.

D. Compliance with Federal, State, and Local Law. A wholesale distributor shall:

(1) Operate in compliance with applicable federal, State, and local laws and regulations;

(2) Permit at reasonable times and in a reasonable manner, the Board, the State Division of Drug Control, and any other authorized federal, State, and local law enforcement officials showing proper identification to:

(a) Enter and inspect the distributor's premises and delivery vehicles; and

(b) Audit and copy the distributor's records and written operating procedures; and

(3) If dealing in controlled substances:

(a) Register with the:

(i) Maryland Division of Drug Control; and

(ii) United States Drug Enforcement Administration; and

(b) Comply with all applicable federal, State, and local regulations.

E. Salvaging and Reprocessing.

(1) A wholesale distributor is subject to the provisions of applicable federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including 21 CFR Parts 207, 210, and 211, as amended.

(2) A wholesale distributor is subject to the provisions of any applicable federal, State, or local laws or regulations that relate to prescription device product salvaging or reprocessing.

COMAR **10**. **34**.22.07, MD ADC **10**. **34**.22.07

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.08 Due Diligence.

Wholesale distributors having transactions with persons not licensed by the Board or not certified by a third party recognized by the Board shall have in place policies and procedures to perform due diligence on transactions that take place that include:

A. Verification of alternate licensure;

B. Verification of identity; and

C. Verification of recent inspections by a state or third party entity recognized by the Board.

COMAR **10**. **34**.22.08, MD ADC **10**. **34**.22.08

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Chapter 23 Pharmaceutical Services to Patients in Comprehensive Care Facilities (Refs & Annos)
.01 Scope.

This chapter applies to 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.

COMAR **10**. **34**.23.01, MD ADC **10**. **34**.23.01

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.02 Definitions.

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

B. Terms Defined.

(1) “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, 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 container or electronic storage system containing medications which:

(a) May be required for the emergency need of a patient; and

(b) Are not available from an authorized source in a timely manner.

(4) “Interim box” means a container or an electronic system holding minimal quantities of medications:

(a) Agreed upon by the comprehensive care facility's pharmaceutical services committee, as defined in COMAR 10.07.02.15; and

(b) Intended to expedite immediate initiation of emergency or nonemergency dosing until the pharmacy is able to provide a regular supply.

(5) “Licensed pharmacist” means 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:

(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 a licensed pharmacist to the patients of a comprehensive care facility.

(8) “Pharmacy” means a holder of a pharmacy permit issued by the Board, located either on the premises of or outside the comprehensive care facility and which provides pharmaceutical services to patients in a comprehensive care facility.

(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.

(11) “Verbal order” means a directive that is orally communicated to a licensed pharmacist to accept a prescription order by a person who is authorized to communicate a prescription.

(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.

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.03 Policies and Procedures.

The permit holder shall establish and operate under a policies and procedures manual which:

A. Complies with this chapter;

B. Defines the scope and method of pharmacy services provided to the patients of the comprehensive care facility;

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:

(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 in accordance with Regulation .09 of this chapter;

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

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G. Is in a form that is:

(1) Written or electronic; and

(2) Readily retrievable.

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.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 comprehensive care facility pharmaceutical services;

(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;

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

(6) On site full time; and

(7) Responsible for only one comprehensive care pharmacy.

B. Staff.

(1) The permit holder:

(a) May employ registered pharmacy technicians as required to provide pharmaceutical services to the patients of the comprehensive care facilities; and

(b) Shall provide policies and procedures that specify the duties that may be performed by registered

pharmacy technicians under the supervision of a licensed pharmacist and the duties that may be performed only by a licensed pharmacist.

(2) The permit holder may employ unlicensed personnel to provide operational support as defined in COMAR **10**. **34**.21.02B.

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.05 Physical Requirements.

A. Storage. The director of pharmacy or designee shall ensure that medications and supplies within the pharmacy are properly stored according to the manufacturer's specifications and State and federal laws and regulations with respect to:

(1) Sanitation;

(2) Temperature;

(3) Light;

(4) Ventilation;

(5) Moisture control;

(6) Segregation; and

(7) Security.

B. Equipment and Materials.

(1) The director of pharmacy or designee shall ensure that the pharmacy contains appropriate:

(a) Equipment;

(b) Supplies; and

(c) Physical facilities for proper compounding, preparation, and dispensing of medications as outlined in COMAR **10**. **34**.19.

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

(2) The permit holder and the director of pharmacy or designee shall ensure compliance with COMAR **10**. **34**.05.

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.06 Medication and Device Distribution and Pharmaceutical Services.

A. The director of pharmacy or designee shall be responsible for the safe and efficient dispensing, delivery, control of, and accountability for medications and devices 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:

(1) Meeting the responsibilities set forth in §C of this regulation; and

(2) Ordering, storing, and accounting for pharmaceutical materials.

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

(1) The preparation of medications compounded in the pharmacy as applicable;

(2) The proper preparation, storage, and distribution of compounded sterile preparations according to COMAR **10**. **34**.19 to the extent that the functions are performed at the pharmacy;

(3) The packaging and labeling of medications;

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

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

(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 facility.

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.07 Medication Packaging.

A. A licensed pharmacist shall verify the:

(1) Selection of medication to be packaged; and

(2) Completed packaging of medication performed by registered pharmacy technicians for the following:

(a) Accuracy;

(b) Completeness;

(c) Appropriateness; and

(d) 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 pharmacy;

(4) 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 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 in a master log if kept with respect to drugs that are 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;

(6) Quantity packaged;

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

(8) Manufacturer's expiration date;

(9) Date of packaging;

(10) Name of pharmacy technician packaging; and

(11) Name and initials of verifying licensed pharmacist.

E. Packaged from Another Pharmacy. The licensed pharmacist may package patient specific medication received from another pharmacy licensed in Maryland or operated by the government of the United States provided that:

(1) The licensed pharmacist determines that the 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 time it was dispensed by the original pharmacy and received by the packaging pharmacy;

(2) The licensed pharmacist packages and dispenses all at one time the entire quantity of the prescription medications received from another pharmacy for packaging;

(3) The manufacturer's name is present on the container received from the other pharmacy; and

(4) The licensed pharmacist maintains a master log that includes the following information:

(a) Name of the drug;

(b) Lot number assigned by the packaging pharmacy;

(c) Strength;

(d) Manufacturer;

(e) Name, address, and telephone number of the original dispensing pharmacy;

(f) Prescription number for the original dispensing pharmacy;

(g) Quantity packaged;

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

(i) Date of packaging;

(j) Name of pharmacy technician packaging;

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

(l) Name of the patient.

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Chapter 23 Pharmaceutical Services to Patients in Comprehensive Care Facilities (Refs & Annos)

.08 Labeling of Patient Medications.

A. The director of pharmacy or designee shall ensure that 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 patient;

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

(6) Name of the prescriber;

(7) Expiration date of the drug;

(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. The director of pharmacy or designee shall ensure that medication provided per dosing period in a single container, slot, blister package, any other method of delivering an entire single dosing unit, or as part of a multi-dose dispensing package is labeled with at least the following:

(1) Drug name;

(2) Drug strength;

(3) Name of manufacturer;

(4) Name of the patient;

(5) Lot number; and

(6) Expiration date.

C. The director of pharmacy or designee shall be responsible for the safe and efficient dispensing, delivery, control of, 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 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.

COMAR **10**. **34**.23.08, MD ADC **10**. **34**.23.08

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MD Health & Men. **10**. **34**.23.09

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 23 Pharmaceutical Services to Patients in Comprehensive Care Facilities (Refs & Annos)
.09 Drug Control and Accountability.

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

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.

F. Emergency Drug Kit.

(1) The director 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 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) 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; and

(c) Medications contained in the emergency drug kit are labeled with the:

(i) Name of the drug;

(ii) Strength of the drug;

(iii) Expiration date of the drug;

(iv) Lot number of the drug; and

(v) 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 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.

G. Interim Box.

(1) An interim box may be provided by the pharmacy and kept at the comprehensive care facility if comprehensive care facility policies and procedures address an interim box and the pharmacy complies with these policies and procedures.

(2) A licensed pharmacist shall perform the final check on the contents of the interim box.

H. Prescriber Orders.

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

(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 prescribed;

(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, prescription requirements as described in 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.

(4) The licensed pharmacist shall document immediately a verbal order in writing.

(5) A licensed pharmacist may receive a verbal order:

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

(b) By a voice messaging system.

I. Controlled Dangerous Substances.

(1) Drug Accountability. The permit holder shall ensure that personnel employed by the pharmacy abide by 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.

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

K. Adverse Drug Reactions.

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

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

(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 patient's chart at the time it is reported.

L. Records and Reports. The director 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.

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COMAR **10**. **34**.23.09, MD ADC **10**. **34**.23.09

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Chapter 23 Pharmaceutical Services to Patients in Comprehensive Care Facilities (Refs & Annos)
.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.

COMAR **10**. **34**.23.10, MD ADC **10**. **34**.23.10

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MD Health & Men. **10**. **34**.24.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 24 Record of Drug Inventory Acquisition (Refs & Annos)
.01 Purpose.

The purpose of this chapter is to establish the minimum requirements for drug acquisition records to be maintained by pharmacy permit holders.

COMAR **10**. **34**.24.01, MD ADC **10**. **34**.24.01

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MD Health & Men. **10**. **34**.24.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 24 Record of Drug Inventory Acquisition (Refs & Annos)
.02 Scope.

A. This chapter applies to all pharmacy permit holders in this State.

B. This chapter applies to the acquisition of all prescription medication drug inventories.

C. This chapter applies to a pharmacy's acquisition of drug inventory from all sources including, but not limited to, pharmacies, distributors, and manufacturers, and through all means including, but not limited to, purchases, barter or exchange, free goods, rebates, and replacement products.

COMAR **10**. **34**.24.02, MD ADC **10**. **34**.24.02

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MD Health & Men. **10**. **34**.24.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 24 Record of Drug Inventory Acquisition (Refs & Annos)
.03 Minimum Requirements for Maintenance of Drug Acquisition Records.

A. A pharmacy permit holder shall maintain records of all drug inventory acquisitions.

B. The records maintained shall include:

(1) The name and principal address of the source of the drugs;

(2) The identity and quantity of the drugs received; and

(3) The date the drugs were received.

C. The acquisition records shall be kept for a period of 2 years from the date the inventory was received.

COMAR **10**. **34**.24.03, MD ADC **10**. **34**.24.03

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MD Health & Men. **10**. **34**.24.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 24 Record of Drug Inventory Acquisition (Refs & Annos)
.04 Violation and Inspection.

A. A pharmacy permit holder shall make the drug inventory acquisition records required under this chapter available for inspection upon request by any federal, state, or local law enforcement agent, or any other duly authorized agent of the Board of Pharmacy or the Division of Drug Control, within 72 hours of the request.

B. A pharmacy permit holder shall produce and maintain the records required under this chapter for drug acquisitions for all acquisitions except those replaced within 7 days.

COMAR **10**. **34**.24.04, MD ADC **10**. **34**.24.04

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MD Health & Men. **10**. **34**.25.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 25 Delivery of Prescriptions (Refs & Annos)
.01 Scope.

This chapter governs the manner in which a Maryland licensed pharmacy delivers filled prescriptions for individual patients by United States Postal Service, common carrier, or delivery service to an address within the State.

COMAR **10**. **34**.25.01, MD ADC **10**. **34**.25.01

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MD Health & Men. **10**. **34**.25.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 25 Delivery of Prescriptions (Refs & Annos)
.02 Definitions.

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

B. Terms Defined.

(1) “Delivery” means to send a prescription medication from a pharmacy by the United States Postal Service, common carrier, or delivery system to an address within the State.

(2) Depot.

(a) “Depot” means a location where filled prescriptions are stored before delivery to the intended patient or the intended patient's authorized agent.

(b) “Depot” does not include:

(i) A licensed health care facility;

(ii) A prescriber's office;

(iii) The prescription area of a pharmacy as defined by COMAR **10**. **34**.05.01;

(iv) The United States Postal Service or common carrier's warehouse; or

(v) A multiple family residence.

(3) “Patient” means the individual or companion animal for whom a prescription is written and to whom a prescription medication will be administered.

(4) “Patient profile” means a record of dispensing activity maintained by a pharmacist for a specific patient.

(5) “Residence” means the street address at which a patient resides.

(6) “Storage” means the maintenance of a supply of medication before receipt of the medication by the patient or an agent authorized by the patient.

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 25 Delivery of Prescriptions (Refs & Annos)

.03 Requirements for Packaging and Delivery of Prescription Medication.

A. Packaging. Prescription medications delivered under this chapter to individuals in the State shall be:

(1) Enclosed in a container that reveals to the patient any tampering of the container that occurred during delivery or storage;

(2) Packaged in a shipping container in a manner that does not indicate that the contents are medications;

(3) Packaged in a manner that indicates:

(a) The name and address of the patient or authorized agent; and

(b) Any special storage conditions or requirements; and

(4) Packaged to contain:

(a) Written information regarding the prescription drug or device which is considered significant in the professional judgment of the pharmacist;

(b) A local or toll-free telephone number for the pharmacy; and

(c) Notification to the patient if the appearance of the patient's medication has changed from the patient's last refill.

B. Delivery.

(1) Location.

(a) A prescription medication may be delivered to the patient for whom the prescription is prescribed,

wherever the patient is located.

(b) Instead of delivering medication directly to the patient under §B(1)(a) of this regulation, medication may be delivered to:

(i) An agent authorized by the patient; or

(ii) The residence of the patient, regardless of whether the patient is present at the residence at the time of delivery.

(2) The pharmacy permit holder shall:

(a) Enclose information to inform the patient if the patient's prescription is a temperature sensitive medication that is at risk for damage due to extreme hot or cold temperatures or moisture:

(i) During shipment; or

(ii) After delivery to the patient's mailbox or other designated location; and

(b) Inform the patient within 24 hours of being notified of the delay if the scheduled delivery of the patient's prescription will be interrupted or late.

COMAR **10**. **34**.25.03, MD ADC **10**. **34**.25.03

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MD Health & Men. **10**. **34**.25.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 25 Delivery of Prescriptions (Refs & Annos)
.04 Depots.

A pharmacy may not knowingly deliver prescription medications to a depot, or establish or cooperate in the establishment of a depot.

COMAR **10**. **34**.25.04, MD ADC **10**. **34**.25.04

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MD Health & Men. **10**. **34**.25.05

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 25 Delivery of Prescriptions (Refs & Annos)
.05 Record Keeping.

A. If a patient authorizes delivery of prescription medication to an agent at a location other than the pharmacy, or the patient's residence, the pharmacist shall document the authorization:

(1) On the prescription;

(2) In the patient profile; or

(3) In another record maintained in the pharmacy and established for this purpose.

B. If prescription medication is sent to an agent authorized by the patient at a location other than the patient's residence, or the place of business of the patient's authorized prescriber, the pharmacy shall maintain a record of the:

(1) Identity of the agent to whom the medication is sent;

(2) Location where the medication is sent;

(3) Date and time the medication is sent; and

(4) Prescription number or description of the medication sent.

COMAR **10**. **34**.25.05, MD ADC **10**. **34**.25.05

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 26 Patient Safety Improvement (Refs & Annos)
.01 Definitions.

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

B. Terms Defined.

(1) “High-alert medication” means a medication with:

(a) A significant potential for involvement in a mediation error due to the medication's name, packaging, appearance, dosing, or other characteristics of the agent; or

(b) A high potential for causing serious harm or injury if used incorrectly.

(2) Medication Error.

(a) “Medication error” means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

(b) “Medication error” includes events that may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

(3) Ongoing Quality Assurance Program.

(a) “Ongoing quality assurance program” means a program that systematically and routinely reviews the medication delivery system of a pharmacy for the purpose of minimizing the occurrence of medication errors.

(b) “Ongoing quality assurance program” includes:

(i) The systematic and routine collection of information regarding the performance of the

medication delivery system as it becomes available;

(ii) The investigation of medication errors at the time the error is reported or discovered, or within a reasonable amount of time after the medication error is reported or discovered; or

(iii) A record, proceeding, file, or other document maintained to comply with Regulations .03 or .04 of this chapter, COMAR **10**. **34**.21.03, COMAR **10**. **34**.28.09, or COMAR **10**. **34**.28.10.

COMAR **10**. **34**.26.01, MD ADC **10**. **34**.26.01

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Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 26 Patient Safety Improvement (Refs & Annos)

.02 Patient Education.

A. The pharmacy permit holder shall establish methods to provide patients with information regarding the patient's role and responsibility in preventing medication errors in a manner that is reasonably likely to convey the information to the patient, and if applicable, the patient's health care agent or surrogate decision maker, under Health-General Article, Title 5, Subtitle 6, Annotated Code of Maryland, and that is in addition to any other patient counseling or information required to be given by other laws and regulations.

B. The information in §A of this regulation shall be provided to the patient before or at the time the drug or device is presented to the patient.

C. Exception. If the patient is an inpatient at a health care facility, the information in §A of this regulation shall be:

(1) Provided directly to a patient and, if applicable, a patient's health care agent or surrogate decision maker before discharge; or

(2) Available in a conspicuous location on the institution's premises where the patient and, if applicable, the patient's health care agent or surrogate decision maker, are reasonably likely to have an opportunity to review the information.

D. The information provided to patients shall include:

(1) A patient's rights when receiving a medication or a prescription;

(2) The patient's role and responsibility in preventing a medication error;

(3) The procedures to follow when reporting a suspected medication error to the pharmacy permit holder, pharmacist, health care facility, or other healthcare provider; and

(4) How to report a suspected medication error to the Board.

MD Health & Men. **10**. **34**.26.02

COMAR **10**. **34**.26.02, MD ADC **10**. **34**.26.02

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MD Health & Men. **10**. **34**.26.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 26 Patient Safety Improvement (Refs & Annos)
.03 Pharmacy Staff Education.

As part of a pharmacy permit holder's ongoing quality assurance program, the pharmacy permit holder shall:

A. Ensure that each member of the pharmacy staff involved in the medication delivery system receive at least once a year, education regarding the role and responsibility of pharmacy staff in preventing medication errors; and

B. Maintain records for a minimum of 2 years:

(1) Verifying completion of education referred to in §A of this regulation; and

(2) Demonstrating the content of the education.

COMAR **10**. **34**.26.03, MD ADC **10**. **34**.26.03

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MD Health & Men. **10**. **34**.26.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 26 Patient Safety Improvement (Refs & Annos)
.04 Ongoing Quality Assurance Program.

A. A pharmacy permit holder shall establish and maintain an ongoing quality assurance program to:

(1) Identify, investigate, and promote the prevention of medication errors; and

(2) Establish protocols and procedures to minimize the potential for medication errors.

B. The ongoing quality assurance program shall include the records, proceedings, files, and any other documents of the ongoing quality assurance program, including for each medication error:

(1) The date of the error;

(2) A brief description of the error;

(3) The results of the evaluation by the ongoing quality assurance program's investigation; and

(4) Remedial action taken or recommendations.

C. Periodic Review.

(1) A pharmacy permit holder shall analyze the records, proceedings, files, and any other documents of the ongoing quality assurance program required under §B of this regulation, including any medication errors relating to automated medication systems or unlicensed personnel, at least every 3 months as part of the periodic review that is required to maintain an ongoing quality assurance program.

(2) Each pharmacy permit holder shall conduct an analysis of its medication delivery system at least every 6 months to determine which medications in the prescription area of the pharmacy are high-alert medications, as part of the pharmacy's ongoing quality assurance program.

D. Documentation of Periodic Review. The records, proceedings, files, and any other documents of the ongoing

quality assurance program shall include for each:

(1) Periodic review required under §C(1) of this regulation:

(a) Documentation of the periodic review;

(b) A description of the system's weaknesses found during the periodic review; and

(c) A description of the actions taken to remedy any weaknesses identified in the medication system; and

(2) Analysis of a pharmacy's medication delivery system to identify high-alert medications required under §C(2) of this regulation:

(a) A list of high-alert medications present in the prescription area of the pharmacy;

(b) The date that a high-alert medication was added to or removed from the list of high-alert medications;

(c) Dates that the list was reviewed by the pharmacy permit holder; and

(d) Remedial actions taken based on the review of the list of high-alert medications and any medication errors relating to the high-alert medications.

E. Unless otherwise specified in law, the permit holder shall maintain the ongoing quality assurance program records referred to in this regulation for 2 years.

F. The proceedings, records, and files of an ongoing quality assurance program that meets the requirements of Health Occupations Article, §1-401, Annotated Code of Maryland, and this chapter, are not discoverable and are not admissible in evidence in any civil action, as provided in Health Occupations Article, §1-401, Annotated Code of Maryland.

COMAR **10**. **34**.26.04, MD ADC **10**. **34**.26.04

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MD Health & Men. **10**. **34**.27.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 27 Compelling Purpose Disclosure (Refs & Annos)
.01 Disclosure for Compelling Public Purpose.

The custodian of records may find that a compelling public purpose warrants disclosure of information in a certification, licensing, or investigative file, regardless of whether there has been a request for the information, if the information concerns:

A. Possible criminal activity and is disclosed to a federal, state, or local law enforcement or prosecutorial official or authority;

B. A possible violation of law and is disclosed to a federal, state, or local authority that has jurisdiction over the individual whose conduct may be a violation and the information disclosed is limited to information relevant to the possible violation by that individual; or

C. Conduct by an individual that the custodian of records reasonably believes may pose a risk to the public health, safety, or welfare, and is disclosed to a law enforcement authority, administrative official, or agency that regulates the individual, or to a hospital or other health care facility where the individual has privileges.

COMAR **10**. **34**.27.01, MD ADC **10**. **34**.27.01

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MD Health & Men. **10**. **34**.27.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 27 Compelling Purpose Disclosure (Refs & Annos)
.02 Other Disclosures.

This chapter does not prohibit or limit the ability of the Board to disclose general licensing information as provided in State Government Article, §10-617(h), Annotated Code of Maryland, or any information that the Board may otherwise disclose by law.

COMAR **10**. **34**.27.02, MD ADC **10**. **34**.27.02

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MD Health & Men. **10**. **34**.28.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 28 Automated Medication Systems (Refs & Annos)
.01 Scope.

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

COMAR **10**. **34**.28.01, MD ADC **10**. **34**.28.01

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 28 Automated Medication Systems (Refs & Annos)
.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, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland; or

(b) Prepare medications for final dispensing by a licensed pharmacist.

(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, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland, 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.

(6) “Interim box” means a tamper evident and secure container or secure electronic storage system holding minimal quantities of medications agreed on by the health care facility intended to expedite immediate initiation of emergency or nonemergency dosing until the pharmacy is able to provide a regular supply.

(7) Remote Automated Medication System.

(a) “Remote automated medication system” means an automated medication system that is located in a health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland, that does not have an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.

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

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

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

(iii) Is stocked with unit dose medications;

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

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

(vi) Is stocked and controlled by a pharmacy providing services to a health care facility.

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

(9) “Starter dose” means a dose of medication removed from a remote or decentralized automated medication system within the first 24 hours after it is ordered.

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

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.03 Limitation on Privileges to Administer.

In this chapter, “privileges to administer medication” does not include privileges created by delegation from a licensed health care professional to an unlicensed health care professional.

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Chapter 28 Automated Medication Systems (Refs & Annos)
.04 Usage Requirements for Centralized Automated Medication Systems.

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

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

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

(3) The permit holder ensures that:

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

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

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

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

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

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

COMAR **10**. **34**.28.04, MD ADC **10**. **34**.28.04

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.05 Usage Requirements for Decentralized Automated Medication Systems.

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

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

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

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

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

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

(4) The permit holder ensures that:

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

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

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

(5) It is designed to distribute medications in a licensed health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland.

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:

(1) The pharmacist reviews the order within 24 hours of removal from the decentralized automated medication system; or

(2) The prescriber reviews the patient medical history and authorizes the administration of the dose to the patient.

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

(1) Limits simultaneous access to multiple:

(a) Drug strengths;

(b) Dosage forms; or

(c) Drug entities;

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

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

D. The requirements listed in §C(1) and (2) of this regulation do not apply to automated supply towers which contain:

(1) Noncontrolled medications that are:

(a) Refrigerated;

(b) Bulk; or

(c) Intravenous fluids; or

(2) Prescription devices.

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

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

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

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.06 Usage Requirements for Remote Automated Medication Systems.

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

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

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

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

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

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

(4) The permit holder ensures that:

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

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

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

(5) It is designed to distribute medications in a licensed health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19-713.6, Annotated Code of Maryland.

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

C. If a licensed pharmacist is not physically present where the remote automated medication system is located, the pharmacist shall have access to the system by electronic and visual means in order to ensure the safe and efficient operation of the system.

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

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

(a) Drug strengths;

(b) Dosage forms; or

(c) Drug entities;

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

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

E. The requirements listed in §D(1) and (2) of this regulation do not apply to automated supply towers which contain:

(1) Noncontrolled medications that are:

(a) Refrigerated;

(b) Bulk; or

(c) Intravenous fluids; or

(2) Prescription devices.

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

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

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

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

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

(3) Restricts access to medications to a licensed pharmacist or an individual authorized to administer medication under Health Occupation Article, Annotated Code of Maryland; 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.

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

(1) A licensed pharmacist available for consultation 24 hours per day;

(2) Technical assistance regarding operation of the system available 24 hours per day; and

(3) A quality assurance program as set forth in Regulation .10 of this chapter.

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

(1) Whether the permit holder operated a remote automated medication system; and

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

COMAR **10**. **34**.28.06, MD ADC **10**. **34**.28.06

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.07 Stocking of Automated Medication Systems.

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

B. Stocking of Automated Medication System. A registered pharmacy technician may stock an automated medication system provided that:

(1) The pharmacy technician's selection of medications is verified by a pharmacist; and

(2) The system uses positive drug identification such as bar code technology.

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.08 Return of Unused Medication.

A. Single-Drug Unit Dose Packaging.

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

(a) The medication is returned to a designated common, secure, one-way returns bin; and

(b) A licensed pharmacist determines whether the medication is in an unadulterated form.

(2) Only a licensed pharmacist may return medications directly to the automated medication system under §A(1) of this regulation.

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 proper disposal.

C. Unused medications dispensed from a centralized automated medication system stocked with bulk medications may not be returned to the system.

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.09 Education and Training.

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

A. The capabilities and limitations of the system;

B. Procedures for the operation of the system; and

C. Procedures for system downtime.

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.10 Quality Assurance Program.

A. The responsible pharmacist, in consultation with the health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19.713.6, Annotated Code of Maryland, shall develop, maintain, and review annually a quality assurance program regarding the automated medication system that addresses, at minimum:

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

(2) Investigation of medication errors related to the automated medication system, and remedial actions taken;

(3) Review of discrepancies and transaction reports to identify patterns of inappropriate use and access;

(4) Review of the overall functioning of the system2;

(5) Security and access:

(6) Preventative maintenance;

(7) Sanitation;

(8) Storage conditions;

(9) Inventory of drugs;

(10) Drug procurement, delivery, and receipt;

(11) Record keeping;

(12) Proper labeling procedures; and

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

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

(b) A plan for system recovery.

B. The responsible pharmacist, in consultation with the health care facility, a related institution as defined in Health-General Article, §19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, §19.713.6, Annotated Code of Maryland, shall develop, maintain, and review annually a quality assurance program regarding the remote or decentralized automated medication system that addresses, at a minimum, system override management to include:

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

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

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.11 Record Keeping.

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

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

(1) Maintenance records and service logs;

(2) System failure reports;

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

(4) Accuracy audits and system performance audits;

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

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

(7) Training records including:

(a) Contents of the training program;

(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 or removed, dispensed, or distributed from the system;

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

(i) Identity of the particular automated medication 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; and

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

(i) Date;

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

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

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.12 Security.

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

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

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

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

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

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

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.13 Laws and Compendial Standards.

The responsible pharmacist shall ensure compliance with the laws and compendial standards for packaging and labeling.

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Chapter 28 Automated Medication Systems (Refs & Annos)
.14 Controlled Dangerous Substances.

Controlled dangerous substances shall only be dispensed and distributed in accordance with applicable State and federal statutes and regulations.

COMAR **10**. **34**.28.14, MD ADC **10**. **34**.28.14

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Chapter 29 Drug Therapy Management (Refs & Annos)
.01 Definitions.

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

B. Terms Defined.

(1) “Amendment” means a change to:

(a) A protocol or physician-pharmacist agreement; or

(b) The parties to the physician-pharmacist agreement.

(2) “Applicants” means physicians and pharmacists submitting a physician-pharmacist agreement and protocol to their respective Boards.

(3) “Boards” means the Board of Physicians and the Board of Pharmacy.

(4) “Condition” means a disease-state or health circumstance necessitating monitoring or intervention.

(5) “Emergency first care” means triage of emergent conditions or treatment of the condition in those cases in which a protocol specifies treatment for the emergent condition.

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Chapter 29 Drug Therapy Management (Refs & Annos)

.02 Content of Protocol.

A. A protocol shall:

(1) Be:

(a) Written; and

(b) Condition or disease-state specific; and

(2) Contain the following:

(a) The condition that the protocol is designed to manage;

(b) A list of medications that may be used under the auspices of the protocol;

(c) Monitoring parameters including laboratory tests for the:

(i) Condition; and

(ii) Medication employed;

(d) A list of circumstances requiring contact with the physician or physicians who are a party to the physician-pharmacist agreement;

(e) A statement prohibiting substitution of a chemically dissimilar drug product by the pharmacist for the product prescribed by the physician unless permitted in the therapy management contract;

(f) A list of circumstances under which the pharmacist may alter doses, modify the treatment regimen, or switch the agent under the terms of the therapy management contract;

(g) Information to be documented;

(h) A listing of provisions within the protocol that may be customized within a therapy management contract; and

(i) An action plan for situations when the pharmacist encounters a situation that is not addressed in the protocol.

B. A protocol may authorize:

(1) The modification, continuation, and discontinuation of drug therapy;

(2) The ordering of laboratory tests; and

(3) Other patient care management measures related to monitoring or improving the outcomes of drug or device therapy.

C. A protocol may not authorize acts that exceed the scope of practice of the parties to the physician-pharmacist agreement.

D. Technical modifications to the protocol shall be registered with the Board of Pharmacy within 30 days of the technical modification.

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Chapter 29 Drug Therapy Management (Refs & Annos)
.03 Content of Physician-Pharmacist Agreement.

A. The physician-pharmacist agreement shall contain the following:

(1) The names and signatures of the physicians and pharmacists authorized to act under a therapy management contract;

(2) The locations where the pharmacists may provide therapy management services;

(3) The titles of the protocols to which the physician-pharmacist agreement pertains;

(4) The methods and timeframes by which documentation and routine communication will occur between the physicians and the pharmacists, including the timeframes in which the pharmacist will fully update the patient's record in writing;

(5) The name, address, and telephone number of the party to the physician-pharmacist agreement who is to receive correspondence from the Boards related to the physician-pharmacist agreement;

(6) A statement that the physicians and pharmacists shall comply with all State and federal laws relating to patient confidentiality; and

(7) A list of devices available to the pharmacists performing under the physician-pharmacist agreement, which are relevant to the disease-states or conditions to be managed.

B. Technical modifications to the physician-pharmacist agreement shall be registered with the Board of Pharmacy within 30 days of the technical modification.

C. The party designated as the contact person to receive correspondence from the Boards shall ensure that the parties to the physician-pharmacist agreement are notified in a timely manner of the information received from the Boards.

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D. If the contact information for the party to the agreement designated to receive correspondence from the Boards changes, the designee shall notify the Boards of the change within 30 days of the change.

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Chapter 29 Drug Therapy Management (Refs & Annos)

.04 Requirements for Participation in Drug Therapy Management.

A. In order to enter into a therapy management contract, a pharmacist:

(1) Shall be licensed by and in good standing with the Board of Pharmacy;

(2) Shall possess a Doctor of Pharmacy degree or equivalent training as established in §B of this regulation;

(3) May not have:

(a) A public final order by the Board of Pharmacy disciplining the pharmacist's license within the 5 years immediately before the application is submitted; or

(b) Limitations placed on the pharmacist's license by the Board of Pharmacy in a public order;

(4) Shall possess relevant advanced training as indicated by one of the following:

(a) Certification as a specialist related to the disease state specified by the protocol by:

(i) The Board of Pharmacy Specialties;

(ii) The American Society of Consultant Pharmacist's Certified Geriatric Practitioner certification program; or

(iii) Another credentialing body approved by the Board of Pharmacy; or

(b) Successful completion of:

(i) A residency accredited by the American Society of Health-Systems Pharmacists, a body approved by the Board of Pharmacy or offered by a body accredited by the Accreditation Council

for Pharmacy Education;

(ii) A certificate program approved by the Board of Pharmacy;

(iii) A National Association of Boards of Pharmacy credentialing examination; or

(iv) An examination approved by the Board of Pharmacy;

(5) Shall have successfully completed:

(a) 1,000 hours of relevant clinical experience; or

(b) 320 hours in a structured experience program approved by the Board of Pharmacy; and

(6) Shall document training related to the disease state specified in the protocol.

B. A pharmacist who does not possess a Doctor of Pharmacy degree shall document that the pharmacist's training has included the following components:

(1) Designing, implementing, monitoring, evaluating, and modifying or recommending modifications in drug therapy to insure effective, safe, and economical patient care;

(2) Identifying, assessing, and solving medication-related problems, and providing clinical judgments as to the continuing effectiveness of individualized therapeutic plans and intended therapeutic outcomes;

(3) Conducting appropriate physical assessments, evaluating patient problems, and ordering and monitoring medications and laboratory tests in accordance with established standards of practice;

(4) Monitoring patients and patient populations regarding the purposes, uses, effects, and pharmacoeconomics of their medications and related therapy;

(5) Providing emergency first care, including cardiopulmonary resuscitation;

(6) Using clinical data to optimize therapeutic drug regimens; and

(7) Documenting interventions and evaluating pharmaceutical care outcomes.

C. The Board of Pharmacy shall determine whether the pharmacist meets the requirements of §§A and B of this regulation.

D. A licensed physician who has entered into a physician-pharmacist agreement shall submit to the Board of Physicians a copy of:

(1) The physician-pharmacist agreement;

(2) Subsequent amendments made to the:

(a) Physician-pharmacist agreement; or

(b) Protocols specified in the physician-pharmacist agreement; and

(3) Changes to participants of the:

(a) Physician-pharmacist agreement; or

(b) Protocols specified in the physician-pharmacist agreement.

E. The Board of Physicians shall notify the physician of any additional information needed within 30 days of the receipt of the submitted information.

F. A licensed pharmacist who has entered into a physician-pharmacist agreement shall submit to the Board of Pharmacy a copy of:

(1) The physician pharmacist agreement;

(2) Subsequent amendments made to the:

(a) Physician-pharmacist agreement; or

(b) Protocols specified in the physician-pharmacist agreement; and

(3) Changes to participants of the:

(a) Physician-pharmacist agreement; or

(b) Protocols specified in the physician-pharmacist agreement.

G. The Board of Pharmacy shall determine whether a pharmacist added under §F of this regulation meets the requirements of §§A and B of this regulation.

H. The Board of Pharmacy shall notify the pharmacist of any additional information needed within 30 days of the receipt of the submitted information.

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Chapter 29 Drug Therapy Management (Refs & Annos)
.05 Guidelines for Use of Protocols.

A. On receipt of specific instructions from the physician regarding a specific patient, the pharmacist may execute the physician's specific instructions even if the instructions deviate from the protocol.

B. The protocol may not prohibit the pharmacist from providing other pharmaceutical services that are within the pharmacist's scope of practice.

C. Documentation of activities performed under a protocol or the physician's specific instructions shall be maintained in such a manner that it is accessible to the:

(1) Physician; and

(2) Pharmacist.

D. Documentation may be maintained in written or electronic form.

E. Oral communications between the physician and pharmacist shall be summarized in the documentation maintained by the pharmacist and forwarded to the physician.

F. Unless an alternative time period is stated in the physician-pharmacist agreement, the pharmacist shall inform the physician within 48 hours if the pharmacist:

(1) Modifies the dose or agent under the therapy management contract; or

(2) Detects an abnormal result from an assessment activity.

COMAR **10**. **34**.29.05, MD ADC **10**. **34**.29.05

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MD Health & Men. **10**. **34**.29.05

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MD Health & Men. **10**. **34**.29.06

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 29 Drug Therapy Management (Refs & Annos)
.06 Therapy Management Contracts.

A. A therapy management contract shall be signed by the:

(1) Physician or physicians involved in the management of the patient under a physician-pharmacist agreement;

(2) Pharmacist or pharmacists involved in the management of the patient under a physician-pharmacist agreement; and

(3) Patient receiving care under the therapy management contract.

B. A therapy management contract shall contain:

(1) A list of allowable substitutions of chemically dissimilar drugs, if any;

(2) A statement that:

(a) None of the parties involved in the therapy management contract have been:

(i) Coerced into participating in the therapy management contract;

(ii) Given economic incentives, excluding normal reimbursement for services rendered; or

(iii) Involuntarily required to participate in the therapy management contract; and

(b) The pharmacist shall notify the physician under the terms of the physician-pharmacist agreement if the pharmacist:

(i) Modifies the dose or agent under the therapy management contract; or

(ii) Detects an abnormal result from an assessment activity;

(3) Notice to the patient stating:

(a) That the patient may terminate the therapy management contract at any time; and

(b) The procedure by which the patient may terminate the therapy management contract;

(4) A procedure for periodic review by the physician of the drugs modified under the physician-pharmacist agreement or changed with the consent of the physician;

(5) A reference to the protocol or protocols under which the pharmacist shall act; and

(6) Exceptions or limitations to the protocol or protocols for the specific patient.

C. The therapy management contract shall terminate 1 year from the date of signing unless renewed by the parties to the therapy management contract, including the patient.

COMAR **10**. **34**.29.06, MD ADC **10**. **34**.29.06

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MD Health & Men. **10**. **34**.29.07

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 29 Drug Therapy Management (Refs & Annos)
.07 Fees.

A. Scope. This regulation governs physicians and pharmacists participating in drug therapy management or amendment of physicians and pharmacists that participate in the physician-pharmacist agreements relating to drug therapy management.

B. Fees. The Board of Pharmacy requires a fee for the physician-pharmacist agreement and protocol application (which includes review of the qualifications of the pharmacist participants) of $100 per physician-pharmacist agreement.

COMAR **10**. **34**.29.07, MD ADC **10**. **34**.29.07

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.30.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 30 Change to Permit -Pharmacy or Wholesale Distribution Permit Holder (Refs & Annos)
.01 Name Change Requirements.

The name of an individual or entity required to possess a pharmacy or wholesale distribution permit may be changed on a permit if:

A. The permit holder submits to the Board within 30 days before or after the name change, on a form that the Board requires; and

B. There is no other change in the individual or entity required to possess a pharmacy or wholesale distribution permit including no change in controlling ownership interest, type of business entity, or location.

COMAR **10**. **34**.30.01, MD ADC **10**. **34**.30.01

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.30.01-1

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 30 Change to Permit -Pharmacy or Wholesale Distribution Permit Holder (Refs & Annos)
.01-1 Hours of Operation Change Requirements.

A pharmacy or wholesale distribution permit holder shall notify the Board, on a form that the Board requires, within 30 days before a change in hours of operation.

COMAR **10**. **34**.30.01-1, MD ADC **10**. **34**.30.01-1

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MD Health & Men. **10**. **34**.30.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 30 Change to Permit -Pharmacy or Wholesale Distribution Permit Holder (Refs & Annos)
.02 Fee.

A. There is no fee for a name change under this chapter, if the permit holder complies with Regulation .01 of this chapter.

B. If a permit holder fails to comply with Regulation .01 of this chapter, the permit holder shall pay to the Board the name change late fee established in COMAR **10**. **34**.09.

COMAR **10**. **34**.30.02, MD ADC **10**. **34**.30.02

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MD Health & Men. **10**. **34**.31.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit (Refs & Annos)

.01 Settings.

A. If a setting otherwise complies with State and federal laws, a pharmacist may request Board approval to dispense or distribute at a setting that does not possess a pharmacy permit if:

(1) The dispensing or distribution occurs while the pharmacist is providing drug therapy management services in:

(a) The office of a licensed physician;

(b) A clinic; or

(c) A medical facility; or

(2) The setting is:

(a) Operated or funded by a public health authority of the State;

(b) A medical facility or clinic that is operated on a nonprofit basis and is not otherwise required to possess a pharmacy permit; or

(c) A health center that operates on a campus of an institution of higher education.

B. If the drug therapy management services referred to in §A(1)(a) of this regulation include the dispensing or distribution of controlled dangerous substances, the request may be approved by the Board if the physician possesses a dispensing permit issued by the Board of Physicians.

C. If a pharmacist seeks to obtain Board approval to dispense or distribute at a setting that is not set forth in §A of this regulation, the pharmacist shall apply to the Board for a waiver permit under COMAR **10**. **34**.17.

MD Health & Men. **10**. **34**.31.01

COMAR **10**. **34**.31.01, MD ADC **10**. **34**.31.01

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MD Health & Men. **10**. **34**.31.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit (Refs & Annos)

.02 Pharmacist Approval.

A. Before a pharmacist may dispense or distribute at a setting that does not hold a pharmacy permit under Regulation .01A(1) of this chapter, the pharmacist shall submit to the Board a request for approval signed by the pharmacist, which includes:

(1) The name and license number of the pharmacist;

(2) The scope of services to be provided by the pharmacist at the nonpharmacy setting;

(3) The name and address of the nonpharmacy setting where the pharmacist intends to dispense or distribute; and

(4) A statement indicating the pharmacist's criminal history, if any.

B. If the pharmacist intends to provide drug therapy management services in a licensed physician's office under Regulation .01A(1)(a) of this chapter, in addition to the requirements of §A of this regulation, the pharmacist shall provide:

(1) The name and license number of the licensed physician; and

(2) Proof of an approved physician-pharmacist agreement with the licensed physician.

COMAR **10**. **34**.31.02, MD ADC **10**. **34**.31.02

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.31.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit (Refs & Annos)

.03 Grounds for Denial.

The Board may deny a pharmacist's request for approval under Regulation .02 of this chapter if the:

A. Pharmacist has:

(1) A pending or final disciplinary action before the Board; or

(2) A criminal history; or

B. Criteria set forth in Regulations .01B or .02 of this chapter are not satisfied.

COMAR **10**. **34**.31.03, MD ADC **10**. **34**.31.03

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.31.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit (Refs & Annos)

.04 Change in Information.

If any of the information set forth in Regulation .02 of this chapter changes during the effective period of the Board's approval:

A. The pharmacist shall immediately advise the Board in writing of the change; and

B. The change in information may cause the Board to withdraw or modify the Board's approval of the nonpharmacy setting.

COMAR **10**. **34**.31.04, MD ADC **10**. **34**.31.04

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MD Health & Men. **10**. **34**.31.05

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit (Refs & Annos)

.05 Approval During Catastrophic Health Emergency.

In the event of a catastrophic health emergency proclaimed by the Governor under Article 41, §2-202, Annotated Code of Maryland, or by the Secretary under Health-General Article, §18-902, Annotated Code of Maryland, assignment of a pharmacist to a location by the State constitutes application and approval under Regulation .02 of this chapter.

COMAR **10**. **34**.31.05, MD ADC **10**. **34**.31.05

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MD Health & Men. **10**. **34**.31.06

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit (Refs & Annos)

.06 Governing Laws.

A. Except as provided in §B of this regulation, a pharmacist approved by the Board to dispense or distribute at a nonpharmacy setting shall comply with the Health Occupations Article, Title 12, Annotated Code of Maryland.

B. A pharmacist approved by the Board to dispense or distribute at a nonpharmacy setting shall comply with the labeling, storage, and record keeping requirements governing the nonpharmacy setting.

COMAR **10**. **34**.31.06, MD ADC **10**. **34**.31.06

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MD Health & Men. **10**. **34**.31.07

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit (Refs & Annos)

.07 Term and Renewal.

A. Unless otherwise determined by the Board, the Board's approval of a pharmacist's request to dispense or distribute at a setting that does not possess a pharmacy permit is in effect until the expiration of the pharmacist's license.

B. The pharmacist shall request renewal of the Board's approval when renewing the pharmacist's license.

COMAR **10**. **34**.31.07, MD ADC **10**. **34**.31.07

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.31.08

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 31 Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit (Refs & Annos)

.08 Pharmacy Rendered Inoperable.

A. If a pharmacy for which a permit is issued is destroyed or otherwise rendered inoperable, a pharmacist may dispense or distribute from a temporary site if the permit holder:

(1) Obtains approval from the Board before continuing pharmacy operations from a temporary site; and

(2) Ensures that the temporary pharmacy site complies with State and federal laws.

B. Under §A of this regulation, the Board may approve the operation of a pharmacy from a temporary site for a period not to exceed 60 days from the date of the original approval, unless an extension is approved by the Board before the expiration of the preceding approval.

COMAR **10**. **34**.31.08, MD ADC **10**. **34**.31.08

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MD Health & Men. **10**. **34**.32.01

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 32 Pharmacist Administration of Vaccinations (Refs & Annos)
.01 Scope.

This chapter does not limit or affect the right of an individual to practice a health occupation that the individual is authorized to practice.

COMAR **10**. **34**.32.01, MD ADC **10**. **34**.32.01

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MD Health & Men. **10**. **34**.32.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 32 Pharmacist Administration of Vaccinations (Refs & Annos)
.02 Definitions.

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

B. Terms Defined.

(1) “Board” means the State Board of Pharmacy.

(2) “Pharmacist” means an individual who practices pharmacy regardless of the location where the activities of practice are performed.

(3) “Pharmacy” means an establishment holding a permit under Health Occupations Article, §12-401, Annotated Code of Maryland.

(4) “Pharmacy permit holder” means a person authorized by the Board to operate a pharmacy while the pharmacy permit is effective.

(5) “Pharmacy Experiential Program” means a program under the American Council on Pharmacy Education.

(6) Practice Pharmacy.

(a) “Practice pharmacy” means to engage in any of the following activities:

(i) Providing pharmaceutical care;

(ii) Compounding, dispensing, or distributing prescription drugs or devices;

(iii) Compounding or dispensing nonprescription drugs or devices;

(iv) Monitoring prescriptions and nonprescription drugs or devices;

(v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;

(vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;

(vii) Acting within the parameters of a therapy management contract, as provided under Health Occupations Article, Subtitle 6A, Annotated Code of Maryland; or

(viii) Administering vaccinations in accordance with Health Occupations Article, §12-508, Annotated Code of Maryland.

(b) "Practice pharmacy" does not include the operations of a person who holds a permit issued under Health Occupations Article, §12-602, Annotated Code of Maryland.

(7) "Vaccination" means a herpes zoster, influenza, or pneumococcal pneumonia vaccination authorized by Health Occupations Article, §12-508, Annotated Code of Maryland.

COMAR **10**. **34**.32.02, MD ADC **10**. **34**.32.02

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MD Health & Men. **10**. **34**.32.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 32 Pharmacist Administration of Vaccinations (Refs & Annos)
.03 Requirements to Administer Vaccinations.

A. Registration.

(1) A licensed pharmacist shall submit a registration to the Board on the form that the Board requires.

(2) The registration form shall include verification from the licensed pharmacist of the following:

(a) Successful completion of a certification course approved by the Board of Pharmacy that includes the current guidelines and recommendations of the Centers for Disease Control and Prevention for herpes zoster, influenza, and pneumococcal pneumonia vaccines; and

(b) Possession of an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction.

(3) A registration authorizing a licensed pharmacist to administer vaccinations expires with the expiration of the license to practice pharmacy unless the licensed pharmacist has completed:

(a) Except as provided in §A(5) of this regulation, 4 hours of continuing education credits related to vaccinations; and

(b) All other requirements for licensure renewal.

(4) A licensed pharmacist may not administer vaccinations until the licensed pharmacist receives a written confirmation from the Board accepting the licensed pharmacist's registration.

(5) A pharmacist registered to administer vaccines before October 1, 2008 shall, for the first renewal of the registration after that date, demonstrate that 4 continuing education credits taken include education about the herpes zoster and pneumococcal pneumonia vaccines.

B. A licensed pharmacist may not administer:

(1) An influenza vaccination to an individual who is younger than 9 years old; or

(2) Vaccinations, other than influenza, to any individual younger than 18 years old.

C. A pharmacist shall report to the Maryland Immunization Registry an influenza vaccination administered by the pharmacist to individuals who are from 9 to 18 years old.

D. A pharmacist shall:

(1) Provide the patient with a vaccine information statement issued by the Centers for Disease Control and Prevention;

(2) Obtain a signed consent form from the patient or custodial parent; and

(3) Observe the patient for a period of 15 minutes after administration of the vaccine for adverse effects including syncope.

E. A pharmacy student in a Pharmacy Experiential Program, who has successfully completed a Board-approved certification course, may administer vaccinations under direct supervision of a licensed pharmacist who meets requirements in §A of this regulation.

COMAR **10**. **34**.32.03, MD ADC **10**. **34**.32.03

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MD Health & Men. **10**. **34**.32.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 32 Pharmacist Administration of Vaccinations (Refs & Annos)
.04 Training Program Requirements.

In order to administer vaccinations, the Board shall assure that any course that it approves contains at a minimum the following elements:

A. Responses to an emergency situation as a result of the administration of a vaccination;

B. Administration of intramuscular and subcutaneous injections and intranasal vaccination;

C. Record-keeping and reporting requirements; and

D. Advisory Committee on Immunization Practices and Centers for Disease Control guidelines for herpes zoster, influenza, and pneumococcal pneumonia vaccines.

COMAR **10**. **34**.32.04, MD ADC **10**. **34**.32.04

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 32 Pharmacist Administration of Vaccinations (Refs & Annos)

.05 Record Keeping.

A. The pharmacy permit holder shall maintain documentation in the pharmacy from which the vaccine was administered for a minimum of 5 years that includes the:

(1) Name, address, and date of birth of the individual receiving the vaccination;

(2) Date of administration and route and site of vaccinations;

(3) Name, dose, manufacturer's lot number, and expiration date of the vaccine;

(4) Name and address of the primary health care provider of the individual receiving the vaccination, as identified by that individual;

(5) Name of the pharmacist, pharmacy student, physician, or nurse administering the vaccination;

(6) Version of the vaccination information statement provided to the individual receiving the vaccination;

(7) Copy of the signed patient consent form of those individuals to whom the vaccine was administered; and

(8) Nature and outcome of an adverse reaction and documentation that the adverse reaction was reported to:

(a) The primary care physician; and

(b) The Vaccine Adverse Event Reporting System.

B. The records required in this regulation shall be:

(1) Readily retrievable; and

(2) Made available on the request of the Board.

C. The pharmacist administering a vaccination as an independent provider at a location that is not a pharmacy shall maintain the following documentation for a minimum of 5 years:

(1) Name, address, and date of birth of the individual receiving the vaccination;

(2) Date of administration, and route and site of vaccinations;

(3) Name, dose, manufacturer's lot number, and expiration date of the vaccine;

(4) Name and address of the primary health care provider of the individual receiving the vaccination, as identified by that individual;

(5) Name of the pharmacist or pharmacy student administering the vaccination;

(6) Version of the vaccination information statement provided to the individual receiving the vaccination;

(7) Copy of the signed patient consent form of those individuals to whom the vaccine was administered; and

(8) Nature and outcome of an adverse reaction, and documentation that the adverse reaction was reported to:

(a) The primary care physician; and

(b) The Vaccine Adverse Event Reporting System.

D. The pharmacist administering a vaccination on behalf of a permit holder at a location that is not a pharmacy shall maintain the following documentation with the permit holder for a minimum of 5 years:

(1) Name, address, and date of birth of the individual receiving the vaccination;

(2) Date of administration, and route and site of vaccinations;

(3) Name, dose, manufacturer's lot number, and expiration date of the vaccine;

(4) Name and address of the primary health care provider of the individual receiving the vaccination, as identified by that individual;

(5) Name of the pharmacist or pharmacy student administering the vaccination;

(6) Version of the vaccination information statement provided to the individual receiving the vaccination;

(7) Copy of the signed patient consent form of those individuals to whom the vaccine was administered; and

(8) Nature and outcome of an adverse reaction, and documentation that the adverse reaction was reported to:

(a) The primary care physician; and

(b) The Vaccine Adverse Event Reporting System.

COMAR **10**. **34**.32.05, MD ADC **10**. **34**.32.05

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MD Health & Men. **10**. **34**.32.06

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 32 Pharmacist Administration of Vaccinations (Refs & Annos)
.06 Patient Information and Consent.

A. Every patient receiving a vaccination shall be provided with a current vaccine information statement.

B. Every patient receiving a vaccination shall:

(1) Sign a consent form consenting to the administration of the vaccine; and

(2) Be given a copy of the consent form for the patient's future reference.

C. The consent form shall disclose the credentials of the pharmacist administering the vaccination.

COMAR **10**. **34**.32.06, MD ADC **10**. **34**.32.06

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MD Health & Men. **10**. **34**.32.07

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 32 Pharmacist Administration of Vaccinations (Refs & Annos)
.07 Approved Protocols.

A. The pharmacist shall administer vaccinations only within a protocol signed and dated by a licensed Maryland physician. A copy of that protocol shall be maintained by the administering pharmacist and permit holder of the pharmacy site at which the vaccination is administered, if applicable.

B. The pharmacist shall review the protocol annually with the physician.

C. The pharmacist shall provide the physician-established protocol for vaccinations to the Board on request.

COMAR **10**. **34**.32.07, MD ADC **10**. **34**.32.07

Complete through Maryland Register Vol. 41, Issue 2, dated January 24, 2014.

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MD Health & Men. **10**. **34**.32.08

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 32 Pharmacist Administration of Vaccinations (Refs & Annos)
.08 Fees.

Fees charged for the administration of vaccinations may not exceed the Medicare reimbursement rate.

COMAR **10**. **34**.32.08, MD ADC **10**. **34**.32.08

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MD Health & Men. **10**. **34**.32.09

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 32 Pharmacist Administration of Vaccinations (Refs & Annos)
.09 Requirements for Administration of Herpes Zoster or Pneumococcal Pneumonia Vaccine.

A. In addition to the requirements set forth in this chapter, a pharmacist may administer a vaccination for herpes zoster or pneumococcal pneumonia to an individual if the individual has a prescription from a physician.

B. Once the pharmacist has administered the vaccination, the pharmacist shall:

(1) Inform the prescribing physician by reasonable means within 7 days of the following:

(a) The identity of the patient;

(b) The identity of the vaccination;

(c) The route of administration;

(d) The site of administration;

(e) The dose administered; and

(f) The date of administration; and

(2) If the prescribing physician is not the patient's primary care physician, make a reasonable effort to provide the patient's primary care physician with the information set forth in §B(1) of this regulation.

COMAR **10**. **34**.32.09, MD ADC **10**. **34**.32.09

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 33 Prescription Drug Repository Program (Refs & Annos)
.01 Definitions.

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

B. Terms Defined.

(1) “Board” means the State Board of Pharmacy.

(2) “Drop-off site” means a pharmacy or other health care facility designated by the Board for the purpose of receiving donated prescription drugs or medical supplies.

(3) Health Care Facility.

(a) “Health care facility” means:

(i) A hospital, as defined in Health-General Article, §19-301(g), Annotated Code of Maryland;

(ii) A limited service hospital, as defined in Health-General Article, §19-301(e), Annotated Code of Maryland;

(iii) A related institution, as defined in Health-General Article, §19-301(o), Annotated Code of Maryland;

(iv) An ambulatory surgical facility;

(v) A rehabilitation facility;

(vi) A home health agency, as defined in Health-General Article, §19-401(b), Annotated Code of Maryland;

(vii) A hospice, as defined in Health-General Article, §19-901, Annotated Code of Maryland;

(viii) A kidney disease treatment facility, or the kidney disease treatment stations and services provided by or on behalf of a hospital, if the facility or the services do not include kidney transplant services or programs;

(ix) The office of one or more individuals licensed to practice dentistry under Health Occupations Article, Title 4, Annotated Code of Maryland, for the purposes of practicing dentistry;

(x) A comprehensive care facility located in Maryland; or

(xi) Other health institutions, services, or programs that may be specified as requiring a Certificate of Need under State law.

(b) "Health care facility" does not mean a hospital or related institution operated, or listed and certified, by the First Church of Christ Scientist, Boston, Massachusetts.

(4) "Health care practitioner" means an individual who is licensed, certified, or otherwise authorized under the Health Occupations Article, Annotated Code of Maryland, to provide health care services in the ordinary course of business or practice of a profession and has prescribing authority in this State.

(5) "Pharmacist" means an individual who practices pharmacy regardless of the location where the activities of practice are performed.

(6) "Pharmacy" means an establishment holding a permit under Health Occupations Article, §12-401, Annotated Code of Maryland.

(7) "Program" means the Prescription Drug Repository Program.

(8) "Repository" means a pharmacy that applies to and is designated by the Board for the purpose of:

(a) Accepting donated prescription drugs or medical supplies from a drop-off site;

(b) Inspecting donated prescription drugs or medical supplies; and

(c) Dispensing donated prescription drugs or medical supplies for use by needy individuals.

MD Health & Men. **10**. **34**.33.01

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MD Health & Men. **10**. **34**.33.02

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 33 Prescription Drug Repository Program (Refs & Annos)
.02 Eligible Drugs.

A. Prescription drugs or medical supplies may be donated at a drop-off site.

B. Prescription drugs or medical supplies may be accepted for dispensing if the prescription drugs and medical supplies are:

(1) In their original unopened and sealed packaging; or

(2) Packaged in single unit doses when the outside packaging is opened if the single unit dose packaging is undisturbed.

COMAR **10**. **34**.33.02, MD ADC **10**. **34**.33.02

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MD Health & Men. **10**. **34**.33.03

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 33 Prescription Drug Repository Program (Refs & Annos)
.03 Ineligible Drugs.

A. Prescription drugs or medical supplies may not be accepted for dispensing if the prescription drugs or medical supplies:

(1) Bear an expiration date that is less than 90 days from the date the drug is donated to ensure the potency and quality of the prescription drugs or medical supplies;

(2) Have been adulterated, according to the standards of Health-General Article, §21-216, Annotated Code of Maryland, because adulterated prescription drugs or medical supplies have been determined to be a threat to public health;

(3) Are designated controlled dangerous substances by the U.S. Drug Enforcement Administration which has determined that controlled dangerous substances may not be donated under a repository program;

(4) Require refrigeration because the potency and quality may not be guaranteed; or

(5) Have been previously compounded because compounded prescription drugs are patient specific.

B. The repository shall dispose of donated prescription drugs or medical supplies if they are not accepted into the Program for the purpose of dispensing.

COMAR **10**. **34**.33.03, MD ADC **10**. **34**.33.03

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MD Health & Men. **10**. **34**.33.04

Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
Subtitle 34 Board of Pharmacy
Chapter 33 Prescription Drug Repository Program (Refs & Annos)
.04 Donor Form.

A. A donor of a prescription drug or medical supply shall sign a form containing the following statements:

(1) That the donor is the owner or the owner's representative of the prescription drug or medical supply; and

(2) That the donor intends to voluntarily donate the prescription drug or medical supply to the Program.

B. The drop-off site shall:

(1) Require that the donor form contain:

(a) The signature of the donor or the donor's representative;

(b) Contact information of the donor or the donor's representative; and

(c) The date of donation;

(2) Require that the donor form be completed before any donation;

(3) Provide a copy of the donor form to the donor or the donor's representative; and

(4) Maintain a copy of the donor form for 5 years.

COMAR **10**. **34**.33.04, MD ADC **10**. **34**.33.04

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Chapter 33 Prescription Drug Repository Program (Refs & Annos)
.05 Drop-Off Sites.

A. In order to become a drop-off site, a pharmacy or other health care facility:

(1) Shall submit an application to the Board to be designated as a voluntary drop-off site;

(2) Shall be in good standing with the Board or the Office of Health Care Quality;

(3) May not have a final disciplinary order issued against it by a health occupations board;

(4) May not be owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations boards;

(5) Shall maintain records of donated prescription drugs or medical supplies; and

(6) Shall assign a pharmacist or other health care practitioner the responsibility to accept donated prescription drugs or medical supplies at the drop-off site.

B. Assigned Pharmacist or Other Health Care Practitioner's Responsibility. A pharmacist or health care practitioner accepting donated prescription drugs or medical supplies at a drop-off site as set forth in §A(6) of this regulation:

(1) May not delegate acceptance of donated prescription drugs or medical supplies;

(2) May refuse to accept hazardous prescription drugs or medical supplies for donation if the decision is based on professional judgment, experience, knowledge, or available reference materials;

(3) Shall be in good standing with the pharmacist's or health care practitioner's respective health occupations board; and

(4) Shall have fulfilled the requirements of a final disciplinary order that may have been issued against the pharmacist or health care practitioner by a health occupations board.

C. Record Requirements. A drop-off site shall:

(1) Obtain a signed donor form releasing the prescription drug or medical supplies to the Program;

(2) Provide a copy of the signed donor form to the donor; and

(3) Maintain records of signed donor forms for 5 years.

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A drop-off site shall:

(a) Place the donated prescription drug or medical supply and the donor form in a sealed bag;

(b) Store the bag containing the donated prescription drugs or medical supplies in an area accessible only to those pharmacists or health care practitioners who have been assigned the responsibility to accept the donated prescription drugs or medical supplies; and

(c) Forward the sealed bags of donated prescription drugs or medical supplies to the repository at least every 2 weeks.

(2) A drop-off site may not:

(a) Dispense donated prescription drugs or medical supplies;

(b) Resell prescription drugs or medical supplies donated to the Program;

(c) Charge a fee for accepting a donation; or

(d) Accept donated prescription drugs or medical supplies until the drop-off site applicant has been approved by the Board.

COMAR **10**. **34**.33.05, MD ADC **10**. **34**.33.05

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Title 10 Department of Health and Mental Hygiene
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Chapter 33 Prescription Drug Repository Program (Refs & Annos)

.06 Repositories.

A. In order to become a repository, a pharmacy:

(1) Shall submit an application to the Board to be designated as a repository;

(2) Shall be in good standing with the Board;

(3) May not have a final disciplinary order issued against it by the Board; and

(4) May not be owned or operated by a health care practitioner who has not fulfilled the requirements of a final disciplinary order that may have been issued against the owner or operator by a health occupations board.

B. Designated Pharmacist. A repository shall designate a pharmacist who shall:

(1) Accept donated prescription drugs or medical supplies forwarded by:

(a) A drop-off site; or

(b) A manufacturer regulated by the U.S. Food and Drug Administration;

(2) Inspect donated prescription drugs or medical supplies;

(3) Accept donated prescription drugs or medical supplies that meet the requirements of Regulations .02 and .03 of this chapter; and

(4) Obliterate from the labels of donated prescription drugs or medical supplies patient specific information for which the donated prescription drugs or medical supplies were originally dispensed when it is placed in inventory.

C. Record Requirements. A repository shall:

(1) Maintain a separate inventory of donated prescription drugs or medical supplies;

(2) Maintain separate prescription files for patients receiving donated prescription drugs or medical supplies; and

(3) Submit an annual report on its activities to the Board that includes at least information on the:

(a) Number of recipients by county;

(b) Approximate market value of the prescription drugs or medical supplies dispensed;

(c) 50 prescription drugs or medical supplies most frequently dispensed; and

(d) Total number of donations to the Program.

D. Procedures for Handling of Donated Prescription Drugs or Medical Supplies.

(1) A repository shall store donated prescription drugs or medical supplies in a secure location separate from other inventory in accordance with State and federal laws and regulations.

(2) A repository may not:

(a) Resell prescription drugs or medical supplies donated to the Program; or

(b) Establish or maintain a waiting list for prescription drugs or medical supplies dispensed by the Program.

(3) A repository may charge a fee of not more than $10 for each prescription drug or medical supply dispensed under the Program.

E. Limitations. A repository is under no obligation to obtain a prescription drug or medical supply that is not in inventory at the time of the request.

COMAR **10**. **34**.33.06, MD ADC **10**. **34**.33.06

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Chapter 33 Prescription Drug Repository Program (Refs & Annos)
.07 Procedure for Dispensing Donated Prescription Drugs or Medical Supplies.

A repository shall dispense donated prescription drugs or medical supplies in compliance with applicable federal and State laws and regulations for dispensing prescription drugs or medical supplies.

COMAR **10**. **34**.33.07, MD ADC **10**. **34**.33.07

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Title 10 Department of Health and Mental Hygiene
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.08 Procedure for Shipping Donated Prescription Drugs or Medical Supplies.

A repository shall comply with COMAR **10**. **34**.25 when shipping donated prescription drugs or medical supplies to recipients of this Program.

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Chapter 33 Prescription Drug Repository Program (Refs & Annos)
.09 Procedures for Disposing of Donated Prescription Drugs or Medical Supplies.

A. A repository shall dispose of donated prescription drugs or medical supplies that do not meet the requirements of Regulation .02 of this chapter.

B. A repository shall dispose of donated prescription drugs or medical supplies in compliance with applicable State and federal laws and regulations for disposing of prescription drugs or medical supplies.

C. A repository shall maintain records of disposal of donated prescription drugs or medical supplies.

COMAR **10**. **34**.33.09, MD ADC **10**. **34**.33.09

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.10 Determination of Patient Eligibility.

A. A recipient of this program shall be a resident of the State.

B. A health care practitioner with prescribing authority shall:

(1) Determine, at the health care practitioner's discretion, the financial need of a patient to participate in the Program; and

(2) Indicate on the patient's prescription eligibility for this Program.

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Chapter 33 Prescription Drug Repository Program (Refs & Annos)
.11 Recipient Form.

Recipients of a donated prescription drug or medical supply under this Program shall sign a Board approved form before receiving the prescription drug or medical supply to confirm that the recipient understands that:

A. The recipient is receiving prescription drugs or medical supplies that have been donated to the Program; and

B. Entities involved in the program have immunity from liability in accordance with Health-General Article, §15-607, Annotated Code of Maryland.

COMAR **10**. **34**.33.11, MD ADC **10**. **34**.33.11

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Subtitle 34 Board of Pharmacy
Chapter 33 Prescription Drug Repository Program (Refs & Annos)
.12 Record Keeping Requirements.

A. Drop-off sites and repositories shall maintain records required by this Program separately from other prescription records.

B. Drop-off sites and repositories shall maintain the following records for a minimum of 5 years:

(1) Inventory;

(2) Donor forms; and

(3) Prescription records.

COMAR **10**. **34**.33.12, MD ADC **10**. **34**.33.12

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Code of Maryland Regulations Currentness
Title 10 Department of Health and Mental Hygiene
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Chapter 34 Pharmacy Technicians (Refs & Annos)
.01 Scope.

This chapter applies to applicants for registration as pharmacy technicians and to registered pharmacy technicians.

COMAR **10**. **34**.34.01, MD ADC **10**. **34**.34.01

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Title 10 Department of Health and Mental Hygiene
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Chapter 34 Pharmacy Technicians (Refs & Annos)
.02 Definitions.

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

B. Terms Defined.

(1) “Board” means the State Board of Pharmacy.

(2) Compounding.

(a) “Compounding” means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; or

(ii) For the purpose of, or incident to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device.

(b) “Compounding” includes the preparation of drugs or devices in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

(3) Delegated Pharmacy Act.

(a) “Delegated pharmacy act” means an activity that constitutes the practice of pharmacy delegated by a licensed pharmacist under Health Occupations Article, Title 12, Subtitle 6B, Annotated Code of Maryland, and this chapter.

(b) “Delegated pharmacy act” does not include:

(i) An act within the parameters of a Drug Therapy Management contract as provided under Health

Occupations Article, Subtitle 6A, Annotated Code of Maryland;

(ii) The administration of an influenza vaccination in accordance with Health Occupations Article, §12-508, Annotated Code of Maryland, or this title;

(iii) The delegation of a pharmacy act by a registered pharmacy technician, pharmacy student, or pharmacy technician trainee;

(iv) A pharmacy activity performed by a pharmacy student in accordance with Health Occupations Article, §12-301(b), Annotated Code of Maryland; or

(v) A pharmacy activity performed by an applicant for a license to practice pharmacy, if the applicant does not perform delegated pharmacy acts for more than 10 months.

(4) “Direct supervision” means that a licensed pharmacist is physically available onsite to supervise the performance of delegated pharmacy acts.

(5) “Experiential learning rotation” means a course offered by an Accreditation Council for Pharmacy Education accredited school of pharmacy that is designed to provide pharmacy practice experiences to students seeking the doctor of pharmacy degree.

(6) “National pharmacy technician certification program” means a program approved by a Board-recognized national accrediting body.

(7) “Pharmacy student” means an individual who is enrolled as a student in a school or college of pharmacy approved by the Board or accredited by the Accreditation Council for Pharmacy Education.

(8) “Pharmacy technician trainee” means an individual engaged in a Board-approved pharmacy technician training program.

(9) “Registered pharmacy technician” means an individual who is registered with the Board to perform delegated pharmacy acts.

(10) “Registration” means, unless the context requires otherwise, a registration issued by the Board to perform delegated pharmacy acts under the direct supervision of a licensed pharmacist.

(11) “Supervision” means reviewing the work, guiding and directing the activities, and monitoring the performance of an individual.

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Chapter 34 Pharmacy Technicians (Refs & Annos)

.03 Delegated Pharmacy Acts.

A. A pharmacy technician may not:

(1) Represent themselves as a pharmacist;

(2) Dispense prescription medications when the pharmacist is not in the pharmacy;

(3) Be present in the pharmacy when the pharmacist is not physically available onsite;

(4) Provide information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;

(5) Delegate a pharmacy act that was delegated to the pharmacy technician or individual engaging in a Board-approved technician training program;

(6) Act within the parameters of a therapy management contract as provided under Health Occupations Article, Subtitle 6A, Annotated Code of Maryland;

(7) Administer an influenza vaccination in accordance with Health Occupations Article, §12-508, Annotated Code of Maryland;

(8) Provide the final verification for accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

(9) Make decisions that require a pharmacist's professional judgment;

(10) Clinically evaluate the patient's profile relative to the pharmaceuticals that have been or will be dispensed;

(11) Consult with the patient concerning the utilization of their pharmaceuticals;

(12) Accept or transcribe new prescriptions;

(13) Give or accept a transferred prescription for controlled dangerous substances;

(14) Accept a transferred prescription;

(15) Independently compound prescriptions;

(16) Administer medications; or

(17) Accept the return of prescription drugs or devices directly from a patient.

B. A pharmacy technician shall be clearly identified as such to the public.

C. When performing tasks in the prescription area, a pharmacy technician shall maintain proper:

(1) Sanitation;

(2) Hygiene;

(3) Biohazard precautions; and

(4) Infection control.

COMAR **10**. **34**.34.03, MD ADC **10**. **34**.34.03

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Title 10 Department of Health and Mental Hygiene
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Chapter 34 Pharmacy Technicians (Refs & Annos)
.04 Registration Requirements.

A. An applicant currently certified by a national pharmacy technician certification program shall:

(1) Submit to the Board a signed completed application on a form provided by the Board;

(2) Submit to the Board evidence of current certification by a national pharmacy certification program;

(3) Pay a fee as set forth in COMAR **10**. **34**.09; and

(4) Submit a request for a State Criminal History Records check.

B. An applicant that does not qualify under §A of this regulation shall:

(1) Submit to the Board a signed completed application on a form provided by the Board;

(2) Be 17 years old or older;

(3) Meet the following educational requirements:

(a) Be a high school graduate or have attained a high school equivalency diploma;

(b) Be enrolled and in good standing at a high school; or

(c) Meet the requirements of §C of this regulation;

(4) Provide satisfactory proof to the Board of the applicant's successful completion of a pharmacy technician training program approved by the Board that:

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(a) Is no longer than 6 months duration; and

(b) Includes 160 hours of work experience;

(5) Pass an examination approved by the Board as set forth in Regulation .06 of this chapter;

(6) Pay a fee as set forth in COMAR **10**. **34**.09; and

(7) Submit a request for a State Criminal History Records check.

C. An applicant who does not meet the requirements of §A or B of this regulation shall:

(1) Submit to the Board a signed application on a form provided by the Board;

(2) Comply with the age requirements as set forth in §B of this regulation;

(3) Provide written verification from the pharmacy permit holder that the applicant has worked in the pharmacy area of a pharmacy operated by the same pharmacy permit holder continuously since January 1, 2006;

(4) Provide written verification from the pharmacist who has supervised the applicant for at least 6 months that the applicant has performed competently;

(5) Pay a fee as set forth in COMAR **10**. **34**.09; and

(6) Submit a request for a State Criminal History Records check.

D. The Board of Pharmacy shall provide the pharmacy technician with a registration card and pocket identification card upon initial registration and renewal.

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Chapter 34 Pharmacy Technicians (Refs & Annos)
.05 Pharmacy Students.

A. Pharmacy students who are practicing in a pharmacy as part of a school of pharmacy sanctioned experiential learning rotation are not subject to the registration requirements of Regulation .04 of the chapter.

B. Pharmacy students performing pharmacy technician functions and who are not in a school of pharmacy sanctioned experiential learning program shall:

(1) Submit to the Board a signed completed application for exemption from the registration requirements of Regulation .04 of this chapter; and

(2) Comply with the following conditions:

(a) Provide verification of enrollment and good standing at an accredited school of pharmacy;

(b) Pay an exemption fee as set forth in COMAR **10**. **34**.09; and

(c) Submit a request for a State Criminal History Records check.

C. A pharmacy student may begin work under this exemption upon compliance with §B(1) and (2) of this regulation.

D. Pharmacy students granted an exemption from registration requirements of Regulation .04 of this chapter:

(1) Are not subject to renewal requirements as set forth in Regulation .08 of this chapter; and

(2) Shall provide to the Board proof of enrollment in good standing at an accredited school of pharmacy once a year and upon request of the Board.

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Chapter 34 Pharmacy Technicians (Refs & Annos)

.06 Standards for Pharmacy Technician Training Programs.

A. Minimum Standards.

(1) Pharmacy technician training programs shall, at a minimum, cover the following areas of pharmacy practice:

(a) Roles and responsibilities of the pharmacy technician;

(b) Knowledge of prescription medications;

(c) Knowledge of strengths or dose, dosage forms, physical appearance, routes of administration, and duration of drug therapy;

(d) The dispensing process;

(e) Pharmaceutical calculations;

(f) Interacting with patients;

(g) Third party prescriptions;

(h) Extemporaneous compounding;

(i) Requirements and professional standards for:

(i) Preparing;

(ii) Labeling;

(iii) Dispensing;

(iv) Storing;

(v) Prepackaging;

(vi) Distributing; and

(vii) How medications are administered;

(j) Confidentiality;

(k) Drugs used to treat the following indications:

(i) Hypertension;

(ii) Antihyperlipidemia;

(iii) Diabetes mellitus;

(iv) Arthritis;

(v) Gastrointestinal disorders;

(vi) Asthma and allergy; and

(vii) Infectious diseases;

(l) Federal and State laws and regulations governing the practice of pharmacy; and

(m) Knowledge of special dosing considerations for pediatric and geriatric populations.

(2) Pharmacy technician training programs may be offered by:

(a) Pharmacy employers;

(b) Nationally recognized pharmacy technician training programs;

(c) Accredited educational institutions pharmacy technician programs;

(d) Pharmacy technician programs approved by the Maryland State Department of Education and the Maryland Higher Education Commission; and

(e) Pharmacy technician training programs offered by the U.S. Armed Forces.

(3) Training programs may not be longer than 6 months.

(4) Training programs shall include 160 hours of work experience.

B. Board Approval of Pharmacy Technician Training Programs.

(1) A program shall submit an application on a form provided by the Board.

(2) A program shall provide the Board with the course outline and any other information requested by the Board.

(3) Any changes in course content shall require notification and approval from the Board.

(4) The Board shall have final approval of a pharmacy technician training program.

(5) The Board may withdraw approval of a program if the Board finds that the program is in violation of this chapter.

(6) The Board shall approve pharmacy technician training programs offered by the U.S. Armed Forces.

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.07 Standards for Examination Approval.

The Board shall approve examinations which have:

A. Content criteria set forth in Regulation .06 of this chapter;

B. A minimum of 100 multiple choice questions;

C. Sufficient additional questions so that the examination questions may be rotated twice a year; and

D. A passing score of 75 percent or higher.

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Chapter 34 Pharmacy Technicians (Refs & Annos)
.08 Renewal Requirements.

A. The pharmacy technician's registration shall expire on the last day of the birth month following 1 year after initial registration.

B. Following initial registration, a pharmacy technician's registration:

(1) Expires on the date set by the Board unless it is renewed for an additional term; and

(2) May not be renewed for a term longer than 2 years.

C. At least 1 month before the registration expires, the Board shall issue a renewal notice to the pharmacy technician registrant that states:

(1) The date on which the current registration expires;

(2) The date by which the renewal application shall be received by the Board for the renewal to be issued and mailed before the registration expires; and

(3) The amount of the renewal fee.

D. The registrant may renew the registration for an additional term of 2 years if the registrant:

(1) Otherwise is entitled to be registered;

(2) Pays to the Board a renewal fee set forth in COMAR **10**. **34**.09; and

(3) Submits to the Board:

(a) A renewal application on the form that the Board requires; and

(b) Satisfactory evidence of compliance with the continuing education requirements set forth in Regulation .09 of this chapter.

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.09 Continuing Education.

A. Requirements.

(1) A pharmacy technician registered to practice in Maryland shall earn 20 hours of approved continuing pharmaceutical education within the 2-year period immediately preceding the registrant's renewal application.

(2) For the first renewal period during which continuing education is mandatory for a pharmacy technician, the Board of Pharmacy shall require only 10 hours of continuing education requirements.

(3) A pharmacy technician shall:

(a) Attest to the fact that the pharmacy technician has completed the continuing pharmacy technician education requirement on the required form; and

(b) Retain supporting documents for inspection by the Board for 4 years after the date of renewal for which the continuing education credits were used.

B. Accredited Continuing Education Providers.

(1) The following providers are approved for any programs they offer which otherwise qualify for continuing education credit:

(a) Accreditation Council on Pharmaceutical Education (ACPE);

(b) All schools of pharmacy accredited by the American Association of Colleges of Pharmacy (AACP); and

(c) Out-of-State providers approved by a state board of pharmacy.

(2) Procedures for Approval of Additional Programs.

(a) Other providers shall initially request Board approval for individual programs.

(b) An approved program is valid for a 2-year period.

(c) The approved provider shall submit to the Board changes to the program that differ from the initial submission of information for Board approval.

(d) Failure to submit to the Board changes to an approved program may result in the Board withdrawing approval of the program.

(3) Providers of continuing education shall furnish a certificate of completion to participants who qualify that includes the:

(a) Name of the participant;

(b) Name of the provider;

(c) Description of course work;

(d) Number of hours;

(e) Date of completion; and

(f) Program identification number or provider number on the certificate.

C. Miscellaneous.

(1) Credits may not be carried over from one continuing education period to another.

(2) The Board of Pharmacy may grant an exception from the continuing education requirements if the pharmacy technician presents evidence that failure to comply was due to circumstances beyond the pharmacy technician's control.

(3) Falsifying continuing education records is grounds for disciplinary action under Health Occupations Article, §12-6B-09(2) and (3), Annotated Code of Maryland.

(4) If the Board provides a form for information, the pharmacy technician shall use the form to supply the requested information to the Board.

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Chapter 34 Pharmacy Technicians (Refs & Annos)
.10 Reinstatement.

A. A pharmacy technician whose Maryland registration expired less than 2 years before applying for reinstatement shall:

(1) Complete 20 hours of continuing education; and

(2) Pay to the Board the reinstatement fee established by the Board in COMAR **10**. **34**.09.

B. A pharmacy technician whose Maryland registration expired more than 2 years before applying for reinstatement, shall:

(1) Complete 20 hours of continuing education;

(2) Pay to the Board the reinstatement fee established by the Board in COMAR **10**. **34**.09; and

(3) Pass a Board-approved exam.

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Chapter 34 Pharmacy Technicians (Refs & Annos)
.11 Reciprocity.

A. An individual applying to register as a pharmacy technician by reciprocity shall:

(1) Submit to the Board an application on a form approved by the Board;

(2) Pay to the Board the fee set forth in COMAR **10**. **34**.09; and

(3) Submit a request for a State Criminal History Records check.

B. An individual applying to register as a pharmacy technician by reciprocity shall:

(1) Submit to the Board evidence of the following:

(a) Registration in another state under requirements similar to the registration requirements of this chapter; and

(b) Evidence of being in good standing in the state or states of current registration; or

(2) Evidence of having worked as a pharmacy technician in another state for at least 6 months.

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Chapter 35 Infusion Pharmacy Services in an Alternate Site Care Environment (Refs & Annos)
.01 Definitions.

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

B. Terms Defined.

(1) “Alternate site care environment” means the location where the patient is receiving infusion therapy other than an inpatient hospital setting.

(2) “Compounding worksheet” means a document or electronic record which:

(a) Specifies instructions for a specific compounded parenteral medication;

(b) Documents the manufacturer's:

(i) Ingredients;

(ii) Lot numbers; and

(iii) Expiration dates; and

(c) Includes a copy of the prescription label.

(3) Delegated Pharmacy Act.

(a) “Delegated pharmacy act” means an activity that constitutes the practice of pharmacy delegated by a licensed pharmacist under Health Occupations Article, Title 12, Subtitle 6B, Annotated Code of Maryland, and this chapter.

(b) “Delegated pharmacy act” does not include:

(i) An act within the parameters of a Drug Therapy Management contract as provided under Health Occupations Article, Title 12, Subtitle 6A, Annotated Code of Maryland;

(ii) The administration of an influenza vaccination in accordance with Health Occupations Article, §12-508, Annotated Code of Maryland, or Health Occupations Article, Title 12, Annotated Code of Maryland;

(iii) The delegation of a pharmacy act by a pharmacy technician, pharmacy student, or pharmacy technician trainee;

(iv) A pharmacy activity performed by a pharmacy student in accordance with Health Occupations Article, §12-301(b), Annotated Code of Maryland;

(v) A pharmacy activity performed by an applicant for a license to practice pharmacy, if the applicant does not perform delegated pharmacy acts for more than 10 months; or

(vi) The performance of other functions prohibited in regulations adopted by the Board.

(4) “End of therapy” means the conclusion of parenteral infusion therapy as ordered by the prescriber.

(5) “Infusion nurse” means a registered nurse providing infusion therapy as defined in COMAR 10.27.20.02B in an alternate site environment.

(6) “Infusion pharmacy” means a pharmacy that provides pharmaceutical care to patients receiving parenteral therapy in an alternate site care environment.

(7) “Licensed authorized prescriber of record” means an individual with the authority to prescribe and monitor a patient's parenteral infusion therapy for the duration of the patient's infusion therapy.

(8) “Parenteral infusion access device” means, but is not limited to, intravenous, subcutaneous, intrathecal, epidural, or peripheral nerve catheter device through which parenteral medications may be administered.

(9) “Patient care plan” means an individualized care plan that reflects the patient's parenteral infusion therapy pharmaceutical monitoring plan aimed at optimizing the outcome of therapy while minimizing untoward effects from the medication.

(10) “Patient triage form” means a written or electronic tool used by a clinician or by a registered pharmacy technician when communicating with a patient, a patient's caregiver, or an infusion nurse to document the patient's current status, including but not limited to, the patient's response to therapy, medication changes or

adverse reactions, and pain level.

(11) “Permit holder” means a person, corporation, or other legal entity authorized by the Board to establish and operate a pharmacy.

(12) “Pharmacy technician” means an individual who is registered with the Board to perform delegated pharmacy acts.

(13) “Pharmacist” means an individual who is licensed to practice pharmacy.

(14) “Supervision” means the on-site provision of management, direction, oversight and review of tasks assigned to personnel.

COMAR **10**. **34**.35.01, MD ADC **10**. **34**.35.01

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Chapter 35 Infusion Pharmacy Services in an Alternate Site Care Environment (Refs & Annos)
.02 Permit Holder Responsibilities.

The permit holder shall:

A. Develop and maintain a policy and procedure manual which establishes the pharmacy's policies and standard operating procedures related to the provision of infusion therapy services;

B. Ensure that an annual review of the policy and procedure manual is performed by a qualified clinician or clinicians to assure that the policies and procedures meet the current standards of practice and regulatory requirements;

C. Ensure that there is a process to verify the name, address, and contact information of the licensed authorized prescriber of record before initiation of therapy;

D. Establish and maintain a training program which includes, but is not limited to, the requirements set forth in Regulation .07 of this chapter;

E. If the infusion pharmacy is performing sterile compounding, ensure compliance with COMAR **10**. **34**.19;

F. If the infusion pharmacy outsources sterile compounding to another pharmacy, confirm that the secondary pharmacy is appropriately licensed and in compliance with COMAR **10**. **34**.04 and COMAR **10**. **34**.19;

G. Assign a supervising pharmacist to provide oversight of the facility and operations as specified in Regulation .03 of this chapter;

H. Ensure adequate supervision to unlicensed personnel;

I. Limit access to the infusion pharmacy area to authorized personnel;

J. Secure the facility and patient records in compliance with federal and State laws and regulations; and

MD Health & Men. **10**. **34**.35.02

K. Develop and implement a written performance improvement program as set forth in Regulation .08 of this chapter.

COMAR **10**. **34**.35.02, MD ADC **10**. **34**.35.02

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.03 Supervising Pharmacist Responsibilities.

The supervising pharmacist or the supervising pharmacist's designee shall ensure compliance with:

A. State and federal regulations;

B. Infusion pharmacy practice standards:

(1) As set forth in this chapter; and

(2) As established by nationally recognized professional organizations and accrediting bodies as appropriate;

C. The infusion pharmacy's policies and procedures manual;

D. An established training program; and

E. An established performance improvement program.

COMAR **10**. **34**.35.03, MD ADC **10**. **34**.35.03

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.04 Pharmacist Responsibilities.

A. A pharmacist in an infusion pharmacy shall adhere to the policies and procedures set forth in Regulation .06 of this chapter.

B. A pharmacist shall:

(1) Provide infusion therapy services in accordance with:

(a) Orders issued by a licensed authorized prescriber of record; and

(b) Where applicable, protocols issued by a licensed authorized prescriber of record.

(2) Perform and document initial and ongoing assessments of the appropriateness of infusion therapy using the following information:

(a) Patient demographics including:

(i) Name;

(ii) Address;

(iii) Telephone number;

(iv) Gender; and

(v) Date of birth;

(b) Emergency contact information;

(c) Diagnoses, including:

(i) Diagnosis being treated; and

(ii) Concurrent conditions, including pregnancy and lactation status if applicable;

(d) Medical history;

(e) Allergies;

(f) If applicable, height;

(g) Weight;

(h) Parenteral medication orders, including length of therapy;

(i) Parenteral infusion access device:

(i) Location;

(ii) Type; and

(iii) If available, date of placement;

(j) Ongoing medication profile review and reconciliation at end of therapy;

(k) First dose status;

(l) Caregiver information including, but not limited to:

(i) Name;

(ii) Address;

(iii) Phone number; and

(iv) Relationship to patient;

(m) If applicable, contact information for other agencies or individuals involved in the patient's home care;

(n) Documented applicable medical and social factors and functional limitations which may affect infusion therapy including but not limited to:

(i) Language;

(ii) Sight;

(iii) Hearing;

(iv) History of IV drug abuse;

(v) History of drug or alcohol abuse; or

(vi) Other physical or mental limitations; and

(o) If applicable to therapy, baseline labs;

(3) Create a patient care plan specific to the patient's:

(a) Diagnosis;

(b) Prescribed therapy; and

(c) Concurrent conditions;

(4) When compounding sterile preparations, comply with COMAR **10**. **34**.19;

(5) If sterile compounding is outsourced, comply with COMAR **10**. **34**.04;

(6) As applicable, retrieve and assess lab values and other monitoring parameters;

(7) Document in the patient chart:

(a) New prescription orders;

(b) Changes in prescription orders;

(c) Information obtained from the patient or caregiver; and

(d) Other necessary information obtained from the:

(i) Patient;

(ii) Caregiver;

(iii) Infusion nurse;

(iv) Licensed authorized prescriber of record; or

(v) Other sources relevant to patient care;

(8) Verify prescription label accuracy;

(9) Communicate as appropriate, throughout the patient's therapy with the:

(a) Licensed authorized prescriber of record or agent of the licensed authorized prescriber of record;

(b) Patient's infusion nurse;

(c) Patient; and

(d) Caregiver; and

(10) Review therapy-specific considerations such as pain and nutrition status.

COMAR **10**. **34**.35.04, MD ADC **10**. **34**.35.04

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Chapter 35 Infusion Pharmacy Services in an Alternate Site Care Environment (Refs & Annos)
.05 Support Personnel.

A. Pharmacy Technicians.

(1) A pharmacist working in an infusion pharmacy may delegate pharmacy acts to a pharmacy technician in accordance with COMAR **10**. **34**.34.

(2) A pharmacy technician working in an infusion pharmacy may not perform delegated pharmacy acts as set forth in COMAR **10**. **34**.34.03.

(3) A pharmacy technician working in an infusion pharmacy shall:

(a) Communicate immediately to the pharmacist reported changes in:

(i) Patient condition;

(ii) Patient medication list; and

(iii) Allergies; and

(b) Obtain pharmacist approval before processing refills.

(4) A pharmacy technician working in an infusion pharmacy may not:

(a) Except as provided in COMAR **10**. **34**.34, accept or transcribe a new or change verbal order from an licensed authorized prescriber of record or the licensed authorized prescriber of record's agent;

(b) Perform the clinical assessment of a patient;

(c) Communicate clinical matters except as required in §A(3)(a) of this regulations;

(d) Provide therapy-related direction to a patient or caregiver; and

(e) Create a patient care plan specific to a patient's therapy.

B. Unlicensed Personnel.

(1) Unlicensed personnel working in an infusion pharmacy under the supervision of a pharmacist may perform operational support which the unlicensed personnel have been trained to adequately perform in accordance with COMAR **10**. **34**.21.

(2) Unlicensed personnel shall be appropriately trained to perform the following tasks, as applicable, including but not limited to:

(a) Schedule delivery dates based on;

(i) Patient supply needs;

(ii) Patient or caregiver availability; and

(iii) If applicable, geographic delivery zones;

(b) Create delivery tickets;

(c) Communicate with the infusion nurse or pharmacist concerning supply needs and problems; and

(d) Clean, test, and maintain patient-use equipment.

(3) Unlicensed personnel working in an infusion pharmacy shall refer clinical questions or concerns reported by patients or caregivers immediately to the pharmacist.

(4) Unlicensed personnel may not perform delegated pharmacy acts.

COMAR **10**. **34**.35.05, MD ADC **10**. **34**.35.05

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Chapter 35 Infusion Pharmacy Services in an Alternate Site Care Environment (Refs & Annos)

.06 Minimum Requirements for Policies and Procedures.

The policies and procedures shall:

A. Be congruent with State regulations and standards of care from accrediting bodies and professional organizations; and

B. Address:

(1) Personnel:

(a) Training and Orientation;

(b) Duties; and

(c) Qualifications;

(2) Security of the facility;

(3) Standards of patient care;

(4) Infection control;

(5) Initial and ongoing home safety assessments;

(6) The provision of patient or caregiver education including, but not limited to:

(a) Drug and therapy administration-specific information and precautions;

(b) Reporting adverse drug reactions;

(c) Reporting side effects;

(d) Infusion pharmacy contact information;

(e) Emergency measures related to:

(i) Changes in patient condition requiring medical intervention; and

(ii) Events which may delay or prevent delivery of pharmaceuticals or nursing care; and

(f) Equipment use and safety.

(7) Patient care operations, including but not limited to:

(a) If applicable, pharmacist checking procedures related to order entry and compounding accuracy;

(b) Therapy-specific monitoring parameters for:

(i) Laboratory testing;

(ii) Appropriate frequency of testing; and

(iii) Patient follow-up; and

(c) Pump, or other patient-use equipment, between-patient cleaning, testing, and preventive maintenance, which include specific:

(i) Procedures and documentation of cleaning, testing and preventive maintenance for patient equipment according to manufacturer's guidelines; and

(ii) Frequencies for all equipment maintenance activities;

(8) Delivery arrangements;

(9) Patient confidentiality and the Health Insurance Portability and Accountability Act, 45 CFR Parts 160 and 164; and

(10) Availability of a pharmacist on call after-hours to respond to:

(a) Pharmacy related patient or caregiver inquiries; and

(b) Medication or supply needs.

COMAR **10**. **34**.35.06, MD ADC **10**. **34**.35.06

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.07 Training Requirements.

A. Personnel shall be trained in the following areas where appropriate:

(1) Patient rights and responsibilities;

(2) Patient safety;

(3) Performance improvement program;

(4) Universal precautions which are incorporated by reference in COMAR 10.06.01.01-1;

(5) Warehouse and equipment orientation;

(6) Waste management;

(7) Handling hazardous substances;

(8) Policies and procedures;

(9) Recognizing signs of patient abuse and neglect;

(10) Recognizing signs of IV drug abuse;

(11) Customer service and cultural sensitivity training;

(12) Emergency policies and procedures which support the continuum of patient care during natural or manmade disasters; and

(13) Patient confidentiality and the Health Insurance Portability and Accountability Act, 45 CFR Parts 160

and 164.

B. A pharmacist shall be trained and evaluated in the following areas, including but not limited to:

(1) Clinical management of therapies and disease states managed by the infusion pharmacy services, including but not limited to:

(a) Specific dosing and monitoring protocols;

(b) Care planning;

(c) Lab value ranges; and

(d) Side effects;

(2) Pump use and programming;

(3) Parenteral infusion access devices and therapy-specific appropriateness by device;

(4) Supplies by therapy and device;

(5) Accurate set-up of compounding worksheet instructions;

(6) Pharmacist functions on computer systems;

(7) Documentation;

(8) If performing sterile compounding, COMAR **10**. **34**.19;

(9) Medication storage;

(10) IV compatibility and stability;

(11) Calculations to ensure:

(a) IV dose appropriateness; and

(b) Compounding accuracy, if applicable; and

(12) On-call requirements and procedures for handling after-hours care.

C. A pharmacy technician obtaining clinical information shall be trained and evaluated in the following areas, including but not limited to:

(1) Pharmacy technician functions on computer systems;

(2) Parenteral infusion access devices

(3) Supplies specific to therapy and device

(4) Storage and shipping protocols;

(5) Pharmaceutical calculations for IV compounding, if applicable;

(6) Patient triage forms -therapy-specific training and communication with the pharmacist as specified in Regulation .05A(3)(a) of this chapter; and

(7) Documentation of:

(a) Communication with patients or caregiver; and

(b) Delivery scheduling.

D. Unlicensed personnel shall be trained and evaluated in the following areas as applicable:

(1) Insurance pre-authorization;

(2) Billing;

(3) Delivery procedures;

(4) Supplies;

(5) Picking and packing of supplies;

(6) Drug storage;

(7) Shipping protocols; and

(8) Cleaning, testing, and maintenance of patient-use equipment according to manufacturers' specifications.

COMAR **10**. **34**.35.07, MD ADC **10**. **34**.35.07

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.08 Performance Improvement Program.

A. The performance improvement program shall consist of:

(1) A committee which:

(a) Consists of representation of personnel and varied areas of job responsibility; and

(b) Is responsible for analysis of data, reporting trends and corrective actions; and

(c) Meets at least quarterly;

(2) Quality assurance and performance improvement monitoring parameters;

(3) Documentation requirements for:

(a) Established monitoring parameters;

(b) Trend analyses; and

(c) Retention of committee meeting minutes for 3 years;

(5) Documentation of tracking, trending, analyzing, resolving, and developing corrective action plans as appropriate for:

(a) Medication errors;

(b) Adverse drug reactions; and

(c) Equipment malfunctions;

(6) Reporting of adverse events to regulatory and standard-setting bodies as applicable to State and federal regulations;

(7) Documentation and resolution of patient care issues involving:

(a) Incorrect equipment, supplies, or medications;

(b) Delays in delivery of care;

(c) Missed doses;

(d) Patient infections;

(e) Failures in after-hours care; and

(f) Patient, caregiver, or health care provider complaints;

(8) Documentation of patient outcomes;

(9) Recall management;

(10) Patient compliance monitoring; and

(11) Staff training and competency compliance.

B. The permit holder shall review the performance improvement program at a minimum of every 3 years.

COMAR **10**. **34**.35.08, MD ADC **10**. **34**.35.08

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Chapter 35 Infusion Pharmacy Services in an Alternate Site Care Environment (Refs & Annos)
.09 Discontinuation of Infusion Therapy.

A. If not addressed in the initial order, the infusion pharmacy shall verify an end of therapy order.

B. The infusion pharmacist shall:

(1) Communicate with the licensed authorized prescriber of record or agent of the prescriber of record to verify:

(a) An end of therapy order, if not addressed in the initial order; and

(b) Parenteral infusion access device disposition, including orders for removal or line maintenance; and

(2) Forward the most current medication list to:

(a) The licensed authorized prescriber of record; and

(b) To the patient or caregiver.

C. If appropriate, the infusion pharmacy shall arrange with the patient or caregiver for pick-up of medical equipment.

COMAR **10**. **34**.35.09, MD ADC **10**. **34**.35.09

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Chapter 35 Infusion Pharmacy Services in an Alternate Site Care Environment (Refs & Annos)
.10 Reference Materials.

A. An infusion pharmacy shall maintain an adequate reference library to enable it to prepare and dispense infusion therapy properly.

B. In addition to the requirements of COMAR **10**. **34**.07.03, an infusion pharmacy's reference library shall include:

(1) Material Safety Data Sheets (MSDSs);

(2) IV compatibility references;

(3) Stability and extended stability references;

(4) Websites and electronic references authored by established medical publishers recognized within the field of infusion pharmacy practice as a supplement to its printed library;

(5) Pediatric dosing reference, if applicable; and

(6) Appropriate clinical references for the population served.

COMAR **10**. **34**.35.10, MD ADC **10**. **34**.35.10

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Chapter 36 Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes (Refs & Annos)

.01 Scope.

This chapter applies to pharmacies and licensed pharmacists serving assisted living programs or group homes as defined in Regulation .02 of this chapter, except for pharmacies providing only emergency services for assisted living programs or group homes.

COMAR **10**. **34**.36.01, MD ADC **10**. **34**.36.01

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Chapter 36 Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes (Refs & Annos)

.02 Definitions.

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

B. Terms Defined.

(1) Assisted Living Program.

(a) “Assisted living program” means a residential or facility-based program that provides housing and supportive services, supervision, personalized assistance, health-related services, or a combination of these services 24 hours a day, 7 days a week, to meet the needs of individuals who are unable to perform, or who need assistance in performing, the activities of daily living or instrumental activities of daily living, in a way that promotes optimum dignity and independence for the individuals.

(b) “Assisted living program” does not include:

(i) A nursing home or comprehensive care facility, as defined under Health-General Article, §19-301, Annotated Code of Maryland;

(ii) A State facility, as defined under Health-General Article, §10-101, Annotated Code of Maryland;

(iii) A program licensed or approved by the Department under Health-General Article, Title 7 or Title 10, Annotated Code of Maryland;

(iv) A hospice care program licensed by the Department under Health-General Article, Title 19, Annotated Code of Maryland;

(v) Services provided by family members;

(vi) Services provided by a licensed residential service agency or licensed home health agency in an individual's own home; or

(vii) A Certified Adult Residential Environment Program that is certified by the Department of Human Resources under Article 88A, §140, Annotated Code of Maryland.

(2) “Chart order” means a lawful order entered on the chart or a medical record of a resident of an assisted living program or group home by an authorized prescriber or the authorized prescriber's designated agent for a drug or device.

(3) “Group home” means a residence owned, leased, or operated by a licensed group home provider that:

(a) Provides residential services for individuals who, because of a developmental disability, require specialized living arrangements;

(b) Admits at least two, but not more than eight individuals; and

(c) Provides 10 or more hours of supervision per week.

(4) “Interim box” means a tamper evident container or an electronic system holding minimal quantities of medications:

(a) Agreed upon by the appropriate committee of the assisted living program; and

(b) Intended to expedite immediate initiation of emergency or nonemergency dosing until the pharmacy is able to provide a regular supply.

(5) “Licensed pharmacist” means 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:

(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;

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

(c) Packaged as further defined in Regulation .07 of this chapter.

(7) “Pharmaceutical services” means the care within practice standards, laws, regulations, and guidelines which is afforded by a licensed pharmacist to the residents of an assisted living program or group home.

(8) “Pharmacy area” means that portion of the licensed pharmacy where over-the-counter medications and other products requiring a prescription by federal or State law are stored and where the prescriptions are compounded or prepared.

(9) “Registered pharmacy technician” means an individual who is registered with the Board to perform delegated pharmacy acts.

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

(b) Knowledgeable in, and thoroughly familiar with, the specialized functions of an assisted living program's or group home's pharmaceutical services; and

(c) Responsible for and in full and actual charge of the pharmacy and its personnel.

(11) “Verbal order” means a directive that is orally communicated to a licensed pharmacist to accept a prescription order by a person who is authorized to communicate a prescription.

(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.

COMAR **10**. **34**.36.02, MD ADC **10**. **34**.36.02

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.03 Policies and Procedures.

The permit holder shall establish and operate under a policies and procedures manual which:

A. Complies with this chapter;

B. Defines the scope and method of pharmacy services provided to the residents of the assisted living program or group home;

C. Determines under what circumstances 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:

(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 assisted living program;

F. Is provided to:

(1) The personnel of the pharmacy;

(2) The assisted living program;

(3) Group home; and

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

G. Is in a form that is:

(1) Written or electronic; and

(2) Readily retrievable.

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Chapter 36 Pharmaceutical Services to Residents in Assisted Living Programs and Group Homes (Refs & Annos)

.04 Personnel.

A. The permit holder shall appoint a responsible pharmacist who shall:

(1) Be 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;

(2) Be responsible for reviewing the policies and procedures manual of the pharmacy annually and revising it as necessary;

(3) Be responsible for the safe and efficient dispensing, delivery, and control of, and be accountable for, medications and devices dispensed or distributed by the pharmacy;

(4) Work in cooperation with the other professional staff of the assisted living program or group home in meeting the responsibilities set forth in Regulation .06 of this chapter and in ordering, storing, and accounting for pharmaceutical materials; and

(5) Develop a process for the pharmacy to be notified of medications which have been discontinued.

B. Staff.

(1) The permit holder:

(a) May employ registered pharmacy technicians as required to provide pharmaceutical services to the residents of the assisted living program or group home; and

(b) Shall provide policies and procedures that specify the duties that may be performed by registered pharmacy technicians under the supervision of a licensed pharmacist and the duties that may be performed only by a licensed pharmacist.

(2) The permit holder may employ unlicensed personnel to provide operational support as defined in COMAR **10**. **34**.21.02B.

COMAR **10**. **34**.36.04, MD ADC **10**. **34**.36.04

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.05 Physical Requirements.

A. Storage. The permit holder or designee shall ensure that medications and supplies within the pharmacy are properly stored according to the manufacturer's specifications and State and federal laws and regulations with respect to:

(1) Sanitation;

(2) Temperature;

(3) Light;

(4) Ventilation;

(5) Segregation; and

(6) Security.

B. Equipment and Materials.

(1) The permit holder or designee shall ensure that the pharmacy contains as appropriate to the level of services provided:

(a) Equipment;

(b) Supplies; and

(c) Physical facilities for proper compounding, preparation, and dispensing of medications as outlined in COMAR **10**. **34**.19.

(2) The permit holder 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 permit holder or designee shall ensure that no individual enters the pharmacy area unless a licensed pharmacist is on duty.

(2) The permit holder or designee shall ensure compliance with COMAR **10**. **34**.05.

COMAR **10**. **34**.36.05, MD ADC **10**. **34**.36.05

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.06 Medication and Device Distribution and Pharmaceutical Services.

A. The responsible pharmacist shall be accountable for, at a minimum:

(1) The preparation of medications compounded in the pharmacy as applicable;

(2) The proper preparation, storage, and distribution of compounded sterile preparations according to COMAR **10**. **34**.19 to the extent that the functions are performed at the pharmacy;

(3) The packaging and labeling of medications;

(4) Records of transactions of the pharmacy as may be required by applicable law and as may be necessary to maintain accurate control over and accountability for pharmaceuticals;

B. In addition to §A of this regulation, the responsible pharmacist may:

(1) Participate in those aspects of the assisted living program's or group home's quality assurance improvement program, if such program exists, which relate to pharmaceutical care and effectiveness; and

(2) Implement the policies and decisions of the appropriate committee or committees of the assisted living program or group home related to these regulations and to other regulations of the assisted living program or group home.

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.07 Medication Packaging.

A. A licensed pharmacist shall verify the:

(1) Selection of medication to be packaged; and

(2) Completed packaging of medication performed by registered pharmacy technicians for the following:

(a) Accuracy;

(b) Completeness;

(c) Appropriateness; and

(d) Compliance with the U.S. Food and Drug Administration and current United States Pharmacopeia approved packaging.

B. A 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;

(3) Name of the pharmacy; and

(4) Expiration date of the medication.

C. Unless a 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 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 in a master log if kept with respect to drugs that are 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;

(6) Quantity packaged;

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

(8) Manufacturer's expiration date;

(9) Date of packaging;

(10) Name of pharmacy technician packaging; and

(11) Name and initials of verifying licensed pharmacist.

E. Packaged from Another Pharmacy. A licensed pharmacist may package medication received directly from another pharmacy licensed in Maryland or operated by the government of the United States provided that:

(1) A licensed pharmacist determines that the 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 time it was dispensed by the original pharmacy and received by the packaging pharmacy;

(2) A licensed pharmacist packages and dispenses all at one time the entire quantity of the prescription medications received from another pharmacy for packaging;

(3) The manufacturer's name is present on the container received from the other pharmacy; and

(4) A licensed pharmacist maintains a master log that includes the following information:

(a) Name of the drug;

(b) Lot number assigned by the packaging pharmacy;

(c) Strength;

(d) Manufacturer;

(e) Name, address, and telephone number of the original dispensing pharmacy;

(f) Prescription number from the original dispensing pharmacy;

(g) Quantity packaged;

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

(i) Date of packaging;

(j) Name of pharmacy technician packaging;

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

(l) Name of the resident.

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.08 Labeling of Resident Medications.

A. A licensed pharmacist shall ensure that medications dispensed by the pharmacy and intended for use within an assisted living program or group home 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, or consumer, as appropriate;

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

(6) Name of the prescriber;

(7) Expiration date of the drug;

(8) Required precautionary information regarding controlled substances;

(9) Directions for use as set forth in the:

(a) Medication administration record; and

(b) Prescriber's orders; and

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

B. A licensed pharmacist shall ensure that medication provided per dosing period in a single container, slot, blister package, any other method of delivering an entire single dosing unit, or as part of a multi-dose dispensing package, are labeled with at least the following:

(1) Drug name;

(2) Drug strength;

(3) Name of manufacturer;

(4) Name of the resident, patient or consumer, as appropriate;

(5) Lot number, unless prepared extemporaneously;

(6) Directions for use as set forth in the:

(a) Medication administration record; or

(b) Prescriber's orders; and

(7) Expiration date.

C. 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.

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.09 Drug Control and Accountability.

A. 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) A licensed pharmacist determines that procedures are in place 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.

B. 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 resident.

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

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

E. Interim Box. An interim box may be provided to an assisted living program by a permit holder if:

(1) A licensed nurse is present on site 24 hours a day, 7 days a week;

(2) The assisted living program is compliant with the pharmacy's policies and procedures regarding usage of the interim box under Regulation .03 of this chapter; and

(3) The contents of the interim box are part of the pharmacy inventory until administered.

F. Prescriber Orders.

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

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

(a) The full name of the resident, patient, or consumer, as appropriate;

(b) The date of issuance;

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

(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, prescription requirements as described in 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.

(4) The licensed pharmacist shall document immediately a verbal order in writing.

(5) A licensed pharmacist may receive a verbal order:

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

(b) By a voice messaging system.

G. Controlled Dangerous Substances.

(1) Drug Accountability. The permit holder shall ensure that personnel employed by the pharmacy abide by the laws and regulations as defined in:

(a) Health-General Article, Title 27, Annotated Code of Maryland; and

(b) 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.

H. Drug Recalls. The licensed pharmacist shall develop and implement a recall procedure that can be readily activated to ensure that drugs which have been recalled are:

(a) Returned to the pharmacy;

(b) Sequestered; and

(c) Handled as appropriate to the level of the recall.

I. Adverse Drug Reactions.

(1) The licensed pharmacist shall participate on the appropriate committee, if applicable of the assisted living program or group home, to establish procedures to report and record adverse drug reactions.

(2) The licensed pharmacist shall ensure the procedures established include, at a minimum:

(a) The reporting of significant adverse drug reactions to the attending prescriber or designee and other parties as specified by the appropriate committee of the assisted living program or group home; and

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

J. Records and Reports. The licensed pharmacist shall maintain records and reports as may be required by law, this chapter, and the policies of the assisted living program or group home.

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.10 Quality Management.

A. The responsible pharmacist, in cooperation with the appropriate committee of the assisted living program, shall develop procedures for an ongoing quality management program that includes a mechanism for reviewing and evaluating pharmaceutical services as defined in this chapter and COMAR 10.07.14.29 where appropriate.

B. The responsible pharmacist, in cooperation with the appropriate committee of the group home, if applicable, may develop procedures for an ongoing quality management program that includes a mechanism for reviewing and evaluating pharmaceutical services as defined in this chapter.

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