MEETING NOTICE

Missouri Board of Pharmacy
Long-Term Care Working Group

Missouri Division of Professional Registration
3605 Missouri Blvd.
Jefferson City, MO 65109

June 12, 2018
9:00 a.m.

Notice is hereby given that the Long-Term Care Working Group formed by the Missouri Board of Pharmacy will be meeting on June 12, 2018 at 9:00 a.m. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 9:00 a.m. on June 12, 2018.

Except to the extent disclosure is otherwise required by law, the Working Group is authorized to close meetings, records and votes pursuant to Section 610.021(1), (13) and (14) and section 324.001.8, RSMo. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.
TENTATIVE AGENDA

Missouri Board of Pharmacy
Long-Term Care Working Group

Missouri Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

June 12, 2018
9:00 a.m.

1. Welcome & Introductions
2. Board Update
3. Missouri DHSS Update
4. Missouri DMH Update
5. Approval of Minutes
   a. June 6, 2017
   b. May 2, 2017
6. Discussion/Review of Working Group Suggestions
7. Rule Discussion/Review
   a. 20 CSR 2220-2.140 (Prescription Services in Long-Term Care Facilities)
   b. 20 CSR 2220-2.145 (Minimum Standards for Multi-Med Dispensing)
   c. 20 CSR 2220-6.055 (Non-Dispensing Activities)
   d. Automated Distribution Draft
   e. Remote/Electronic Supervision of Missouri Pharmacy Technicians
   f. Missouri Patient Counseling Requirements and Long-Term Care
8. Development of Long-Term Care Education/Resource Documents
   a. Federal vs. State Allowances
   b. Applicability of Board, DHSS, DMH Regulation/Jurisdiction
   c. DHSS oversight over long-term care facilities/pharmacy
   d. Pharmacist long-term care consulting
9. Future Agenda Topics/Meetings
10. Questions/Comments
11. Adjournment
The Missouri Board of Pharmacy’s Long-Term Care Working Group met in open session via conference call during the times and dates stated in the following minutes. The meeting was called to order by President Christian Tadrus at approximately 12:01 p.m. on May 2, 2018. Each item in the minutes is listed in the order discussed.

**Board Members Present**
Christian Tadrus, PharmD, President

**Attendees Present**
Janice Ceriotti (Infinium Pharmacy)
Jennifer Kemna (Omnicare)
John Long (CVS Health)
Tracey Lashbrook (Senior Scripts)
Bert McClary (Hospital Advisory Committee)
Curt Wood (Long-Term Care Consultant)
Carmen Slattery-Grove (Regulation Manager, DHSS)

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
Katie DeBold, Inspector
Christa Nilges, Senior Office Support Assistant

PRESIDENT CHRISTIAN TADRUS CALLED THE MEETING TO ORDER AT 9:04 A.M. AND ROLL CALL WAS TAKEN.

**ITEM # 1-2 Working Group Update**

**DISCUSSION:** Executive Director Kimberly Grinston reported the Working Group previously met on June 6, 2017, and agreed to meet again in July 2017. However, Mrs. Grinston reported the Board/staff has been working on the comprehensive rule review required by Executive Order 17-03 resulting in scheduling conflicts. Working Group members also had conflicts with previously suggested meeting dates. Mrs. Grinston advised the Board is still interested in Working Group feedback. Specifically, feedback has been requested on:
a. 20 CSR 2220-2.140 (Prescription Services in Long-Term Care Facilities)
b. 20 CSR 2220-2.145 (Minimum Standards for Multi-Med Dispensing)
c. 20 CSR 2220-6.055 (Non-Dispensing Activities)
d. Automated Distribution/Dispensing
e. Remote/Electronic Supervision of Missouri Pharmacy Technicians,
   and
f. Missouri Patient Counseling Requirements

Working Group discussion held; Member consensus to survey available meeting dates during
the week of June 11th or June 18th 2018.

MOTION TO ADJOURN
The Working Group adjourned by consensus at approximately 12:17 p.m.

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KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
The Missouri Board of Pharmacy’s Long-Term Care Working Group met in open session during the times and dates stated in the following minutes. The meeting was called to order by President Christian Tadrus at approximately 9:04 a.m. on June 16, 2017. Each item in the minutes is listed in the order discussed.

**Board Members Present**
Christian Tadrus, PharmD, President

**Working Group Members Present**
Janice Ceriotti (Infinium Pharmacy)
Carmen Slattery-Grove (Missouri Dept. of Health and Senior Services)
Jennifer Kemna (Omnicare)
Tracey Lashbrook (Senior Scripts)
Bert McClary (Hospital Advisory Committee)
Curt Wood (Long-Term Care Consultant)

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
Katie DeBold, Inspector
Christa Nilges, Senior Office Support Assistant

**PRESIDENT CHRISTIAN TADRUS CALLED THE MEETING TO ORDER AT 9:04 A.M. AND ROLL CALL WAS TAKEN.**

**ITEM # 1-2 Welcome & Introductions/Working Group Purpose and Scope of Review**

**DISCUSSION:** President Tadrus welcomed attendees and introductions were made. Mr. Tadrus reported Governor Greitens issued an Executive Order requiring all state agencies to review their rules. As part of its review, the Board voted to form a Long-Term Care Working Group to review Missouri’s long-term care regulations which have not been updated or modified in a significant period of time. Mr. Tadrus reported the Working Group has been asked to:

1) Advise the Board on whether the rules are appropriate for current long-term care pharmacy practice; and  
2) Make recommendations on potential rule suggestions or changes.
DISCUSSION: Working Group discussion held on Missouri’s regulation of long-term care pharmacy practice. The following strengths were identified:

- While changes are needed, the Board’s rules are not overly restrictive and allow a degree of flexibility, including, for emergency kits (e-kits); and
- Missouri law allows the relatively broad use of medication orders which helps to facilitate long-term care dispensing.

The following additional suggestions/comments were discussed:

- **Regulatory Clarification:** Board, DHSS and BNDD statutes/rules should be harmonized to ensure consistent regulation. Additionally, statutes/rules should be simplified to clearly address rule requirements and to clearly identify Board/DHSS jurisdiction.
- **Licensure:** Additional clarification is needed on DHSS licensure requirements, including, licensure requirements for newer medical delivery models such as retirement care and medical homes.
- **Board Regulation:** The definitions for “long-term care facility” and “extended health care services” are unclear and need to be updated. Clarification is also needed on when a Board pharmacy permit is required for non-dispensing activities.
- **Medication Orders:** Given the nature of long-term care services, medication orders should not be treated as prescriptions or required to include unnecessary prescription information. Specifically, Missouri law should allow renewable orders instead of imposing the current one (1) year expiration date. Additionally, Missouri law should address the use of orders on discharge and the use of previous orders on readmission. Members further recommended allowing any duly authorized agent of the prescriber to communicate a medication order to prevent interruptions in care.
- **Pharmacist Supervision:** Missouri law should ensure the pharmacist is sufficiently involved in and has proper oversight over the entire medication system. Bert McClary suggested Missouri law address/recognize the pharmacist’s responsibility for reviewing medication policies/procedures.
- **Emergency Kits:** Additional guidance on emergency kits (e-kits) is needed, including, guidance on who owns e-kit medication, when an initial dose can be dispensed, authorized use of controlled substances, individuals authorized to re-stock the kit and how “excessive quantity” is defined. Missouri law should also address automated dispensing systems to accommodate current and future long-term care practice.
- **Controlled Substances:** Additional education is needed on controlled substance requirements, including, prescription transfers, when a two-line prescription is required and who is deemed the agent of the prescriber. Members recognized federal law may preempt state regulation in certain areas but suggested amending Missouri law where possible.
- **Medication Therapy Services:** Members indicated the current medication therapy services requirements are unduly burdensome for long-term care, especially protocol and notification/documentation requirements. Members suggested simplifying the MTS
rule to accommodate long-term care practice and to allow MT orders to be issued by any individual authorized to order medication.

- **After-Hours Pharmacy Services:** Working Group members reported the current process for obtaining medication after pharmacy hours is complicated given the nature of long-term care pharmacy and that the facility may not have an actual two-line prescription. Members indicated obtaining a prescription that is fillable at a “retail” pharmacy is burdensome and may unnecessarily delay patient care. Members discussed allowing a limited supply of medication to be dispensed based on a medication order with an exemption/allowance for obtaining a Class-J shared services permit.

**ITEM # 8 Future Agenda Topics/Meetings**

**DISCUSSION:** Working Group consensus to meet via conference call on a Friday in July 2017; Staff will survey dates. Committee members also suggested adding representatives from the Missouri Department of Mental Health, infusion pharmacy and an automated dispensing vendor.

**MOTION TO ADJOURN**
The Working Group adjourned by consensus at approximately 2:14 p.m.

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KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED:
20 CSR 2220-2.140 Prescription Services by Pharmacists/Pharmacies for Residents in Long-Term Care Facilities

PURPOSE: This rule establishes standards for pharmacists providing prescription services to residents in long-term care facilities. The standards are directed to licensed pharmacists and pharmacies, and not to long-term care facilities.

PUBLISHER’S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency’s headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

1) Licensure. A pharmacist who or pharmacy which provides prescription services to a long-term care facility must be licensed to practice pharmacy in this state. A long-term care facility means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

2) Medication Services.
   (A) Policies and procedures shall be formulated to cover all packaging and dispensing responsibilities of the pharmacist/pharmacy to the residents of the long-term care facility and shall include, at a minimum:
   1. Methods used to dispense medications in a timely fashion to the facility;
   2. Proper notification to the facility when a medication is not readily available;
   3. Proper labeling requirements to meet the needs of the facility and which are consistent with state and federal laws; and
   4. Appropriate medication destruction, return of unused medication, or both, which is consistent with state and federal laws.

   (B) Container labeling, at all times, shall conform to Chapter 338, RSMo. If a label change is required to reflect a change in directions, the pharmacist personally shall affix the correct label to the container. However, direction change labels which are defined as indicator labels that notify long-term care facility personnel that a change in directions for medication has taken place, may be used and affixed to the container by nursing home personnel in a way as not to deface the original label. Labeling of unit dose packages may be distinguished from the requirements as set forth in section 338.059, RSMo by ensuring that the drug name and strength, control number and expiration date and manufacturer’s name appear on the package itself. A patient’s name and directions may not have to appear directly on the medication container but a mechanism should exist to identify for the personnel administering medications what medications each patient is to receive and the directions for administration.

   (C) All prescription containers, including, but not limited to, single unit, unit dose and unit-of-use containers utilized for distribution within a long-term care facility shall meet minimum requirements as referenced by the United States Pharmacopoeia (USP) which is incorporated herein by reference. Where applicable, light-sensitive packaging shall be used.

   (D) Packaging and labeling of containers shall bear the manufacturer’s expiration date or twelve (12) months, whichever is less.

   (4) Remote dispensing systems are defined as an automated or manual design of a machine or device. All prescription drug orders shall be processed and transmitted to a licensed pharmacy for the dispensing of medication. When a separate file system for prescription drug orders is utilized, it must comply with all applicable provisions of state and federal laws governing the maintenance and use of a prescription file by a pharmacy and the numbering system used to number prescription drug orders must be distinct from any other prescription file that is maintained.

   (D) Packaging and labeling of containers shall comply with all applicable state and federal laws for any medications that leave the facility or are provided to the patient by the pharmacy for use outside the facility. Prescription drug orders issued for use within the long-term care facility are not valid for refill outside the facility.

   (6) Nothing in this rule shall be deemed to constitute a waiver or abrogation of any of the provisions of Chapter 338, RSMo or other applicable provisions of state and federal laws and rules, or should this rule be construed as authorizing or permitting any person not
Chapter 2—General Rules

20 CSR 2220-2

A patient med pak is a package prepared stating:

1. The name of the patient;
2. A serial number for the patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;
3. The name, strength, physical description or identification and total quantity of each drug product contained therein;
4. The directions for use and cautionary statements required by the official compendia;
5. The name of the prescriber of each drug product;
6. The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date shall be not later than sixty (60) days from the date of preparation);
7. The name, address, and telephone number of the dispenser; and
8. Any other information, statements, or warnings required for any of the drug products contained therein.

Each record shall contain, at a minimum:

1. The name and address of the patient;
2. The serial number of the prescription order for each drug product contained therein;
3. The name of the manufacturer or labeler and lot number for each drug product contained therein;
4. Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;
5. The date of preparation of the patient med pak and the beyond-use date that was assigned;
6. Any special labeling instructions; and
7. The name or initials of the pharmacist who prepared the patient med pak.

(A) The patient med pak shall bear a label identifying each of the drug products contained therein.

(B) If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug products contained therein.

(C) The patient med pak shall be accompanied by a patient package insert, in the event that any medication therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall, educational insert provided by the pharmacist for the total patient med pak.

(D) In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med pak shall comply with the moisture permeation requirements for a Class B single-unit or unit-dose container. Each container shall be either not reclosable or so designed as to show evidence of having been opened.

(E) It is the responsibility of the dispenser, when preparing a patient med pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the medications. In this regard, pharmacists are encouraged to report to United States Pharmacopeia (USP) headquarters any observed or reported incompatibilities.

(F) In addition to any individual prescription filing requirements, a record of each patient med pak shall be made and filed. Each record shall contain, at a minimum:

1. The name and address of the patient;
2. The serial number of the prescription order for each drug product contained therein;
3. The name of the manufacturer or labeler and lot number for each drug product contained therein;
4. Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;
5. The date of preparation of the patient med pak and the beyond-use date that was assigned;
6. Any special labeling instructions; and
7. The name or initials of the pharmacist who prepared the patient med pak.

(G) There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards, shall be placed in an outer package that does comply, or the necessary consent of the purchaser or physician to dispense in a container not intended to be child-resistant, shall be obtained.

(H) Once a patient med pak has been delivered to an institution or to a patient it shall not be returned to the pharmacy, unless the following requirements are met:

1. The med pak is returned to the pharmacy from which it was originally dispensed;
2. The med pak is modified/repackaged, per prescription order, for the patient to whom it was originally dispensed;
3. The med pak is labeled in compliance with the requirements of this rule, provided the med pak shall retain the original beyond-use date assigned to the med pak before modification/repackaging;
4. The med pak is assigned a new serial number;
5. The medications removed from the med pak are destroyed in compliance with state and federal law. In no event shall medication removed from a med pak be returned to stock/inventory or dispensed to another patient; and
6. Licensees shall comply with all applicable record-keeping requirements.

(I) Multi-med packaging of controlled substances is prohibited.

(J) Except as otherwise allowed in subsection (H) of this section, once a drug has been compounded with other drugs in a med pak the drug may not be returned to stock, dispensed, or distributed except for destruction purposes.


Chapter 6—Pharmaceutical Care Standards

20 CSR 2220-6.055 Non-Dispensing Activities

PURPOSE: This rule establishes procedures and requirements for the performance of non-dispensing activities outside of a pharmacy.

(1) Pursuant to section 338.220, RSMo, a pharmacist may perform the following non-dispensing activities outside of a licensed pharmacy:

(A) Patient counseling/education, as authorized by Missouri law, provided the pharmacist shall be obligated to comply with 20 CSR 2220-2.190, when applicable;

(B) Obtain patient history/information;

(C) Review patient records/medical histories;

(D) Patient assessment/evaluation, as authorized by Missouri law;

(E) Billing and insurance claim submissions/review;

(F) Drug utilization review;

(G) Assess health plan and medication eligibility/coverage;

(H) Pharmacy compliance audits/evaluations;

(I) Administer drugs, vaccines, or biologicals, as authorized by law and the rules of the board;

(J) Peer review/peer consultations;

(K) Review, select, and develop formulas or plan/practice guidelines;

(L) Review compliance with benefit guidelines;

(M) Manage inventory, including purchasing and ordering;

(N) Manage/review information systems;

(O) Patient medication review;

(P) Consultation with other health care professionals;

(Q) Patient referrals;

(R) Prescription order entry/review, provided that a pharmacist shall only be authorized to accept a prescription on the premises of a Missouri licensed pharmacy, as required by section 338.095.5, RSMo; and

(S) Medication therapy management, pursuant to and as authorized by Chapter 338, RSMo, and the rules of the board.

(2) Confidentiality. A pharmacist performing non-dispensing activities pursuant to this rule shall comply with all applicable state and federal confidentiality laws and regulations and shall provide sufficient storage and security for confidential documents and electronic data processing hardware. In addition, data processing systems must utilize sufficient security software to ensure confidentiality and prevent unauthorized access. Any breach in the security or confidentiality of the data processing systems or confidential documents shall be documented and reported to the board in writing within seven (7) days of the breach.

(3) Notwithstanding any other provision of this rule, a pharmacist shall not meet with patients in the pharmacist’s residence or living quarters.

(4) A pharmacist performing non-dispensing activities pursuant to this rule shall ensure compliance with Chapter 338, RSMo, and the rules of the board at all times. Nothing in this rule shall be construed to eliminate or otherwise exempt any pharmacist from the record-keeping, confidentiality, or security requirements otherwise imposed by Chapter 338, RSMo, or the rules of the board. Violations of this section shall constitute grounds for discipline.

(5) This rule shall not be construed to authorize a pharmacist to conduct the unauthorized practice of medicine or to conduct any activity for which a license is required pursuant to Chapters 330, 331, 332, 334, or 337, RSMo.
(6) A pharmacy permit shall be required for performing non-dispensing activities if the pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the location where non-dispensing activities are being performed, provided that a pharmacy permit shall not be required for sites used solely by the pharmacist for administering vaccines as authorized by Chapter 338, RSMo, and the rules of the board. Pharmacy technicians shall only be authorized to work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.


20 CSR 2220-6.060 General Provisions

PURPOSE: This rule establishes definitions for 20 CSR 2220-6.060 to 20 CSR 2220-6.080 governing medication therapy services by pharmacists.

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080:

(A) Authorizing physician(s)—The physician identified in the written protocol as authorizing the pharmacist to provide medication therapy services;

(B) Health care entity—For purposes of this rule, a health care entity shall be defined as any entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility, or a habilitation center as defined by Chapter 630, RSMo, and that is required to maintain patient medical records by state or federal law;

(C) Medication therapy protocol—A written agreement between a physician and a pharmacist for the provision of medication therapy services. A medication therapy protocol shall comply with the provisions of 20 CSR 2220-6.080;

(D) Medication therapy services—The designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient's medication therapy or device usage pursuant to a medication therapy protocol. For purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080, medication shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product, generic substitutions made pursuant to section 338.056, RSMo, or medication therapy management that does not include the initiation or implementation of a modification of medication therapy, as provided herein;

(E) Pharmacy resident—A Missouri-licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists;

(F) Prescription order for medication therapeutic plan—A lawful order that is issued by the authorizing physician within the scope of his/her professional practice for the provision of medication therapy services by a pharmacist for a specific patient, including, patients of a health care entity; and

(G) Protocol—A medication therapy protocol, as defined herein.

(2) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026 to 20 CSR 2150-5.028 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Pharmacy and the Missouri State Board of Registration for the Healing Arts, as established by Chapter 338, RSMo, and Chapter 334, RSMo.


20 CSR 2220-6.070 Certificate of Medication Therapeutic Plan Authority

PURPOSE: This rule establishes procedures for obtaining a certificate of medication therapeutic plan authority, as authorized by section 338.010, RSMo.

(1) A pharmacist shall obtain a certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include initiating or implementing a medication of patient's medication therapy or device usage. Pharmacists with a certificate of medication therapeutic authority shall enter into a written protocol with a Missouri-licensed physician that complies with the requirements of 20 CSR 2220-6.080, prior to performing medication therapy services.

(2) Applicants for certification shall hold an active Missouri pharmacist license. Applications shall be submitted on forms provided by the Missouri State Board of Pharmacy and shall be accompanied by the certificate of medication therapeutic plan authority fee and proof the applicant—

(A) Holds a doctor of pharmacy (PharmD) degree earned from a school, accredited by the Accreditation Council for Pharmacy Education (ACPE); or

(B) Has successfully completed a post-graduate medication therapy certificate course or program accredited or granted by the APCE, American Society of Health-System Pharmacists, American Society of Consultant Pharmacists, or the American Pharmacists Association; or

(C) Holds a current certification from the Board of Pharmaceutical Specialties, the Commission for Certification in Geriatric Pharmacy, or the National Certification Board for Diabetes Educators; or

(D) Has completed a post-graduate medication therapy certificate course that, at a minimum, included training in the following areas:

1. Assessing patient specific data and issues;
2. Establishing medication therapeutic goals or medication related action plans for identified medication conditions and medication related concerns;
3. Assessing and addressing adverse reactions and adverse drug events;
4. Modifying and monitoring medication regimens;
5. Improving patient care and outcomes through medication therapy services;
6. Evaluating treatment progress;
20 CSR 2220-2.0XX

(This could either be done as a new rule, placed in the DD section or added to an existing rule).

(1) Definitions.

(A) “Automated Distribution Cabinet”- A computerized or electronic drug storage device or cabinet used to store prepackaged medication that electronically tracks and records medication access and drug distribution.

(B) “Electronic Verification System”- An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly placed or loaded into an automated distribution cabinet or drug storage area.

(C) “Health Care Facility”- CONSENSUS TO RESEARCH THIS DEFINITION
  1. The practice location of a licensed health care practitioner authorized to prescribe or dispense/administer medication; or
  2. An entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility, or a habilitation center as defined by Chapter 630, RSMo.

(D) “Secure Drug Storage Area”- A locked room or other locked area used to store medication that is only accessible to licensed health care practitioners or to designated pharmacy staff as authorized by the pharmacist-in-charge.

(F) “Supervising Pharmacy”- The Missouri licensed pharmacy operating or maintaining an automated distribution cabinet or a secure drug storage area.

(2) A Missouri licensed pharmacy may operate or maintain an automated distribution cabinet (“ADC”) or a secure drug storage area at a health care facility for the purposes of distributing medication to licensed health care practitioners for patient use or administration. An automated distribution cabinet or secure drug storage area may only be used to distribute medication for use or administration by a licensed health care practitioner and shall not be used by, or accessible to, patients or the general public.
(A) A current written or electronic list of all locations/addresses where ADCs or secure drug storage areas are located must be maintained at the pharmacy and available on inspection or on request of the Board or the Board’s authorized designee.

(B) A drug distributor license is not required for an automated distribution cabinet or secure drug storage area used solely to distribute medication as authorized by this rule if the total amount of medication annually distributed via an ADC or from a secure drug storage area does not exceed five-percent (5%) of the pharmacy’s total gross sales. For purposes of this rule, total gross sales is calculated based on the pharmacy’s total annual prescription medication sales or, if prescriptions are not sold, five percent (5%) of the pharmacy’s total annual medication purchases.

(C) Pharmacies providing prescription services for residents in long-term care facilities must comply with 20 CSR 2220-2.140, including, pharmacies operate or providing remote dispensing systems in a long-term care facility for emergency dispensing (e.g., an e-kit).

(3) Standards of Operation. The supervising pharmacy and the pharmacist-in-charge shall ensure:

(A) Medication is properly and accurately distributed;

(B) Automated distribution cabinets and secure drug storage areas are operated in compliance with this rule and all applicable state and federal laws, including, any applicable controlled substance laws.

(C) Automated distribution cabinets are maintained in good working order;

(D) Medication is properly stored and maintain within temperature and humidity requirements as provided in the FDA approved drug product labeling or the United States Pharmacopeia (USP). A temperature monitoring system or device must be used to ensure proper temperature storage.

(E) No outdated, misbranded or adulterated drugs or devices are stored in an automated distribution cabinet or secure drug storage area;

(F) Medication is labeled in accordance with section 338.059, RSMo, or alternatively labeled with the drug name, strength, expiration date, lot number and, if applicable, beyond-use date; and

(G) A pharmacist is available to answer questions in the event of an emergency.
(4) Stocking.

(A) Automated distribution cabinets and secure drug storage areas may be stocked/re-
stocked by a Missouri licensed pharmacist or by a registered Missouri pharmacy technician or
intern pharmacist without a pharmacist physically present if-

1. An electronic verification [or other mechanical] system is used to verify medication
has been properly stocked or loaded; or

2. The system is stocked using manufacturer unit of use packages or prepackaged
containers that have been verified by a pharmacist to ensure the container has been properly
packaged and labeled. The identity of the verifying pharmacist must be documented in the
pharmacy’s records. Prepackaging must comply with 20 CSR 2220-2.130.

(5) Security. Adequate security must be maintained to deter drug theft and diversion.

(A) ADCs and secure drug storage areas shall not be accessible to the public and must be
securely placed or located within the designated health care facility. ADCs may not be located
in or near exit doors.

(B) All access to an ADC or secured drug storage area must be manually or electronically
documented, including, the date and time the ADC/secure area was accessed, the identity of
individuals making access and the name, strength, quantity and dosage form of medication
placed in, distributed by or removed by each individual.

(C) All medication distributed by an ADC must be reviewed by a pharmacist on a
(monthly/weekly) basis to ensure proper distribution. The identity of the pharmacist, date of
review and any medication discrepancies or errors must be documented in writing and
maintained in the pharmacy’s records.

(D) Medication inventory must be reconciled for each ADC or secure drug storage area
every (2-weeks, month/six (6) months). A perpetual inventory must [also] be maintained for any
ADC that stocks or provides controlled substances.

(E) Any theft or diversion of or from an automated dispensing system or secure drug storage
area must be reported to the Board in writing within fourteen (14) days in a manner designated
by the Board. Any suspected or discovered theft or diversion from an automated dispensing
system must be promptly investigated and prompt corrective action taken to prevent future theft or losses.

(6) Policies and Procedures. The pharmacy shall establish and follow written policies and procedures to ensure the proper, safe and secure operation of an ADC or secure drug storage area. Policies and procedures must be current and accurate and, at a minimum, include policies and procedures for-

(A) Maintaining the automated dispensing system and any accompanying electronic verification system in good working order;

(B) Ensuring adequate security and accurate stocking and distribution of the system;

(C) Reporting, investigating, and addressing known or suspected errors, system malfunctions, thefts/diversion or security breaches;

(E) Tracking, documenting and investigating medication errors;

(F) Conducting routine and preventive maintenance and, if applicable, calibration;

(G) Removing expired, adulterated, misbranded, or recalled drugs;

(H) Monitoring and preventing unauthorized access to the system, including, assigning, discontinuing, restricting or changing security access as deemed necessary or appropriate; and

(I) Ensuring compliance with state and federal law, including, all applicable controlled substance laws.

(7) Records. Distribution records must be maintained for all medication stocked in, distributed by or removed from an ADC or a secure drug storage area. At a minimum, distribution records must include the date of distribution and the identity, quantity and dosage form of medication distributed or removed. Except as otherwise provided by law or other rule of the Board, all records required by this rule shall be manually or electronically maintained in the pharmacy’s records for a minimum of two (2) years and available on inspection or request of the Board.

(8) This rule is solely applicable to pharmacies operating an ADC or secure drug storage area pursuant to this rule. This rule does not apply to compounding, administering, prescribing
or dispensing of medication by a non-pharmacist healthcare practitioner as otherwise authorized by law.
20 CSR 2220-2.190 (Patient Counseling)

(1) Pharmacies shall maintain appropriate patient information to facilitate patient counseling and allow proper drug utilization review. Appropriate information may include, but is not limited to, the patient's name, address, telephone number, age, gender, clinical information, disease states, allergies and a listing of other drugs prescribed/used.

(2) Prospective Drug Utilization Review.
   (A) Prior to dispensing [any new prescription or medication order], the patient's profile shall be reviewed by a pharmacist or an intern pharmacist under the pharmacist's supervision for:
      (A) Therapeutic duplication;
      (B) Appropriateness of dose, dosage form and duration of use;
      (C) Appropriateness for the patient;
      (D) Drug-disease contraindication;
      (E) Drug-drug, drug-diet and drug-laboratory test interactions;
      (F) Incorrect dosage/duration;
      (G) Clinical abuse/misuse, and
      (H) Relevant patient factors (e.g., age, gender).

   (B) The pharmacist shall take any action deemed necessary or appropriate in his/her professional judgment to address or resolve identified drug utilization concerns or issues. Nothing in this subsection shall be construed to interfere with or restrict a pharmacist's exercise of professional judgment.

(3) General Requirements. Patient counseling must be offered or provided as required by this rule and applicable state and federal law. Counseling should include matters that will, in the professional judgment of the pharmacist, enhance or optimize therapy and allow the patient to safely and appropriately use the prescribed medication, device or equipment so that maximum therapeutic outcomes can be obtained. Such matters may include, but are not necessarily limited to:

   1. The medication name and description;
   2. The dosage, dosage form, route of administration and duration of therapy;
   3. Any special directions or instructions for patient preparation, administration or use;
   4. Significant side effects, adverse effects or interactions, and therapeutic contraindications.

Comment [GK1]: This list is advisory and not mandatory.
5. Techniques for self-monitoring;
6. Proper storage;
7. Appropriate disposal methods;
8. Refill information;
9. Suggested action in the case of a missed dose or equipment/device malfunction;
10. Any other matter deemed necessary or appropriate in the pharmacist’s professional judgment to allow the patient to safely and appropriately use the prescribed medication, device or medical equipment.

(4) New Patients/Medication. A pharmacist or an intern pharmacist under the pharmacist’s supervision shall personally counsel a patient or caregiver before dispensing any new prescription medication, device or equipment to a patient for the first time. For purposes of this rule, new medication, device or equipment does not include a change in dose, strength, route of administration or directions for use or a transferred prescription/medication order that was previously dispensed to the patient by another pharmacy. At a minimum, counseling for new patients/medication must include:
1. The name, strength and purpose of the medication, device or equipment;
2. The indication for which the medication, device or equipment is prescribed, if known;
3. Directions for use and preparation, if applicable;
4. Duration of therapy;
5. Significant side effects, adverse effects or interactions, and therapeutic contraindications;
6. Proper storage; and
7. Any other matter identified in subsection (2) of this rule as deemed necessary or appropriate by the pharmacist.

(5) Refills/Continued Therapy. For prescriptions/medication orders not identified in subsection (3), a pharmacist or his/her designee shall personally offer to counsel each patient or caregiver prior to dispensing. The offer must be verbally made to the patient or caregiver either in person or electronically (e.g., voice recording/voice announcement). The patient must be clearly asked if he/she has any questions for a pharmacist or would like to consult with the pharmacist.
(6) Patient counseling may only be conducted by a pharmacist or a pharmacy intern under the pharmacist’s immediate supervision. Counseling must be provided in-person or via an electronic mechanism that allows the pharmacist and patient/caregiver to communicate in real-time either verbally or face-to-face. Licensees shall ensure compliance with all applicable state and federal laws, including, state and federal laws governing patient privacy/confidentiality, medication guides and federal risk evaluation and mitigation strategy (REMS) requirements.

(A) If the prescription/medication order is mailed or if the patient or caregiver is not available at the time of dispensing, a written offer to counsel with a toll-free telephone number for the dispensing pharmacy must be supplied for contacting a pharmacist for counseling at no charge to the patient/caregiver. Provided counseling must comply with the requirements of this rule.

(B) In addition to the requirements of this rule, pharmacies shall post a manual or electronic sign in every prescription/medication pickup area, including any drive-through areas, in a manner clearly visible to the patient that Missouri law requires the pharmacist to discuss with the patient any new prescriptions dispensed to the patient. The required counseling notice is not required for pharmacies that are not accessible to the public (e.g., a “closed-door pharmacy”).

(7) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples may include, but shall not be limited to, written information leaflets, pictogram labels, video programs, and the like.

(8) Patient counseling, as described in this rule is not required for inpatients of a hospital, institution or other setting where prescription medication or a prescription device/medical equipment is provided or administered to the patient by other licensed or certified health care professionals.

(9) A pharmacist is not required to counsel a patient or caregiver if the patient or caregiver refuses consultation.