OPEN MINUTES
Missouri Board of Pharmacy

January 18-19, 2017
Courtyard Columbia
3301 Lemone Industrial Boulevard
Columbia, MO

The Missouri Board of Pharmacy met in open session during the times and dates stated in the following minutes. The regular meeting was called to order by President Christina Lindsay at approximately 8:08 a.m. on January 18, 2017. Each item in the minutes is listed in the order discussed.

**Board Members Present**
Christina Lindsay, R.Ph., President
Christian Tadrus, PharmD., Vice-President
Barbara Bilek, PharmD., Member
Douglas R. Lang, R.Ph., Member
Pamela Marshall, R.Ph., Member
Anita Parran, Public Member

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, R.Ph., Chief Inspector
Bennie Dean, R.Ph., Inspector
Katie DeBold, PharmD., Inspector
Joe Dino, R.Ph., Inspector
Amber Cundiff, Compliance Coordinator
Jennifer Luebbert, Administrative Coordinator
Andi Miller, PharmD., Inspector
Lisa Thompson, R.Ph., Inspector
Dan Vandersand, R.Ph., Inspector
Elaina Wolzak, R.Ph., Inspector
Barbara Wood, R.Ph., Inspector

**Others Present**
Curtis Thompson, Legal Counsel

**PRESIDENT LINDSAY CALLED THE OPEN SESSION MEETING TO ORDER AT APPROXIMATELY 8:03 AM**

**MOTION TO CLOSE 8:09 A.M.**
At 8:09 a.m., Barbara Bilek made a motion, seconded by Christian Tadrus, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), Missouri Board of Pharmacy
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(13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:00:00 with roll call vote as follows:

Barbara Bilek – yes    Pamela Marshall – yes    Anita Parran – yes
Douglas Lang – yes    Christian Tadrus - yes

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 8:09 AM

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 9:13 AM

MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 9:13 a.m.

PRESIDENT LINDSAY CALLED THE OPEN SESSION MEETING TO ORDER AT APPROXIMATELY 9:27 AM

President Lindsay indicated the rule review noted in the agenda will begin at approximately 1:00 p.m.; Mrs. Lindsay noted comments would be limited to two (2) minutes per speaker to accommodate all attendees. Mrs. Lindsay further noted the Board will accept written public comments for an additional thirty (30) days.

SECTION D- OPEN

#A1 Agenda Additions/Corrections

No agenda additions/corrections reported.

#A2 Board Member Report:

ITEMS ENCLOSED:
- MTS Advanced Practice Agenda (1-3-17)
- MSHP PAI Collaborative Practice Survey
- MTS Draft Language

DISCUSSION: Staff provided the following updates:
- Tom Glenski reported Bert McClary invited the Board to attend a meeting at the University of Missouri-Kansas City to discuss expanding pharmacy clinical practice. The meeting included pharmacists from different practice settings; the Board attended in an advisory capacity. Meeting attendees developed a preliminary draft of amendments to Chapter 338, RSMo, that would expand pharmacist collaborative practice. Mr. Glenski noted the group may propose legislation during the 2017 session.

Bert McClary was asked to provide additional information. Mr. McClary reported multiple pharmacy groups have discussed ways to enhance collaborative practice over the years. Mr. McClary subsequently worked with stakeholders to form a Medication
Therapy Services (MTS) Advanced Pharmacy Practice group to discuss ways to expand and develop pharmacist clinical practice. Mr. McClary reported one priority goal is to give pharmacists authority to prescribe both controlled and non-controlled medication similar to Advanced Practice Registered Nurses and Physician Assistants. Mr. McClary commented the DEA would allow controlled substance handling if authorized by state law. The group would also like to remove the requirement for a separate patient order to initiate a MTS protocol. Legislative changes have been generally discussed with the Missouri Pharmacist Association (MPA). Ron Fitzwater indicated MPA staff is in the process of reviewing the draft language and noted a separate legislative bill will likely be necessary.

#A3 General Administration Report
- Financial Report
- Fee Decreases
- Staff/Office Update
- Intern Renewal Update
- Rule Update
- MSHP Fingerprint Audit
- Kansas City Pharmacy Diversion Conference
- 2017 Patient Safety Conference
- Strategic Planning 2016 Update
- 2017 Government Transition Updates
- 2017 Legislative Updates
- Future Board Meeting Dates
- Executive Order 17-03 (Rulemaking)

DISCUSSION: Kimberly Grinston provided the following updates:
- **Financial Report**: Mrs. Grinston presented the financial report for Board review and noted the office was able to spend additional funds on training and equipment in 2017.
- **Fee Decreases**: Revenue continues to trend upward; Ms. Grinston reported the Board may be looking at a fund sweep in 2019 due to an excessive fund balance and suggested the Board consider decreasing 2018 renewal fees for pharmacies and drug distributors. Ms. Grinston noted the Board previously reduced the 2018 technician renewal fee to $10.

Douglas Lang asked how potential state budget cuts may affect the Board; Kimberly Grinston reported state budget cuts usually impact general revenue agencies and not fee-funded agencies like the Board. Pamela Marshall asked about the impact of a permanent fee decrease versus an annual review and reduction by the Board. Ms. Grinston stated it is harder to get a fee increase approved.

A motion was made by Douglas Lang, seconded by Pamela Marshall, to temporarily reduce the pharmacy and drug distributor renewal fee to $150 and to reduce the pharmacy technician fee to $10. Motion passed 5:0:0:0 by roll call vote as follows:
Anita Parran – yes  Christian Tadrus – yes

- **General Office Updates:** The office is preparing for upcoming technician renewals and the pharmacist graduation season. Amber Cundiff has been promoted to the Compliance Coordinator position; her previous Pharmacist Coordinator position is currently vacant.

- **Rule Updates:** The Governor’s office returned proposed rules not approved by the previous administration, including, the MTS rule, pharmacy technician rule and the compounding for office use comment draft. Board consensus to review the returned rules at a future meeting.

- **MSHP Audit:** The MSHP audit has been completed; Ms. Grinston noted findings were relatively minor and reported the majority of staff have completed the training requirements. Ms. Grinston further reported Jennifer Luebbert has been named as the official MSHP designee. Mr. Lang asked if Board member training was required; Ms. Grinston stated she has not been notified of required Board member training.

- **Kansas City Diversion Conference:** The conference is tentatively scheduled for May 5th with the same speakers as the previous conference. Ms. Grinston reported the office will work on publicizing the event as soon as possible.

- **2017 Patient Safety Conference:** Mrs. Grinston asked if the Board wanted to host a patient safety conference in 2017. Mrs. Grinston noted approximately 450 people registered for the 2016 conference, however, less than 50 attendees were pharmacists or pharmacy technicians. Pamela Marshall indicated the previous conferences were beneficial but suggested adding more topics of interest for retail pharmacy. Specifically, Mrs. Marshall suggested an e-prescribing session and proposed working with the pharmacy schools to host a poster session. Board discussion held. Board consensus to discuss hosting a patient safety conference with the other regulatory boards.

- **Strategic Planning:** A bid from AHC Consulting has been submitted for the April follow-up meeting. Additional information will be provided in the future.

- **2017 Government Transition Updates:** All boards submitted briefing memos to the new Governor’s office to advise of pending issues. The current Division Director and Department Director have been asked to continue serving until their replacements have been designated. The agencies were informed board appointments could be coming shortly.

- **2017 Legislation:** Proposals currently being tracked have been included in the agenda. Multiple prescription drug monitoring bills have been filed; the office will continue to monitor future legislation.

- **Executive Order 17-03:** The Governor’s executive order may impact the pending return of medication rule. The Board’s previously announced rule review schedule can be conducted along with the public rule hearings required by the Executive Order. Board discussion held. Board consensus to begin the public rule review hearings at the April 2017 meeting.

- **Missouri Workforce Database:** Ms. Grinston met with the University of Missouri and the other health boards to discuss establishing a statewide healthcare workforce database. Costs and data collection parameters are still under discussion. Ms. Grinston has
reviewed a prototype that has potential. Curtis Thompson advised material given to the University may be subject to the Sunshine Law. Board discussion held. Douglas Lang asked if the goal is to identify potential healthcare deserts; Ms. Grinston stated identifying areas of need is a primary goal and noted the data may be helpful when presenting legislation or requesting grant funding. Christian Tadrus expressed concerns regarding the use, quality and control of data and suggested proceeding cautiously. Board consensus to continue the current discussions. Ms. Grinston noted the Board has been asked to pay an “indirect fee” to the University which University staff stated could be waived if rejected by the Board. A motion was made by Barbara Bilek, seconded by Anita Parran, to reject the requested “indirect fee.” Motion passed 5:0:0:0 by roll call vote as follows:
Anita Parran – yes Christian Tadrus – yes

#A4 Inspection/Investigation Report
- Inspection/Investigation Updates
- Staff Training
- E-Mailed Inspection Reports
- Sterile Compounding Update/Checklist
- NABP Sterile Compounding Blueprint Program

DISCUSSION: Chief Inspector Tom Glenski provided the following updates:
- Implementation of the revised sterile compounding rule appears to be going well. Approximately fifteen (15) reports of highly pathogenic microorganisms have been received by the Board office since the rule was amended. Staff has received questions regarding the length of time the sterile compounding area must be closed after a highly pathogenic microorganism is found. Licensees have indicated closing the pharmacy until test results are received has caused a burden.
- A training program was hosted for the inspectors in December 2016. Staff is looking at returning to St. Louis College of Pharmacy for additional sterile compounding training with Katie DeBold. Additional inspectors will be scheduled for NABP’s training programs when available.
- The electronic inspection program continues to be updated; an electronic Quality Assurance form will be available shortly. Staff is also piloting a program that will allow inspectors to e-mail inspection reports in lieu of providing a CD.

Douglas Lang asked if the sterile compounding checklist should reference sterile alcohol or the federal Drug Quality and Security Act requirements. Mr. Glenski noted the Board has not made a determination on some of the DQSA issues which may need further discussion.

#A5 Approval of Minutes
- Conference Cal (2/18/16)
- Conference Cal (7/29/2016)
- Conference Cal (8/17/2016)
- Conference Cal (9/27/2016)
DISCUSSION: A motion was made by Pamela Marshall, seconded by Douglas Lang, to approve the February 18, 2016, minutes. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes

A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the July 29, 2016, minutes. Motion passed 4:0:1:0 by roll call vote as follows:

Anita Parran – abstain  Christian Tadrus – yes

Christian Tadrus suggested amending the August 17, 2016, minutes to change “enacted legislative” to “enacted legislation.” A motion was made by Christian Tadrus, seconded by Barbara Bilek, to approve the August 17, 2016, minutes with the requested change. Motion passed 5:0:0:0 by roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes

A motion was made by Douglas Lang, seconded by Anita Parran, to approve the September 27, 2016, minutes. Motion passed 5:0:1:0 by roll call vote as follows:

Anita Parran – yes  Christian Tadrus – yes

SECTION D- OPEN

#D1 2016 Annual Report

- Draft 2016 annual report for Board review/approval

DISCUSSION: Kimberly Grinston presented the annual report and reported Board operations remain stable. Ms. Grinston noted an increase in Board and Committee meetings in FY 16. Board discussion held. Anita Parran commended staff on the annual report format.

#D4 Hospital Advisory Committee Update
- Chairman McClary Update
- Class-B Hospital Guidance

DISCUSSION: Chairman Bert McClary reported two (2) meetings have been held since the October Board meeting and noted Committee discussion focused on the Class-B rule, including, future facility standards and pharmacy access issues. The Committee also reviewed the Class-B guidance document and related labeling issues. The draft Class-N automated dispensing rule and the Board’s MTS rule will be reviewed in the future.

Kimberly Grinston presented the suggested changes from the Hospital Advisory Committee on the draft Class-B guidance document. Board discussion held regarding referencing

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"locked" devices as suggested in the draft. Mr. McClary noted the intent of the labeling language was to address medication started in the hospital and completed offsite. Douglas Lang expressed concerns about emergency situations where emergency care providers may not be able to readily identify incompletely labeled medication containers. Mr. Lang suggested full labeling for external devices; Barbara Bilek agreed. Barbara Bilek further suggested referencing "programmed" devices in lieu of "pre-programmed" devices. Board consensus to amend the draft guidance document as suggested and return for future Board review.

#D2 2020 Rule Review
- Rule Review Calendar
- Draft JCAR Report
- Sample JCAR Review Notice
- 20 CSR 2220-2.005 Definitions
- 20 CSR 2220-2.010 Pharmacy Standards of Operation
- 20 CSR 2220-2.015 Termination of Business as a Pharmacy
- 20 CSR 2220-2.016 Pharmacy Operating Procedures During Declared Disasters
- 20 CSR 2220-2.020 Pharmacy Permits
- 20 CSR 2220-2.025 Nonresident Pharmacies
- 20 CSR 2220-2.090 Pharmacist-in-Charge
- 20 CSR 2220-2.700 Pharmacy Technician Registration
- 20 CSR 2220-2.900 Automated Dispensing and Storage Systems
- Draft Class-N Automated Dispensing Rule
- 20 CSR 2220-2.080 Electronic Prescription Records
- 20 CSR 2220-2.083 Electronic Record-Keeping Systems

DISCUSSION: President Lindsay asked for public comments on the rules identified in the agenda. The following discussion was held:

- 20 CSR 2220-2.005: No public comments. Barbara Bilek asked if the rule should incorporate common industry definitions. Christina Lindsay commented there may be value to adding language but suggested not opening the rule at this time given other rules that need more immediate changes. Board consensus to not amend the rule at this time.

- 20 CSR 2220-2.010: Bert McClary commented the Hospital Advisory Committee will be discussing this rule at a future meeting and noted any changes on remote technician supervision may need to be included in this rule. Douglas Lang suggested the Board should proactively look at ways to accommodate technology. Board consensus to begin the rule update process.

- 20 CSR 2220-2.015: No public comments received; Douglas Lang asked if any rule issues have been raised. Kimberly Grinston noted questions have been raised about notifying the Board where patient records will be kept after the pharmacy closes; Douglas Lang commented record retention is an issue in other states and noted Medicare Part D records must be kept for ten (10) years. Board consensus to not amend the rule at this time.
• **20 CSR 2220-2.090**: No public comments; Staff reported the Board previously reviewed a rule draft that was not finalized. Board discussion to begin the rule update process.

• **20 CSR 2220-2.700**: No public comments; Board consensus to review the draft amendments; previously forwarded to the Governor's office.

• **20 CSR 2220-2.900**: Bert McClary asked if the rule could be combined with the other automated dispensing rules and suggested the proposed requirements are too lengthy which could impact compliance. Mr. McClary suggested the rule should be similar to the emergency-kit rules for long-term care while still addressing basic requirements such as security, records and storage. James Gray commented confusion still exists on the line between the Board's jurisdiction and DHSS' jurisdiction and noted the draft rule may create more confusion.

Board members questioned who would own medication inventory and asked how the rule would impact hospital clinics. Douglas Lang commented this rule also raises the issue of accommodating advances in technology and strongly suggested the Board give the profession ability to meet the access need by leveraging technology to expand accessibility. Christian Tadrus suggested reviewing pharmacy technology issues in a broader manner in lieu of creating exemptions for specific practice settings. Board members asked to review language for a Class-N and Class-O rule at the same time. Board consensus to research additional automated system resources and discuss at a future meeting.

#D9 STLCoP/UMKC Pharmacy Annual School Review and Meeting

**DISCUSSION**: STLCoP and UMKC provided updates to the Board on their current pharmacy programs. Glenda Gleeson and Gloria Grice attended on behalf of STLCoP. Dean Melchart, Valerie Reuther and Trish Markham attended on behalf of UMKC. The following information was provided:

• **STLCoP** celebrated its 152nd year in operation; campus construction is still ongoing. The college is phasing out their 6-year program and the last 6-year students will graduate in 2019. 2016-2017 was the first year students were accepted into the professional program; enrollment was significantly lower which was expected given the transition from the 6-year program. The next accreditation visit will be held in 2021-2022; the college is continuing to develop inter-professional programs with Washington University and the school of nursing. The college is reviewing the decrease in MPJE/NAPLEX scores and will continue to work with graduating students. The college has contracted with Kaplan for additional test preparation services and students could possibly be given a simulated NAPLEX test in the future. GPA requirements and student progression policies may also be reviewed. The PCOA exam was given in 2016, however, student scores were lower than expected possibly because students were aware it was not a high stakes examination and would not affect grading.

• **UMKC** celebrated its 132nd year in operation. The ACPE site visit occurred in 2016; the pharmacy program was accredited for eight (8) years for the first time in history. The Governor’s recent budget decreased funding for the college by approximately $800,000.
which will cause concerns in FY18. The school is investigating recent decreases in NAPLEX and MPJE scores and will also continue working with students.

Board members asked if the schools were experiencing issues with finding qualified preceptors and asked how a preceptor training program might impact the colleges. STLCOP reported experiencing issues with finding health-system pharmacists and stated they were unsure how a training requirement might impact the program. STLCOP noted they currently have a preceptor education center and provide preceptor training on evaluating students. UMKC suggested there may not be a decline in preceptor participation if training requirements are reasonable and noted a variety of continuing education programs currently exist.

Board members asked STLCOP representatives about their request regarding international student intern licensure. (D6 International Pharmacy Student Visitors/Observation Programs). College representatives asked if there was a way to license international learners as technicians without fingerprinting; STLCOP indicated these students cannot be licensed as interns because they are not officially enrolled in the pharmacy program. STLCOP also noted many of the students may have a passport number instead of a social security number. Board staff explained technicians can be fingerprinted once they’re in the United States and can begin working once a completed application is submitted. Staff further noted a passport number may be acceptable for initial registration but could not be used for renewal. Additional discussion ensued; STLCOP representatives agreed to review technician licensure.

**MOTION TO CLOSE 3:50 P.M.**
At 3:50 p.m., Pamela Marshall made a motion, seconded by Barbara Bilek, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021 (1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8 and .9, RSMo. Motion passed 5:0:0:0 with roll call vote as follows:

- Barbara Bilek – yes
- Pamela Marshall – yes
- Anita Parran – yes
- Douglas Lang – yes
- Christian Tadrus - yes

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT 3:50 P.M.

**RETURN TO OPEN**
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 6:31 p.m.

PAMELA MARSHALL REJOINED THE MEETING AND MEMBERS OF THE PUBLIC ENTERED THE MEETING ROOM AT 6:32 P.M.

**#D2 2020 Rule Review (Cont’d)**

**DISCUSSION:** The following discussion was held:
- 20 CSR 2220-2.080: No public comment received; Christina Lindsay noted Walgreens representatives left the meeting but indicated they had comments on
electronic prescription records. Staff will reach out to Walgreens and provide comments at a future meeting.

- **20 CSR 2220-2.083:** No public comments received. Douglas Lang asked to review the automated filling system rule and the two-percent (2%) pharmacist review requirement. Christina Lindsay noted this item was not on the public agenda but could be added to the February meeting.

### D5 DQSA Implementation/FDA Compounding Guidance

- Prescription Requirement Under Section 503(A) of the Federal Food, Drug and Cosmetic Act
- Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities
- Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities
- Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

DISCUSSION: Kimberly Grinston reported these items were provided for informational purposes and asked if the Board wanted to take any further action. Samuel Leveritt noted the FDA met with industry representatives and indicated the Compounding and Repackaging of Radiopharmaceuticals document provides the clearest FDA guidance the nuclear industry has had in years. Mr. Leveritt noted the guidance specifically exempts radioactive biological products and addresses other nuclear issues such as anticipatory compounding. Mr. Leveritt noted additional clarification is needed on issues such as beyond-use dating but commented the guidance document is a positive step overall. Board consensus to take no further action at this time.

### SECTION C- OPEN

### C1 Applications for Intern Training Special Sites/Non-Pharmacist Preceptors

- Harry S. Truman Memorial Veterans Hospital
- Sanofí Genzyme
- Department of Veteran Affairs Medical Center - John Cochran
- Napa State Hospital
- St. Louis College of Pharmacy
- US Medical Center for Federal Prisoners (USMCFP)
- Pharmacy Clinical Services Manager - Walmart Health & Wellness
- Dickerson Park Zoo

DISCUSSION: Tom Glenski recommended approval of the special sites/non-pharmacist preceptors presented; Mr. Glenski noted the Dickerson Park application includes a veterinarian as a preceptor. **A motion was made by Douglas Lang, seconded by Barbara Bilek, to approve all Intern Training Special Sites/Non-Pharmacist Preceptors for 500 hours.** Motion passed 5:0:0:0 with roll call vote as follows:

- Barbara Bilek – yes
- Douglas Lang- yes
- Pamela Marshall – yes
- Anita Parran – yes
- Christian Tadrus – yes

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STLCOP Site Listing
STLCOP Preceptor Listing
UMKC Site Listing
UMKC Preceptor Listing

DISCUSSION: Tom Glenski recommended approval of the sites/preceptors presented. A motion was made by Douglas Lang, seconded by Barbara Bilek, to approve all sites/preceptors for 500 hours. Motion passed 5:0:0:0 with roll call vote as follows:
Anita Parran – yes  Christian Tadrus – yes

SECTION D- OPEN

2016 Annual Report (Cont’d)

Draft 2016 annual report for Board review/approval

DISCUSSION: Kimberly Grinston asked for official Board approval of the annual report. A motion was made by Douglas Lang, seconded by Anita Parran, to approve the FY16 annual report. Motion passed 5:0:0:0 with roll call vote as follows:
Anita Parran – yes  Christian Tadrus – yes

BOARD CONSENSUS TO TABLE ALL REMAINING OPEN SESSION ITEMS UNTIL THE FEBRUARY 2017 MEETING.

THE FOLLOWING ITEMS WERE REVIEWED IN SECTION E, WHICH REQUIRED NO ACTION OR DISCUSSION.

Licensees Presently Under Discipline

Pharmacists
Pharmacies
Drug Distributors
Pharmacy Technicians – Conditional Registration
Pharmacy Technicians – Employment Disqualification List

Board Licensee Statistics

MOTION TO CLOSE
At 7:06 p.m., Barbara Bilek made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13),
(14) and (17), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 5:0:0:0 with roll call vote as follows:
Anita Parran – yes  Christian Tadrus – yes

MEMBERS OF THE PUBLIC LEFT THE MEETING ROOM AT APPROXIMATELY 7:06 P.M.

RECONVENE OPEN 12:44 P.M.
JANUARY 19, 2017

By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 12:44 p.m. on January 19, 2017.

Due to volume, President Lindsay asked if Board members would be available in February for an in-person meeting in Jefferson City; Board members indicated availability if needed.

MOTION TO ADJOURN 12:50 PM
At approximately 12:50 p.m., a motion was made by Barbara Bilek, seconded by Douglas Lang, to adjourn the January 2017 meeting. Motion passed 5:0:0:0 with roll call vote as follows:
Anita Parran – yes  Christian Tadrus – yes

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

DATE APPROVED: 04/18/2017
REVISED Meeting Notice
Missouri Board of Pharmacy
January 18-19, 2017 (Wednesday - Thursday)

Courtyard Columbia
3301 Lemone Industrial Blvd.
Columbia, Missouri

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) 751-0093 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to close meetings, records and votes, to the extent they relate to the following: Sections 610.021(1), (3), (5), (6), (7), (13), (14), and (17), RSMo, and Section 324.001.8 and .9, RSMo.

The Board may go into closed session at any time during the meeting. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.
AGENDA
Missouri Board of Pharmacy
January 18-19, 2017 (Wednesday - Thursday)
Court Yard Columbia
3301 Lemone Industrial Blvd.
Columbia, Missouri

OPEN SESSION

1.  8:00 am Call to Order Christina Lindsay, PharmD, President

2.  Roll Call Christina Lindsay, PharmD, President

3.  8:01 am The Board will go immediately into closed meeting pursuant to Section 610.021(1), (3), (5), (6), (7), (13), (14), and (17), and 324.001.8 and .9, RSMo. The Board will remain in closed until 9:00 am

4.  9:00 am Call to Order Christina Lindsay, PharmD, President

Note: The following items will be discussed as time allows during the open meeting.

5.  Agenda Additions/Corrections

6.  Board Member Report
   • MTS Advanced Practice Agenda (1-3-17)
   • MSHP PAI Collaborative Practice Survey
   • MTS Draft Language

7.  General Administration Report
   • Financial Report
   • Fee Decreases
   • Staff/Office Update
   • Intern Renewal Update
   • Rule Update
   • MSHP Fingerprint Audit
   • Kansas City Pharmacy Diversion Conference
   • 2017 Patient Safety Conference
   • Strategic Planning 2016 Update
   • 2017 Government Transition Updates
   • 2017 Legislative Updates
   • Future Board Meeting Dates
   • Executive Order 17-03 (Rulemaking)
8. Inspection/Investigation Report
   - Inspection/Investigation Updates
   - Staff Training
   - E-Mailed Inspection Reports
   - Sterile Compounding Update/Checklist
   - NABP Sterile Compounding Blueprint Program

9. Approval of Minutes
   - Conference Call (2/18/16)
   - Conference Call (7/29/2016)
   - Conference Call (8/17/2016)
   - Conference Call (9/27/2016)

10. Applications for Intern Training Special Site/Non-Pharmacist Preceptor
    - Harry S. Truman Memorial Veterans Hospital
    - Sanofi Genzyme
    - Department of Veteran Affairs Medical Center- John Cochran
    - Napa State Hospital
    - St. Louis College of Pharmacy
    - US Medical Center for Federal Prisoners (USMCFP)
    - Pharmacy Clinical Services Manager- Walmart Health & Wellness
    - Dickerson Park Zoo

11. STLCOP and UMKC College of Pharmacy Site/Preceptor Approval
    - STLCOP Site Listing
    - STLCOP Preceptor Listing
    - UMKC Site Listing
    - UMKC Preceptor Listing

12. 2016 Annual Report

13. 2020 Rule Review
    (Rule Review will be limited to three (3) minutes per participant)
    - Rule Review Calendar
    - Draft JCAR Report
    - Sample JCAR Review Notice
    - 20 CSR 2220-2.005 Definitions
    - 20 CSR 2220-2.010 Pharmacy Standards of Operation
    - 20 CSR 2220-2.015 Termination of Business as a Pharmacy
    - 20 CSR 2220-2.016 Pharmacy Operating Procedures During Declared Disasters
    - 20 CSR 2220-2.020 Pharmacy Permits
    - 20 CSR 2220-2.025 Nonresident Pharmacies
    - 20 CSR 2220-2.090 Pharmacist-in-Charge
• 20 CSR 2220-2.700 Pharmacy Technician Registration
• 20 CSR 2220-2.900 Automated Dispensing and Storage Systems
• 20 CSR 2220-2.900 Draft Class-N Automated Dispensing Rule
• 20 CSR 2220-2.080 Electronic Prescription Records
• 20 CSR 2220-2.083 Electronic Record-Keeping Systems

14. Draft Rule Discussion
   • 20 CSR 2220-6.050 (Administration of Vaccines Per Protocol)
   • 20 CSR 2220-2.650 (Standards of Operation for a Class J: Shared Services Pharmacy)

15. Hospital Advisory Committee Update
   • Chairman McClary Update
   • Class-B Hospital Guidance

16. DQSA Implementation/FDA Compounding Guidance
   • Prescription Requirement Under Section 503(A) of the Federal Food, Drug and Cosmetic Act
   • Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities
   • Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities
   • Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

17. International Pharmacy Student Visitors/Observation Programs

18. Promoting Safe E-Prescribing

19. Pharmacist Drug Utilization Review

Wednesday January 18, 2017
2:00 pm Annual Meeting with the Schools

20. STLCoP/UMKC Pharmacy Annual School Review and Meeting

21. Implementation of federal DHHS Rule 1557

22. Licensees Presently Under Discipline

23. Board Licensing Statistics

24. The Board may go into closed session at any point during the meeting and all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting will be closed under Section 610.021(1), (5), (7), and (14) and under Section 324.001.8, and .9 RSMo. The Board will return to open session at the conclusion of discussion of closed session items.
25. Adjournment
SECTION A – OPEN
#A1 Agenda Additions/Corrections
**DISCUSSION REQUESTED:** The Board received an invitation from Bert McClary to attend a meeting hosted by MSHP’s Collaborative Practice Subcommittee to discuss potential legislation/initiatives to advance pharmacist collaborative practice. The Subcommittee will be working on potential legislation that would expand or enhance current pharmacist authority. The enclosed agenda material includes a draft concept that the Subcommittee is requesting Board feedback on. The included language is not official or being officially proposed by MSHP at this time.
**MTS Advanced Pharmacy Practice**  
January 3, 2017  
9am – 1pm  
UMKC Pharmacy – Health Sciences Building Room 5309

<table>
<thead>
<tr>
<th>Session</th>
<th>Duration</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introductions</td>
<td>10 min</td>
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<tr>
<td>Background</td>
<td>15 min</td>
<td>Bert McClary</td>
</tr>
<tr>
<td>MSHP PAI Collaborative Practice Survey Results</td>
<td>15 min</td>
<td>Amanda Hays and Melissa Gabriel</td>
</tr>
<tr>
<td>Discussion</td>
<td>30 min</td>
<td>Group</td>
</tr>
<tr>
<td>Break</td>
<td>10 min</td>
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<tr>
<td>Goals</td>
<td>45 min</td>
<td>Group</td>
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<tr>
<td>Challenges/Obstacles</td>
<td>45 min</td>
<td>Group</td>
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<tr>
<td>Break</td>
<td>10 min</td>
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<tr>
<td>Next Steps/Planning</td>
<td>50 min</td>
<td>Group</td>
</tr>
<tr>
<td>Wrap up</td>
<td>10 min</td>
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**Additional Instructions:**  
[Use this section for additional instructions, comments, or directions.]
Top Initiatives for Advancing PAI in Missouri: 
Collaborative Practice Subcommittee 
Leads: Amanda Hays & Melissa Gabriel 
Submitted February 2016 
Prepared in coordination with the Chair of MSHP PAI Committee: Mariah Hollabaugh

Situation:

In November 2015, MSHP held a PAI summit to determine opportunities to support the practice advancement initiative across Missouri. Subcommittees formed to focus on key areas identified. This report is a summary of the collaborative practice subcommittee.

Background:

A subcommittee focused on pharmacist collaborative practice was recommended during the PAI summit. Leads for this subcommittee were identified and an initial goal was established (determine areas of practice/needs for pharmacist ability to prescribe, order labs and adjust medication therapy based on results, and order consults.) 
The plan for the committee was initially defined as:

1. Create task force, position statement, formulate a document of where we want to fall in the direct patient care spectrum, get current / baseline assessment, benchmark with other states 
2. Develop a one page document to send to group already working detailing what is wanted for state of MO. Use this to base next steps. Work in collaboration with Mariah and David

Assessment:

In an effort to collect input from a variety of pharmacists in Missouri a survey was developed using Survey Monkey and distributed to MSHP members through the monthly newsletter January 15th, 2016. The survey was available for responses from January 15th through January 31st. Input was received from 17 members and is summarized below. Questions included what areas the respondents felt pharmacists should have the ability to perform services, an assessment of what types of additional services could be provided in allowed by law/regulation, and a question posed around barriers/concerns with implementation. Comments received during the survey and a list of individuals interested in further participation in this topic/focus area are included in Appendices A and B.
**Question 1:** When considering the potential for expansion of pharmacist services under collaborative practice, how important are the following elements?

<table>
<thead>
<tr>
<th>Areas with Only Critical and Very Important Rating</th>
<th>Areas with Only Critical, Very Important and Moderately Important Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge follow up/transition of care</td>
<td>Discontinuation of medication</td>
</tr>
<tr>
<td>Adjustment of medication therapy</td>
<td>Ability to independently order labs</td>
</tr>
<tr>
<td>Medication reconciliation</td>
<td>Disease state management</td>
</tr>
<tr>
<td>Dose adjustment</td>
<td>Initiation of medication based on lab results</td>
</tr>
<tr>
<td>Initiation of therapy</td>
<td>Change in route</td>
</tr>
</tbody>
</table>

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**Additional types of services you would like to see as a part of collaborative practice within Missouri:**

- Prescriptive authority based on disease state protocols
- Discharge prescriptive writing authority
- Physician extender status – similar to APRN and PA
- Ability to have practice agreement between physician, APRN and pharmacist.
- Dose adjustment based on renal function
- Antibiotic adjustment based on culture results
- Discharge teaching for anticoagulants
**Question 2:** In considering expansion of pharmacist services under collaborative practice, what is the probability in which your facility/health system might add the following types of services within the next 6-12 months if authorized by law/regulation?

**Areas Very Likely or Likely to be implemented if authorized are:**
- Medication reconciliation
- Adjustment to medication therapy based on lab results
- Dose adjustment
- Discharge follow up/transition of care
- Change in route

**Barriers that exist to expand collaborative practices within your health system:**
- Provider status
- Payment for service
- Independent prescriptive authority
- Physician buy-in
- Physician education
- Accountability
- Willingness to be available outside of regular hours for problems
**Recommendation and Summary:**

Based on the results of the survey, we recommend the following services should be considered at a minimum:

- Medication reconciliation
- Disease state management - Adjustment of medication therapy, adjustment of medication therapy based on lab results and initiation of therapy
- Discharge follow up/transition of care
- Change in route

The addition of these services, when authorized by law/regulation would be adopted in many of the respondent’s facilities within 6-12 months and could aid in reducing practice gaps faced by health facilities across Missouri. It is the position of this subcommittee that we pursue and advocate for enhanced pharmacist services and independent prescriptive authority to focus on the above identified areas.
Appendix A: Comments received from the survey

- “The issue with some of these items above will be independent prescriptive authority which will be a major obstacle to get approved through the political process and those prescribers who have that authorization.”
- In relation to a question on what other items should be included in the pharmacist scope of practice:
  - “dosage adjustment for renal function; antibiotic adjustment for culture results”
  - “discharge teaching for anticoagulation patients”
  - I think most areas that come to mind are listed above
- ‘Whatever services we take on we need to be held accountable for them. Accountability’
- “Discharge prescription writing authority Everything that an APRN and PA can do as physician extenders”
- “Prescriptive authority based on disease state protocols”
- “Collaborative practice agreements with nurse practitioners when the NP, pharmacist & collaborating physician are all under the same umbrella (i.e. health system)”
- “Once again, some of these tasks can only occur under the existing regulatory framework with independent prescriptive authority.”
- “I presume the goal of the survey is to gather information for the purpose of implementing or expanding MTS and medication administration activities. The PAI should be coordinating efforts with the Public Policy Committee and the BOP Hospital Advisory Committee. Current rules may be a limiting factor, and changes are slow. The HAC is just beginning to discuss interpretation of current BOP statutes and rules related to MTS and application in specific scenarios. The HAC is currently evaluating the Administration by Medical Prescription Order rule and will make recommendations to BOP for changes. Would PAI like to participate in these discussions? The meetings are open to the public, and MSHP has an appointed representative. I am concerned that there may be duplicative efforts and possibly conflicting recommendations to MSHP Board of Directors.”
Appendix B: Individuals who expressed interested in participating in ongoing pharmacist practice advancement

- Bryan Schuelesser
- Joel Hennefent
- W Shane Edmonson
- Jason Kramer
- Andrew Bzowcyjk
- Bert McClary
General Administration Report

- Financial Report
- Fee Decreases
- Staff/Office Update
- Intern Renewal Update
- Rule Update
- MSHP Fingerprint Audit
- Kansas City Pharmacy Diversion Conference
- 2017 Patient Safety Conference
- Strategic Planning 2016 Update
- 2017 Government Transition Updates
- 2017 Legislative Updates
- Future Board Meeting Dates
<table>
<thead>
<tr>
<th>FY 2016 Actual</th>
<th>FY 2016 Projections</th>
<th>Remaining</th>
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<tr>
<td>Beginning Fund Balance</td>
<td>7,249,523.21</td>
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<tr>
<td>Revenue</td>
<td>794,626.28</td>
<td>1,141,250.00</td>
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<td>Board Expense and Equipment (includes Criminal History Checks)</td>
<td>148,818.33</td>
<td>669,168.00</td>
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<td>Board Personal Service</td>
<td>433,219.69</td>
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<tr>
<td>Total Appropriation Costs</td>
<td>582,038.02</td>
<td>1,758,967.00</td>
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<tr>
<td>Transfers:</td>
<td></td>
<td></td>
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<tr>
<td>License System Costs</td>
<td>0.00</td>
<td>0.00</td>
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<tr>
<td>Board Fringe Benefits</td>
<td>178,429.49</td>
<td>532,803.00</td>
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<tr>
<td>Board - Expense &amp; Equipment Transfer (i.e. computer equipment)</td>
<td>4,996.34</td>
<td>7,789.50</td>
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<td>Board AG Transfers</td>
<td>6,926.66</td>
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<td>Board AHC Transfer</td>
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<td>Total All Other Transfer</td>
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<td>Total Transfer</td>
<td>298,007.27</td>
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<tr>
<td>Total Appropriation Costs and Transfers</td>
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<td>Ending Fund Balance</td>
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<tr>
<td>Date</td>
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<td>Expiration Date</td>
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</tr>
<tr>
<td>12/31/2016</td>
<td>Pharmacy Intern</td>
<td>12/31/2016</td>
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<table>
<thead>
<tr>
<th>Date</th>
<th>Board</th>
<th>Expiration Date</th>
<th>Renewals Mailed (beginning of renewal period)</th>
<th>Total Approved</th>
<th>Percentage Approved</th>
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<tr>
<td>12/31/2014</td>
<td>Pharmacy Interns</td>
<td>12/31/2014</td>
<td>1920</td>
<td>1427</td>
<td>74.32%</td>
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</table>

Renewals Mailed - Number of renewals printed with the initial renewal pull
Renewals Approved by CRR - Renewals that have completed the paper renewal process
Percentage Approved - Percentage of renewals received by paper that have been approved
Renewals Approved by Online - Renewals that have completed the online renewal process
Percentage Approved - Percentage of renewals received online that have been approved
Total approved - Total of paper and online renewals received
Percentage approved - The total percentage of renewals received from both processes based on the total number of renewals mailed
Renewals opened/scanned/Ready to process - Renewals that only show a date rec'd in Promo and are ready for process
Renewals Need Board Approval - Number of renewals sent to board for review
Renewals Rejected - Number of renewals returned to the licensee due to incompleteness
Expiration Date - The date the license expires and renewal processing period ends
Renewals Not Received - Number of renewals that have not yet been rec'd for the current renewal period. Renewals mailed minus
Unopened backlog - The approx. pieces of mail that has been rec'd by CRR but not opened or scanned in yet. This
**Rule Update**  
01/04/17

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<tr>
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<th>Date</th>
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<td>20 CSR 2220-6.080</td>
<td>Medication Therapy Services by Protocol</td>
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<td>20 CSR 2220-2.415</td>
<td>Compounding for Practitioner Use or Administration RUC</td>
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<td>20 CSR 2220-2.700</td>
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<td>20 CSR 2220-2.200</td>
<td>Sterile [Pharmaceutical] Compounding</td>
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<td>1/30/17</td>
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<td>20 CSR 2220-2.200</td>
<td>Sterile [Pharmaceutical] Compounding EMERGENCY</td>
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<td>5/25/16</td>
<td>Formatting</td>
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<td>6/6/16</td>
<td>Meeting with ED</td>
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<td>6/8/16</td>
<td>Sent to DIFP for approval</td>
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<td>7/14/16</td>
<td>Approved to file</td>
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<td>8/4/16</td>
<td>Emergency effective</td>
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<td></td>
<td>9/1/16</td>
<td>Appear in MO Register</td>
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<td></td>
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<td>2/23/17</td>
<td>Emergency Expires</td>
</tr>
</tbody>
</table>

| 20 CSR 2220-2.100 | Collection of Non-Controlled Medication for Destruction | 8/22/16 | Initiated by board |
|                   |                                                          | 8/22/16 | Formatting         |
|                   |                                                          | 8/24/16 | To DIFP for approval |
|                   |                                                          | 8/29/16 | Approved to file   |
|                   |                                                          | 8/30/16 | Filed with JCAR and SOS |
|                   |                                                          | 10/3/16 | Appear in MO Reg   |
|                   |                                                          | 11/2/16 | Last Day of Comments |
|                   |                                                          | 11/18/16| FO Filed with JCAR and SBRFB |
|                   |                                                          | 12/19/16| First day to file FO with SOS |
|                   |                                                          | 1/31/17 | 90 Days            |
#A4 Inspection/Investigation Report

- Inspection/Investigation Updates
- Staff Training
- E-Mailed Inspection Reports
- Sterile Compounding Update/Checklist
This report is based solely on the inspector's observations of a random sampling of the pharmacy's activities. Licensees should review Missouri law to ensure compliance.

### GENERAL

<table>
<thead>
<tr>
<th>Description</th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compounding is completed according to the appropriate risk level [20 CSR 2220-2.200(1)(GG)]</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
</tr>
<tr>
<td>Sterile compounding policies and procedures available, encompass all aspects of compounding, and are reviewed on an annual basis [20 CSR 2220-2.200(2)]</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
</tr>
<tr>
<td>Pharmacist verification occurs prior to the release of the final compounded preparation [20 CSR 2220-2.200(14)]</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
</tr>
<tr>
<td>Every sterile compound is labeled appropriately and has an assigned beyond-use date [20 CSR 2220-2.200(12)]</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
</tr>
<tr>
<td>Point-of-care assembled systems are assembled in a primary engineering control and assigned activated and non-activated beyond-use dates when required [20 CSR 2220-2.200(16)]</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
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<tr>
<td>Sterile preparations are packaged, stored, dispensed, and distributed in a manner that will maintain the preparation's chemical and microbiological stability [20 CSR 2220-2.200(15)]</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
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### PERSONNEL TRAINING AND ASSESSMENT

<table>
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<tr>
<th>Description</th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>Prior to compounding, personnel receive initial didactic/experiential training and pass an aseptic technique skill assessment (visual observation of aseptic competencies and 3 media fill tests) [20 CSR 2220-2.200(10)]</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
</tr>
<tr>
<td>Aseptic technique skill assessment (visual and media fill) is completed annually or semi-annually according to risk level and reevaluations completed, if required. [20 CSR 2220-2.200(10)(C)]</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
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<tr>
<td>Media fill testing complies with USP Chapter 797’s recommended procedures [20 CSR 2220-2.200(10)(B)]</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
</tr>
<tr>
<td>Media fill testing simulates the most challenging or stressful conditions and is appropriate for the risk level [20 CSR 2220-2.200(10)(B)]</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
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<tr>
<td><strong>HAND HYGIENE AND GARBING</strong></td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
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<tr>
<td>Hands are properly washed prior to donning gloves [20 CSR 2220-2.200(9)(A)]</td>
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<tr>
<td>Personnel in the controlled/buffer area are garbed appropriately [20 CSR 2220-2.200(8)(A)]</td>
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<tr>
<td>Sterile gloves are worn for risk level 2 and 3 activity [20 CSR 2220-2.200(8)(B)]</td>
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</table>

**Observations:**

<table>
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<tr>
<th><strong>COMPOUNDING PROCEDURES</strong></th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>Gloves are disinfected prior to use and frequently while compounding [20 CSR 2220-2.200(8)(A)]</td>
<td></td>
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<tr>
<td>Talking and movement is kept to a minimum while compounding [20 CSR 2220-2.900(9)(A)]</td>
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<tr>
<td>Compounding personnel demonstrate proper use of first air [20 CSR 2220-2.200(9)]</td>
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<tr>
<td>Aseptic technique is used to avoid touch contamination of critical sites [20 CSR 2220-2.200(9)]</td>
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<tr>
<td>Appropriate critical sites are properly disinfected prior to needle entry [20 CSR 2220-2.200(7)]</td>
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<tr>
<td>Materials are wiped down prior to placement in the primary engineering control [20 CSR 2220-2.200(9)(A)]</td>
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<tr>
<td>Furniture, carts, supplies and equipment are disinfected prior to entry into ISO classified area [20 CSR 2220-2.200(7)(C)]</td>
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<tr>
<td>All opened vials/containers are labeled with the appropriate in-use time [20 CSR 2220-2.200(9)]</td>
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<tr>
<td>Calibration results for automated compounding devices are reviewed by a pharmacist [20 CSR 2220-2.200(5)(D)]</td>
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<tr>
<td>Pharmacist verification occurs for data entered into any automatic compounder before processing begins [20 CSR 2220-2.200(9)(B)]</td>
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**Observations:**

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<thead>
<tr>
<th><strong>FACILITIES AND EQUIPMENT</strong></th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled/buffer area(s) are clean and maintained appropriately [20 CSR 2220-2.200(7)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tacky mats are prohibited in the controlled area or any ISO classified area [20 CSR 2220-2.200(7)(A)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Removal of trash from the controlled/buffer area is performed at least daily [20 CSR 2220-2.200(4)(A)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A sink with hot and cold water is near, but not in, the controlled/buffer area [20 CSR 2220-2.200(5)(A)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drugs and supplies are stored above the floor [20 CSR 2220-2.200(4)(A)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Removal of drugs and supplies from boxes is performed outside the controlled/buffer area [20 CSR 2220-2.200(4)(A)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Particle shedding items and unnecessary supplies are kept out of the controlled/buffer area [20 CSR 2220-2.200(7)(C)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile preparations are being prepared in an ISO Class 5 primary engineering control [20 CSR 2220-2.200(5)(A)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary engineering control(s) are placed in the appropriate environment according to risk level [20 CSR 2220-2.200(5)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If no ISO 7 buffer area, the controlled area is separated from other operations with a line of demarcation [20 CSR 2220-2.200(1)(I)]</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Observations:

#### CLEANING AND DISINFECTION

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary engineering control(s) are cleaned/disinfected appropriately: daily with a germicidal agent followed by sterile alcohol, properly documented [20 CSR 2220-2.200(17)(E)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buffer/controlled area is cleaned/disinfected appropriately: floors daily, counters/work surfaces daily, ceiling/walls/storage shelving monthly, properly documented [20 CSR 2220-2.200(17)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile water for irrigation is used to dilute germicidal agents (if applicable) that are used in the primary engineering control(s) [20 CSR 2220-2.200(17)(E)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The appropriate contact time for disinfectants is utilized when cleaning [20 CSR 2220-2.200(17)(C)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All cleaning tools are low-lint and dedicated for use in the controlled/buffer area [20 CSR 2220-2.200(17)(D)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If compounding occurs less frequently than the cleaning timeframes, cleaning is performed before each compounding session [20 CSR 2220-2.200(17)]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### ENVIRONMENTAL MONITORING

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary and secondary engineering controls are certified every 6 months and when relocated or major service occurs [20 CSR 2220-2.200(5)(E)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prefilters are inspected and replaced according to manufacturer's specifications [20 CSR 2220-2.200(5)(A)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary and secondary engineering certification results are reviewed by a pharmacist [20 CSR 2220-2.200(5)(E)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk level 2 &amp; 3: Environmental monitoring of air and surfaces is conducted and documented [20 CSR 2220-2.200(5)(B)]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### CYTOTOXIC COMPOUNDING

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxic drugs are compounded in a vertical flow, Class II biological safety cabinet or CACI [20 CSR 2220-2.200(18)(A)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate protective apparel is worn while compounding cytotoxic drugs [20 CSR 2220-2.200(18)(A)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate safety and containment techniques are maintained for cytotoxic drugs such as decontamination and spill kits [20 CSR 2220-2.200(18)(A)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriate disposal of cytotoxic waste [20 CSR 2220-2.200(18)(A)]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Observations:**

**RECORDS**

<table>
<thead>
<tr>
<th>Observation</th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single and batch preparation compounding records accurately maintained</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerator and freezer temperatures are documented daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incubator temperatures are documented appropriately</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calibration records are maintained for automated compounders or pumps</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>If pressure differential monitor(s) present, results are recorded daily</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Required records and documentation maintained for two years</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**INVESTIGATIONS AND NOTIFICATIONS**

<table>
<thead>
<tr>
<th>Observation</th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remedial investigation(s) were conducted when required</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All affected areas of remedial investigation were resampled prior to</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>The Board was notified of any highly pathogenic microorganisms, if detected</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse events/complaints documented and investigated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recalls and prescriber/patient/Board notifications conducted when required</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**RISK LEVEL 3 COMPOUNDING**

<table>
<thead>
<tr>
<th>Observation</th>
<th>Y</th>
<th>N</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel training is specific to risk level 3 activities (sterilization,</td>
<td></td>
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</tr>
<tr>
<td>Non-sterile equipment is sterilized before it comes into contact with the</td>
<td></td>
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</tr>
<tr>
<td>Non-sterile components are compendial grade or have a certificate of</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparation records include sterilization records and quarantine records</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterilization methods are USP recognized and appropriate for preparation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All risk level 3 sterile preparations are tested for sterility according</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All risk level 3 parenteral preparations are tested for pyrogenicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparations with a BUD &gt;30 days have laboratory validation to support the</td>
<td></td>
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</tbody>
</table>
potency. [20 CSR 2220-2.200(13)(B)]

Risk Level 3 preparations shall at a minimum remain Risk Level 3 for the life of the preparation [20 CSR 2220-2.200(5)(C)]

Finished preparations awaiting end-preparation testing results are quarantined appropriately [20 CSR 2220-2.200(14)(C)]

If a preparation is released prior to testing results, all emergency dispensing procedures are followed and documented [20 CSR 2220-2.200(1)(N)]

A recall and sufficient investigation was conducted for any failed end-preparation testing [20 CSR 2220-2.200(21)]

**Observations:**

**General Observations:**

**Comments:**
#A5 Approval of Minutes

- Conference Call (2/18/16)
- Conference Call (7/29/16)
- Conference Call (8/17/16)
- Conference Call (9/27/16)
The Missouri Board of Pharmacy met via telephone conference call in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed at the meeting. The meeting was called to order by President Christina Lindsay at 3:30 p.m. on February 18, 2016.

**Board Members Present**
Christina Lindsay, PharmD, President
Christian Tadrus, PharmD, Vice-President
Barbara Bilek, PharmD, Member
Douglas Lang, R.Ph., Member
Pamela Marshall, R.Ph., Member
Anita Parran, Public Member

**Staff Present**
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Tammy Siebert, Administrative Coordinator
Curtis Thompson, General Counsel

**AGENDA ITEMS # 3 (20 CSR 2220-2.020 Emergency Rule Statement)**

**DISCUSSION:** Executive Director Grinston reported the emergency rule to address telehealth/telemedicine based prescriptions became effective on February 2, 2016, and indicated the office has received calls asking for additional clarification on what constitutes a legally valid medical evaluation. Ms. Grinston reported the Board of Healing Arts has not clarified what type of medical evaluation is required for a telehealth consultation. Board discussion was held.

Barbara Bilek expressed concerns with the Board of Pharmacy being the arbiter and indicated licensees need more guidance than simply being instructed to consult private counsel. Curtis Thompson suggested asking the Board of Healing Arts for additional guidance but noted the Board of Pharmacy could not delegate its authority to interpret and enforce its rules to another entity. Kimberly Grinston reported the Board of Healing Arts believes it is legally restricted from giving a legal opinion in light of the MOANA judicial decision.

Additional Board discussion was held; the Board unanimously agreed licensees should be given as much direction as legally possible. Curtis Thompson suggested asking for an
official Attorney General opinion and explained the previous process for requesting an opinion.

VICE-PRESIDENT CHRISTIAN TADRUS LEFT THE CALL AT 4:00 P.M.

Additional Board discussion was held regarding an Attorney General opinion request; Kimberly Grinston suggested the request should be limited to whether a telehealth/telemedicine examination constitutes a valid medical evaluation and advised against asking for an opinion on what constitutes a valid patient/prescriber relationship.

Board consensus to discuss potential options with legal counsel and to have staff research the possibility of, and process for, requesting an Attorney General opinion. Board consensus to review this issue and the research results on the February 24, 2016, conference call.

**MOTION TO ADJOURN**

At approximately 4:08 p.m., upon motion made by Barbara Bilek, seconded by Pamela Marshall, the February 18, 2016, open session conference call meeting was adjourned. Motion passed 3:0:0:1 with roll call vote as follows:

- Barbara Bilek – yes
- Douglas Lang – yes
- Pamela Marshall – yes
- Anita Parran – yes
- Christian Tadrus – absent

______________________________

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
OPEN MINUTES  
Missouri Board of Pharmacy  
Telephone Conference Call  
July 29, 2016

The Missouri Board of Pharmacy met via telephone conference call in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed at the meeting. The meeting was called to order by President Christina Lindsay at 11:43 a.m. on July 29, 2016.

Board Members Present  
Christina Lindsay, PharmD, President  
Christian Tadrus, PharmD, Vice-President  
Barbara Bilek, PharmD, Member  
Douglas Lang, R.Ph., Member  
Pamela Marshall, R.Ph., Member

Staff Present  
Kimberly Grinston, Executive Director  
Tom Glenski, Chief Inspector  
Jennifer Luebbert, Administrative Coordinator  
Curtis Thompson, General Counsel

Staff/Board Members Absent  
Anita Parran, Public Member

By motion duly made, seconded, passed and recorded in open session minutes, the Board went into closed session at approximately 11:43 a.m.

AGENDA ITEM # 3 (2017 Legislation)  
- Civil Penalties  
- Fund Proposal  
- Pharmacist CE  
- Third-Party Logistics Providers  
- Prescription format Requirements  
- New Decision Items

DISCUSSION: Executive Director Grinston presented the proposed legislative changes as discussed on the July 2016 conference call. Ms. Grinston advised the licensing boards have been asked to limit legislative submissions to ten (10) items, if possible. Ms. Grinston further recommended ranking and prioritizing legislative items as deemed appropriate by the Board. The Board subsequently discussed and approved the legislative proposals/new decision items identified in Attachment A. The following additional discussion was held on specific legislative proposals:
1) **Charitable Pharmacy:** Christian Tadrus suggested pursuing this item in the 2017 legislative session; Pamela Marshall agreed and noted the proposal would improve access to care. Board members expressed concerns about the proposed seven-day expiration date for a charitable pharmacy permit. Christian Tadrus suggested extending the expiration date if there was a legitimate need. Barbara Bilek suggested a three (3) day expiration date may be appropriate. Tom Glenski commented the language would be self-executing and noted the range of entities that may fall under the proposed charitable pharmacy definition. Board discussion was held. Consensus to modify language to provide that a charitable pharmacy permit may not be renewed or reissued unless otherwise allowed by the Board. **A motion was made by Pamela Marshall, seconded by Douglas Lang, to pursue the charitable pharmacy legislative proposal as reflected in Attachment A. Motion passed 4:0:0:1 with roll call vote as follows:**

- Barbara Bilek – yes
- Douglas Lang- yes
- Pamela Marshall – yes
- Anita Parran – absent
- Christian Tadrus – yes

2) **Civil Penalties:** Ms. Grinston advised the proposal may be controversial and may not be supported by the Missouri Pharmacy Association. Douglas Lang asked about other disciplinary options such as requiring the MPJE or restricting intern training abilities. Christian Tadrus asked if a civil penalty would be treated as discipline and questioned how a civil penalty might be perceived by the public. Mr. Tadrus also asked if the $25,000 penalty would be excessive for individual licensees. Board discussion was held on limiting the civil penalty language to entities only. Curtis Thompson suggested connecting the penalty to any economic gain. Additional Board discussion was held regarding a potential abuse of civil penalty authority in the future. **A motion was made by Christian Tadrus, seconded by Douglas Lang, to pursue the civil penalty legislative proposal as reflected in Attachment A. Motion passed 4:0:0:1 with roll call vote as follows:**

- Barbara Bilek – yes
- Douglas Lang- yes
- Pamela Marshall – yes
- Anita Parran – absent
- Christian Tadrus – yes

3) **Board Fund Proposal:** Kimberly Grinston suggested the proposal would likely have bipartisan support given the rise in prescription drug abuse. Board discussion was held on the amount of funds allocated to the program. Board consensus to request a range of spending authority from $500,000 to $750,000. **A motion was made by Christian Tadrus, seconded by Douglas Lang, to pursue the board fund legislative proposal as reflected in Attachment A with the suggested $500,000 to $750,000 spending range. Motion passed 4:0:0:1 with roll call vote as follows:**

- Barbara Bilek – yes
- Douglas Lang- yes
- Pamela Marshall – yes
- Anita Parran – absent
- Christian Tadrus – yes

4) **Pharmacist Continuing Education:** Pamela Marshall asked if the Board could require inactive licensees to retest if they have been out of practice for a significant period of time and noted this is required in Illinois and California. Ms. Marshall noted this is a direct patient safety issue. Board discussion was held. Barbara Bilek suggested discussing this topic at a future board meeting and proposed pursuing...
the current proposal without additional changes. **A motion was made by Douglas Lang, seconded by Pamela Marshall, to pursue the pharmacist continuing education legislative as reflected in Attachment A. Motion passed 4:0:0:1 with roll call vote as follows:**


5) Third-Party Logistic Providers: Christian Tadrus asked if brokers have to be licensed under the proposal; Tom Glenski indicated that broker licensure is required under current law and would remain the same under the proposal. Douglas Lang asked if outsourcers need to be included in the proposal. Kimberly Grinston indicated regulation of drug outsourcers would be on the October agenda. **A motion was made by Douglas Lang, seconded by Barbara Bilek, to pursue the third-party logistic provider legislative proposal as reflected in Attachment A. Motion passed 4:0:0:1 with roll call vote as follows:**


6) Prescription Format: Board discussion was held on allowing automatic substitution unless otherwise requested by the patient; Barbara Bilek noted this standard would place the burden on the patient. Douglas Lang commented that most patients who want a brand name drug will ask the prescriber to specifically write the prescription for the brand name product. Christian Tadrus asked if the Board should remove the current language that requires the generic to be less expensive; Mr. Tadrus commented the generic version may be the better choice for the patient and suggested that substitution should not limited to a monetary decision. Board consensus to reference “purchaser” in the proposal and not just a “patient” to recognize that other individuals may be purchasing medication for the patient. **A motion was made by Douglas Lang, seconded by Barbara Bilek, to pursue the prescription format legislative proposal as reflected in Attachment A. Motion passed 4:0:0:1 with roll call vote as follows:**


**MOTION TO ADJOURN**

At approximately 12:54 p.m., upon motion made by Douglas Lang, seconded by Barbara Bilek, the July 29, 2016, open session conference call meeting was adjourned. Motion passed 4:0:0:1 with roll call vote as follows:

The Missouri Board of Pharmacy met via telephone conference call in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed at the meeting. The meeting was called to order by President Christina Lindsay at 3:07 p.m. on August 17, 2016.

**Board Members Present**
- Christina Lindsay, President
- Christian Tadrus, PharmD, Vice-President
- Barbara Bilek, PharmD, Member
- Douglas Lang, R.Ph., Member
- Anita Parran, Public Member

**Staff Present**
- Kimberly Grinston, Executive Director
- Tom Glenski, Chief Inspector
- Jennifer Luebbert, Administrative Coordinator
- Curtis Thompson, General Counsel

**Staff/Board Members Absent**
- Pamela Marshall, R.Ph., Member

**AGENDA ITEMS # 4 & #5 (2016 Legislative Update/Naloxone Update)**
- 2016 Legislative Update/Newsletter Materials
- Naloxone Update/Guidance Materials

**DISCUSSION:** Executive Director Grinston presented the proposed newsletter summary of newly enacted legislative that will be effective on August 28, 2016. The following Board discussion was held:

1) **Consolidation of Refills:** Christian Tadrus asked if the 90-day maintenance medication requirement meant 90-consecutive days and asked if a pharmacy could consolidate refills if it was not the dispensing pharmacy on prior fills. Ms. Grinston indicated the statute was silent on both issues.

2) **Telemedicine:** Christian Tadrus asked if the provided language could be simplified and noted there are still a number of unanswered questions. Mr. Tadrus asked if the Board could give more definite parameters/guidelines for when a telemedicine prescription can be filled. Ms. Grinston advised the legislative language is not clear and indicated the Board of Healing Arts may need to issue additional guidance to address some of the questions raised.
3) **Naloxone**: Christian Tadrus suggested removing the notation in the sample protocol that pharmacies document the names of the consumers receiving naloxone; Mr. Tadrus noted patients/consumers may not want to be identified given the nature of the product. Douglas Lang asked if the Drug Quality and Security Act needed to be considered/incorporated. Mr. Lang also suggested adding opioid naïve patients to the list of individuals at risk of an overdose. Board consensus to ask the Department of Health about the proposed addition of opioid naïve patients and to remove the suggested addition if the Department raised concerns.

Additional Board discussion of the proposed naloxone summary and guidance documents was held. Christian Tadrus asked if the language had been reviewed by the Department of Health or the Department of Health’s prescription drug abuse task force. Ms. Grinston indicated the language was circulated to the Department of Health for comments and no comments were received. Ms. Grinston further reported she asked the Department of Health about a possible statewide protocol but was informed the Department does not have a single state/Department physician and did not believe the legislative language would allow a single statewide protocol. The Board requested that staff make a limited number of the naloxone materials available to the public for free.

Board consensus to proceed with the drafted language with the above revisions/additions.

#C1 **(Intern Training Special Sites/Non-Pharmacist Preceptors)**
- Balls Food Stores Corporate Office
- BJC Healthcare – Health Information Partners
- Cherokee Indian Hospital
- Outcomes Pharmaceutical Health Care
- Scott Air Force Base Family Health Clinic Pharmacy
- SinfoniaRx
- Southside Family Practice
- St. Louis VA Medical Center – Team 2 Annex

**DISCUSSION:** Tom Glenski recommended approval of all special sites/non-pharmacist preceptors included in the agenda. A motion was made by Barbara Bilek, seconded by Douglas Lang, to approve the special sites/non-pharmacist preceptors for 500 hours as recommended. Motion passed 4:0:0:1 with roll call vote as follows:

- Barbara Bilek – yes
- Douglas Lang– yes
- Pamela Marshall– absent
- Anita Parran – yes
- Christian Tadrus – yes

#C2 **(STLCOP/UMKC Site/Preceptor Lists)**
- STLCOP Site Listing
- STLCOP Preceptor Listing
- UMKC Site Listing
DISCUSSION: Tom Glenski recommended approval of all sites/preceptors included in the agenda. A motion was made by Barbara Bilek, seconded by Douglas Lang, to approve the sites/preceptors as recommended. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes  
Douglas Lang- yes  
Anita Parran – yes  
Christian Tadrus – yes

Pamela Marshall – absent

#A2 (Board Member Reports)

DISCUSSION: President Lindsay provided an update on the Pharmacy Technician Working Group and reported the Working Group has preliminarily suggested setting the minimum technician age at sixteen (16) and also suggested establishing three technician tiers- supporting personnel, registered technician and an advanced technician. President Lindsay provided the names and duties of each group are still in development but noted the current suggestion is to allow an advanced technician to perform enhanced duties (i.e., technician-check-technician or remote supervision) and to require additional certification or training for the advanced technician class. Douglas Lang also reported he has been appointed to the NABP task force on telemedicine.

MOTION TO CLOSE 3:47 P.M.
At 3:47 p.m., Barbara Bilek made a motion, seconded by Anita Parran, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes  
Douglas Lang- yes  
Anita Parran – yes  
Christian Tadrus – yes

Pamela Marshall – absent

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 6:01 p.m.

MOTION TO ADJOURN
At approximately 6:01 p.m., upon motion made by Douglas Lang, seconded by Christian Tadrus, the August 17, 2016, open session conference call meeting was adjourned. Motion passed 4:0:0:1 with roll call vote as follows:

Barbara Bilek – yes  
Douglas Lang- yes  
Anita Parran – yes  
Christian Tadrus – yes

Pamela Marshall – absent

KIMBERLY A. GRINSTON
OPEN MINUTES
Missouri Board of Pharmacy
Telephone Conference Call
September 27, 2016

The Missouri Board of Pharmacy met via telephone conference call in open session during the times and dates stated in the following minutes. Each item in the minutes is listed in the order it was discussed at the meeting. The meeting was called to order by President Christina Lindsay at 3:05 p.m. on September 27, 2016.

Board Members Present
Christina Lindsay, PharmD, President
Christian Tadrus, PharmD, Vice-President
Douglas Lang, R.Ph., Member
Pamela Marshall, R.Ph., Member
Anita Parran, Public Member

Staff Present
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Jennifer Luebbert, Administrative Coordinator
Curtis Thompson, General Counsel

Staff/Board Members Absent
Barbara Bilek, PharmD, Member

The meeting was called to order by President Lindsay. Due to time concerns, President Lindsay indicated the Board will begin review of the closed agenda and return to the open session agenda at the close of the meeting.

MOTION TO CLOSE 3:07 P.M.
At 3:07 p.m., Anita Parran made a motion, seconded by Pamela Marshall, that the Board go into closed session and that all votes, to the extent permitted by law, pertaining to and/or resulting from this closed meeting be closed under Section 610.021(1), (3), (5), (7), (13), (14), (17) and (20), RSMo, and under Section 324.001.8, and .9, RSMo. Motion passed 4:0:0:1 with roll call vote as follows:

   Anita Parran – yes       Christian Tadrus – yes

RETURN TO OPEN
By motion duly made, seconded, passed and recorded in closed session minutes, the Board returned to open session at approximately 4:55 p.m.
#C1 & #C1A Applications for Intern Training Special Site/Non-Pharmacist Preceptor
- MSU Care
- Saint Luke’s Multispecialty Clinic
- University of Missouri – Kansas City School of Pharmacy Drug Information Center
- Veterans Administration Consolidated Mail Outpatient Pharmacy (CMOP-#760)
- Libel-Flarsheim, LLC
- Novo Nordisk Field Medical Affairs

**DISCUSSION:** Tom Glenski recommended approval of the special sites/non-pharmacist preceptors. A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the special sites/non-pharmacist preceptors for 500 hours as recommended. Motion passed 4:0:0:1 with roll call vote as follows:
- Barbara Bilek – absent
- Douglas Lang – yes
- Pamela Marshall – yes
- Anita Parran – yes
- Christian Tadrus – yes

#C2A (STLCoP/UMKC Site/Preceptor Lists)
- STLCOP Site Listing
- STLCOP Preceptor Listing
- UMKC Site Listing
- UMKC Preceptor Listing

**DISCUSSION:** Tom Glenski recommended approval of all sites/preceptors included in the agenda. A motion was made by Douglas Lang, seconded by Pamela Marshall, to approve the sites/preceptors as recommended. Motion passed 4:0:0:1 with roll call vote as follows:
- Barbara Bilek – yes
- Douglas Lang – yes
- Pamela Marshall – absent
- Anita Parran – yes
- Christian Tadrus – yes

**ADDITIONAL DISCUSSION:** Board consensus to table #DC5 in the closed agenda until the October meeting.
MOTION TO ADJOURN
At approximately 4:57 p.m., upon motion made by Douglas Lang, seconded by Pamela Marshall, the September 27, 2016, open session conference call meeting was adjourned. Motion passed 4:0:0:1 with roll call vote as follows:

Anita Parran – yes    Christian Tadrus – yes

______________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
SECTION B – OPEN HEARINGS

THERE ARE NO ITEMS FOR THIS SECTION
SECTION C – OPEN
Applications for Intern Training Special Site/Non-Pharmacist Preceptor

- Harry S. Truman Memorial Veterans Hospital
- Sanofi Genzyme
- Department of Veteran Affairs Medical Center- John Cochran
- Napa State Hospital
- St. Louis College of Pharmacy
- US Medical Center for Federal Prisoners (USMCFP)
- Pharmacy Clinical Services Manager- Walmart Health & Wellness
- Dickerson Park Zoo
STLCOP and UMKC College of Pharmacy

- STLCOP Site Listing
- STLCOP Preceptor Listing
- UMKC Site Listing
- UMKC Preceptor Listing
SECTION D – OPEN

DISCUSSION AGENDA
2016 Annual Report

- Draft 2016 annual report for Board review/approval
2020 Rule Review

(Public comment will be limited to three (3) minutes per participant)

- Rule Review Calendar
- Draft JCAR Report
- Sample JCAR Review Notice
- 20 CSR 2220-2.005 Definitions
- 20 CSR 2220-2.010 Pharmacy Standards of Operation
- 20 CSR 2220-2.015 Termination of Business as a Pharmacy
- 20 CSR 2220-2.016 Pharmacy Operating Procedures During Declared Disasters
- 20 CSR 2220-2.020 Pharmacy Permits
- 20 CSR 2220-2.025 Nonresident Pharmacies
- 20 CSR 2220-2.090 Pharmacist-in-Charge
- 20 CSR 2220-2.700 Pharmacy Technician Registration
- 20 CSR 2220-2.900 Automated Dispensing and Storage Systems
- 20 CSR 2220-2.080 Draft Class-N Automated Dispensing Rule
- 20 CSR 2220-2.083 Electronic Prescription Records
- 20 CSR 2220-2.083 Electronic Record-Keeping Systems
MISSOURI BOARD OF PHARMACY
ADMINISTRATIVE RULE REVIEW CALENDAR

This calendar may be subject to change. Submit a comment online at www.pr.mo.gov/pharmacists-proposed.asp

### OCTOBER 2016

<table>
<thead>
<tr>
<th>Immunization/Administration</th>
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<tbody>
<tr>
<td>20 CSR 2220-6.040 Administration by Medical Prescription Order</td>
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<td>20 CSR 2220-6.055 Non-Dispensing Activities</td>
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### JANUARY 2017

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<thead>
<tr>
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<td>20 CSR 2220-2.010 Pharmacy Standards of Operation</td>
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<td>20 CSR 2220-2.020 Pharmacy Permits</td>
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### APRIL 2017

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<td>20 CSR 2220-2.140 Prescription Services by Pharmacists/Pharmacies for Residents in Long-Term Care Facilities</td>
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<td>20 CSR 2220-2.085 Electronic Transmission of Prescription Data</td>
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<tr>
<td>20 CSR 2220-2.145 Minimum Standards for Multi-Med Dispensing</td>
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<th>Medication Therapy Services</th>
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<td>20 CSR 2220-6.060 General Provisions</td>
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<td>20 CSR 2220-6.070 Certificate of MT Plan Authority</td>
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<td>20 CSR 2220-6.080 MT Services By Protocol</td>
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<td>20 CSR 2220-2.600 Standards of Operation for a Class F: Renal Dialysis Pharmacy</td>
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<td>20 CSR 2220-6.100 Pharmacy Standards for Dispensing Blood-Clotting Products</td>
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<tr>
<td>20 CSR 2220-2.500 Nuclear Pharmacy- Minimum Standards for Operation</td>
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## OCTOBER 2017

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<td>20 CSR 2220-2.950 Automated Filling Systems</td>
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<td>20 CSR 2220-2.190 Patient Counseling</td>
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## JANUARY 2018

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<tr>
<th>Drug Distributor</th>
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<tr>
<td>20 CSR 2220-5.010 Drug Distributor Advisory Committee</td>
<td>4/26/1990</td>
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<td>20 CSR 2220-5.020 Drug Distributor Licensing Requirements</td>
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<td>20 CSR 2220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors</td>
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<td>20 CSR 2220-5.040 Drug Distributor Inspection Exemptions</td>
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<td>20 CSR 2220-5.050 Out-of-State Distributor License/Registration Requirements</td>
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### MISSOURI BOARD OF PHARMACY
### ADMINISTRATIVE RULE REVIEW CALENDAR

#### APRIL 2018

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<tr>
<td>20 CSR 2220 Chapter 7</td>
<td>Board Licensing Rules</td>
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<tr>
<td>20 CSR 2220-2.018</td>
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<td>20 CSR 2220-2.050</td>
<td>Public Complaint Handling and Disposition Procedure</td>
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<tr>
<td>20 CSR 2220-2.060</td>
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<td>20 CSR 2220-2.080</td>
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<td>20 CSR 2220-2.150</td>
<td>Mandatory Reporting Rule</td>
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<td>20 CSR 2220-2.160</td>
<td>Definition of Disciplinary Actions</td>
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<td>20 CSR 2220-2.165</td>
<td>Licensure Disciplinary Agreements</td>
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<td>20 CSR 2220-2.175</td>
<td>Well-Being Program</td>
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<tr>
<td>20 CSR 2220-2.300</td>
<td>Record Confidentiality and Disclosure</td>
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</tbody>
</table>

****The Board filed an emergency and amended rule to amend 20 CSR 2220-2.2000 (Sterile Compounding) in August of 2016. Further review/comment on this rule will be conducted as part of the rulemaking process. Additional information on the emergency/amended sterile compounding rule is available online at [http://pr.mo.gov/pharmacists-proposed.asp](http://pr.mo.gov/pharmacists-proposed.asp)****
<table>
<thead>
<tr>
<th>Rule Number</th>
<th>Rule Title</th>
<th>Date of Adoption or Last Amendment</th>
<th>Is rule necessary?</th>
<th>Is rule obsolete?</th>
<th>Does rule overlap, duplicate or conflict with other rules?</th>
<th>Can a less restrictive rule accomplish same purpose?</th>
<th>Can rule be modified to reduce regulatory burden or eliminate paperwork?</th>
<th>Does the rule properly incorporate material by reference?</th>
<th>For rules affecting small businesses: does the public purpose or interest for adopting justify continued existence of rule</th>
<th>Appendix included? (For rules receiving public comment)</th>
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<td>1 CSR 10-2.010</td>
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<td>1 CSR 10-2.020</td>
<td>Privacy of Computer-accessible, Confidential Personal Information</td>
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<td>Preapproval of Claims and Accounts: Definitions/Examples</td>
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<td>1 CSR 10-4.010</td>
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<td>Parking Regulations for the State Capitol Grounds</td>
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<td>1 CSR 10-8.010</td>
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<td>1 CSR 10-9.010</td>
<td>Requirements for Direct Deposit of Vendor Payments</td>
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Notice of Periodic Rule Review

The General Assembly has instituted a five (5)-year rolling review of existing rules that will begin July 1, 2015, as set forth in Section 536.175 RSMo. The following agencies will begin this process for rules promulgated within their designated Title of the Code of State Regulations with a sixty (60)-day public comment period. The Code of State Regulations may be viewed at http://www.sos.mo.gov/ad/rules/sr/review.aspx

Titles Reviewed Beginning July 1, 2015:

Title 1 - Office of Administration
Title 2 - Department of Agriculture
Title 3 - Department of Conservation
Title 4 - Department of Economic Development
Title 5 - Department of Elementary and Secondary Education
Title 6 - Department of Higher Education

The Public Comment Process: Agencies with rules in Titles 1-6 of the Code of State Regulations may receive comments from the public for any rule within these titles.

- Comments must be received within sixty (60) days of July 1, 2015. (August 31, 2015)
- Comments must identify the commenter.
- Comments must identify the specific rule commented upon
- Comments must be directly associated with a specified rule
- Comments must be submitted to the following agency designee:

Title 1 - Office of Administration
Kristen Paulsmeyer
P.O. Box 809
Jefferson City, MO 65102
Kristen.Paulsmeyer@oa.mo.gov

Title 2 - Department of Agriculture
Amber Buckland
1616 Missouri Blvd.
Jefferson City, MO 65109
Amber.Buckland@nda.mo.gov

Title 3 - Department of Conservation
Denise Bateman
P.O. Box 180
Jefferson City, MO 65102
Denise.Bateman@mdc.mo.gov

Title 4 - Department of Economic Development
Nathan Nickolaus, General Counsel
(HST-680)
PO Box 1157
Jefferson City, MO 65102
Nathan.Nickolaus@ded.mo.gov

Title 5 - Department of Elementary and Secondary Education
Attn: Barbara LePage
PO Box 480
Jefferson City, MO 65102-0480
DESE.AdminRules@dese.mo.gov

Title 6 - Department of Higher Education
Jeremy Kneee
205 Jefferson Street, 11th Floor
PO Box 1469
Jefferson City, MO 65102
Jeremy.Kneee@dhe.mo.gov

The Report: The agency will prepare a report containing the results of the review which will include: whether the rule continues to be necessary; whether the rule is obsolete; whether the rule overlaps; duplicates or conflicts with other rules; whether a less restrictive or more narrowly tailored rule is appropriate; whether the rule needs amendment or rescission; whether incorporated by reference materials are proper; and whether rules affecting small business are still relevant. The report will also contain an appendix with the nature of the comments the department has received on the rules and the agency responses to the comments.

Report Deadline: The report must be filed with the Joint Committee on Administrative Rules by June 30, 2016. Any rule not included in the report may become null and void. However, there is an extensive process, including multiple opportunities to correct the deficiency, in place before nullification of the rule. Such opportunities include the ability of the agency to request an extension from the Joint Committee on Administrative Rules, as well as notification to the agency and opportunity to correct the delinquency.

Questions: If you have further questions about the process, please contact Cindy Kadlec, Joint Committee on Administrative Rules, 573-751-2443 or ckadlec@senate.mo.gov.
**Title 20—DEPARTMENT OF**
**INSURANCE, FINANCIAL**
**INSTITUTIONS AND**
**PROFESSIONAL REGISTRATION**
**Division 2220—State Board of Pharmacy**
**Chapter 2—General Rules**

20 CSR 2220-2.005 Definitions

**PURPOSE**: This rule defines the term “drug” as utilized in Chapter 338, RSMo, and the rules of the board.

(1) “Drug,” “prescription drug,” or “legend drug” means any drug or biological product—

(A) Subject to section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to section 503(b);

(B) Required by federal law to be labeled with one (1) of the following statements, prior to being dispensed or delivered:

1. “Caution: Federal law prohibits dispensing without prescription”;

2. “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian”;

3. “Rx Only”; and

(C) Required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use by practitioners only.

(2) For purposes of sections 338.300 to 338.370, RSMo, the term “drug,” “prescription drug,” or “legend drug” shall not include:

(A) An investigational new drug or biological product, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial/investigation of that drug or product if such clinical trial/investigation is governed by, and being conducted pursuant to, 21 CFR 312, et seq.;

(B) A legend drug or biological product being utilized for the purposes of a clinical trial/investigation that is governed by, and being conducted pursuant to, 21 CFR 312, et seq.; or

(C) A legend drug or biological product being utilized for the purposes of a clinical trial/investigation that is governed or approved by an institutional review board subject to 21 CFR 56 or 45 CFR Part 46.

TO: Board Members
FROM: Kimberly Grinston, Executive Director
RE: 20 CSR 2220-2.010 (Pharmacy Standards of Operation)
DATE: January 5, 2017

The current 20 CSR 2220-2.010 is included in the Board’s agenda for discussion purposes. In addition to the general rule review, the Board asked to discuss the following requirements/issues when considering this rule:

1. Should the rule address pharmacist rest breaks/staffing?
2. Should the rule address what technicians are authorized to do when a pharmacist is temporarily absent from the pharmacy (e.g., a restroom break)? I’ve included the research from other states that was reviewed during the July 2016 strategic planning meeting.
3. Should the rule address remote supervision of technicians or electronic pharmacist verification of the final product?
PURPOSE: This rule defines terms used in the regulations of the State Board of Pharmacy and outlines the conditions necessary for the operation of a pharmacy.

(1) The word medicine or medicines is a word similar or of like import to the words pharmacist, pharmacy, apothecary shop, chemist shop, drug store, druggist and drugs, and no person shall carry on, conduct or transact a business under a name which contains, as part of the name, the word medicine or medicines, unless the place of business is supervised by a licensed pharmacist.

(A) At all times when prescriptions are compounded in a pharmacy or other establishments holding a Missouri pharmacy permit, there shall be on duty and present in that place of business a pharmacist licensed in Missouri as provided by law. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in 20 CSR 2220-2.900 the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient’s or other health professionals’ inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. When there is no pharmacist on duty, no prescription will be compounded, dispensed or otherwise provided and the public will be advised that no pharmacist is on duty by means of signs stating this fact. The signs will be displayed prominently on the doors of all entrances and the prescription counter of the pharmacy and the signs will be composed of letters of a minimum height of two inches (2”).

(B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in 20 CSR 2220-2.900 the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient’s or other health professionals’ inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. The pharmacist personally shall inspect and verify the accuracy of the contents of, and the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.

(C) No pharmacy shall be licensed under the provisions of this chapter unless it is equipped with proper pharmaceutical equipment and reference manuals. Requirements for proper equipment and references may vary between pharmacies and must insure accuracy and safety of all pharmaceutical activity.
1. Basic equipment recognized by the latest edition of the *United States Pharmacopoeia* (USP), the *United States Pharmacopoeia/Drug Information* (USP/DI) or *Remington’s Pharmaceutical Sciences* shall be available for any procedures utilized in the dispensing, compounding or admixture of drugs and drug-related devices, and must maintain conformance with these publications.

2. A suitable machine or electronic data device for the numbering of all prescriptions must be maintained along with appropriate printing equipment for the production of prescription drug labels.

(D) Reference manuals may include any generally recognized pharmaceutical publication other than periodicals or journals. A pharmacy must maintain, at a minimum, the current or latest edition of a reference manual(s) which includes all Federal Drug Administration (FDA)-approved drugs. The following topics must be included in the reference(s) selected:

1. Pharmacology of drugs;
2. Dosages and clinical effects of drugs; and
3. Patient information.

(E) Pharmacies shall maintain at least one (1) current edition of statutes and rules governing the pharmacy’s practice.

(F) All pharmacies shall be maintained in a clean and sanitary condition at all times. Any procedures used in the dispensing, compounding and admixture of drugs or drug-related devices must be completed under clean and, when recommended, aseptic conditions.

1. Appropriate sewage disposal and a hot and cold water supply within the pharmacy must be available.

2. Appropriate housekeeping and sanitation of all areas where drugs are stored or dispensed must be maintained.

3. Animals, except for service animals as defined by the Americans with Disabilities Act (ADA), are not allowed in pharmacies.

(G) The temperature of the facility where drugs are stored must be maintained thermostatically within temperature requirements as provided for by the manufacturer or the latest edition of the USP. Adequate refrigeration must be available to insure enough storage space for drugs requiring refrigeration or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both. Drugs and drug-related devices must be stored separately from food and other items.

(H) Pharmacies must maintain adequate security in order to deter theft of drugs by personnel or the public. Sufficient alarm systems or locking mechanisms must be in place if the pharmacy is located in a facility into which the public has access and the pharmacy’s hours of operation are different from those of the remainder of the facility.
(I) Pharmacies which maintain storage sites or warehouse facilities for the storage of pharmaceuticals at a separate address or premises from the main pharmacy that holds a pharmacy permit shall register those sites as storage facilities of the licensed pharmacy. Information required for proper registration of a storage facility shall include the address of the facility, hours of operation (if applicable), pharmacy permit numbers of the pharmacies that it services, and a certified statement that the facility is used for the sole purpose of distributing drugs only within its own pharmacy operations.

1. Records must be maintained at these facilities to guarantee security, storage and accountability of all drugs and drug-related devices under proper conditions.

2. All storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and shall be subject to inspection by the board as defined in section 338.150, RSMo.

3. No fee will be charged by the board for registering a facility as defined in subsection (I)(I) of this rule.

(J) Pharmacies that maintain storage sites or warehouse facilities for the storage of confidential pharmacy records at a separate address or premises from the main pharmacy that holds a pharmacy permit shall register those sites as storage facilities of the licensed pharmacy. Information required for proper registration of a storage facility shall include the address of the facility, hours of operation (if applicable), pharmacy permit numbers of the pharmacies that it services, and a statement that the facility is used for the sole purpose of storing records within its own pharmacy operations.

1. All storage and warehouse locations must maintain adequate security including an alarm system. Any breach in security must be documented and reported in writing via facsimile, email communication, or letter to the board within fifteen (15) days of the breach of confidentiality.

2. All storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and shall be subject to inspection by the board as defined in section 338.150, RSMo.

3. No fee will be charged by the board for registering a facility as defined in subsection (J)(I) of this rule.

4. All storage and warehouse locations must comply with 19 CSR 30-1.

5. No records less than two (2) years old may be stored offsite.

6. All storage and warehouse locations storing confidential pharmacy records must make records retrievable within two (2) business days when requested by the board or its representatives.

(K) All pharmacists will be required to have a photo of themselves not smaller than two inches by two inches (2" × 2") in the upper right-hand corner of the current renewal licenses. This photo and license renewal shall be conspicuously exposed in the pharmacy or drug store or place of business in which the pharmacist is employed as required by law.
Pharmacists regularly working as relief persons for more than one (1) store shall have in their possession proper identification of their pharmacy licensure.

Pharmacy operations must be conducted at all times under the supervision of a properly designated pharmacist-in-charge. When a licensed pharmacist leaves the employment of a pharmacy where s/he has been pharmacist-in-charge, s/he immediately shall notify the executive director of the board of the termination of his/her services in the pharmacy. Likewise, the holder of the permit shall notify the executive director of the board of the termination of the services and give the name of the new licensed pharmacist-in-charge.

Pharmacists are responsible to inform the executive director of the board in the case of changed address. Any mail or communications returned to the executive director’s office marked Unknown, Incorrect Address, and the like, will not be sent out a second time until the correct address is sent in.

When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

When required by section 338.013(10), RSMo, to report technician disciplinary action, the pharmacy must notify the board in writing within fifteen (15) days of the action. The notification must include:

1. The name and permit number of pharmacy;
2. Name of person making the notification;
3. Name of technician;
4. Technician registration number;
5. Date of action; and

Pharmacists must inform the executive director of the board of any change in their employment address. The notification of an employment change must be provided in writing to the board no later than fifteen (15) days following any effective change.

Every pharmacy shall designate as its primary means of record keeping either a manual system which provides for the consecutive numbering of hard copy prescriptions and complies with the provisions of section (3) of this rule or an electronic system which complies with the provisions of 20 CSR 2220-2.080. The designated record system shall be used to record the pharmacy’s dispensing of all drugs, medicines and poisons.

A pharmacy using a record keeping system other than an electronic system meeting the requirements of 20 CSR 2220-2.080 to record its dispensing of drugs, medicines and poisons shall provide a method of recording all of the following information concerning the refill of any prescription medication on the back or reverse side of every prescription order:

A The date the drug, medicine or poison was dispensed;
(B) The dispensing pharmacist’s initials; and

(C) The amount of drug, medicine or poison dispensed to the patient if different from the amount on the face of the prescription order.

(4) Each licensed pharmacy shall maintain at least three (3) separate files of prescriptions and they shall be as follows:

(A) All prescriptions for controlled drugs listed in Schedules I and II shall be maintained in a separate prescription file;

(B) All prescriptions for controlled drugs listed in Schedules III, IV and V shall be maintained in a separate prescription file; and

(C) All other prescriptions for noncontrolled drugs shall be maintained in a separate prescription file(s).

(5) Pharmacies shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Said records shall be maintained for two (2) years and be readily retrievable upon request by the board or its representatives.

(6) Drugs and devices that are maintained as part of the pharmacy inventory or are being processed for dispensing or other distribution purposes must be physically separated at all times from articles, supplies or other drugs that are for employee personal use or that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances. Areas used for this type of drug storage must be clearly identified. Any prescription drugs that are present in a licensed pharmacy but are for the personal use of pharmacy personnel must be labeled in accordance with section 338.059, RSMo.

(7) All records required by Chapters 195 and 338, RSMo or divisions 20 CSR 2220 and 19 CSR 30 shall be available for photocopying or electronic duplication by a board of pharmacy representative.


(9) A home health or hospice agency licensed or certified according to Chapter 197, RSMo, or any licensed nurses of such agency, may possess drugs in the usual course of business of such agency without being licensed as a pharmacist or a pharmacy.

(A) The list of drugs that may be possessed by a home health or hospice agency without a license or permit, as defined in section (9), is as follows:

1. Injectable dosage forms of sodium chloride and water;

2. Irrigation dosage forms of sodium chloride and water that carry a federal prescription only restriction;
3. Injectable dosage forms of heparin and alteplase in concentrations that are indicated for maintenance of venous access devices;
4. Injectable dosage forms of diphenhydramine and epinephrine;
5. Vaccines indicated for public health needs, such as influenza, pneumonia, hepatitis A and hepatitis B; and
6. Tuberculin test material.

(B) The agency shall have a policy and procedure that addresses at least the following:
1. Specific drugs authorized to be possessed by the agency and the nurse;
2. Indications for use of the drugs possessed;
3. Receiving physicians’ orders for administration of the drugs;
4. Leaving drugs with the patient for routine care procedures;
5. Conditions for storage and transport of the drugs by the agency and the nurse; and
6. Quantity of drugs possessed by the agency and the nurse.

(C) The nurse must have a physician’s authorization, such as an individual patient order, protocol or standing order, to administer the drugs.

(D) When the patient or the patient’s representative has been instructed, verbally and in writing, in the performance of routine care procedures, up to a two (2)-week supply of sodium chloride, water, and heparin may be left with the patient for these procedures. Drugs left with the patient shall be labeled with instructions for use. A record shall be made of all drugs left with the patient in the patient’s medical record. Drugs left with the patient may not be returned to the agency.

(E) Drugs may be stored at the agency or transported by the nurse, and shall be stored or transported at all times in accordance with the manufacturer’s storage requirements. Refrigerator units used by the agency for storing drugs shall not be used for storing non-drug items.

(F) All drugs must be received from a licensed pharmacy or drug distributor. The quantity of drugs possessed by an agency shall be limited to that necessary to meet the needs of the agency’s patient population for two (2) weeks.

(10) Class I: Consultant Pharmacies as defined in 20 CSR 2220-2.020(9)(I) and approved by the board to be located within a residence shall be required to address and comply with the following minimum standards of practice:

(A) Location Requirements—
1. The pharmacy must be located in a separate room that provides for a door with suitable lock;
2. Sufficient storage for securing confidential documents and any hardware used in accessing a central pharmacy by electronic connection must be provided;
3. Ceiling and walls must be constructed of plaster, drywall, brick or other substantial substance that affords a design that makes the room separate and distinct from the remainder of the domicile. Drop down ceilings that allow access into the room are not allowed;
4. All locations must be inspected and have approval by the board prior to the initiation
of services; and
5. Patients are not allowed in the pharmacy.

(B) Documentation—
1. Maintain a current policy and procedure manual that is attested by the signature and
date of review of the pharmacist-in-charge to its accuracy. All pharmacists working at the
pharmacy shall be required to sign the manual attesting to their review and understanding of
all policies and procedures in force;
2. Maintain documentation that the permit holder has provided training to all personnel
on all operations associated with the pharmacy;
3. The permit holder must complete an audit to ensure compliance with pharmacy policy
and procedures and this regulation at a minimum of twice per year, through physical visits
by representatives of the permit holder. Audit results must be maintained by the permit
holder for a period of three (3) years; and
4. If the pharmacist is working under a contract for the permit holder, a copy of the
contract shall be available during an inspection.

(C) Security—Records and Internet—
1. All electronic data processing systems must meet all applicable state and federal
confidentiality laws and regulations;
2. Data processing systems must utilize sufficient security software;
3. Any breach in the security of the system must be documented and reported to the
board of pharmacy within seven (7) days of the breach of confidentiality. Such
documentation shall be available during an inspection.

(D) Licensure and Inspection—
1. Each location must maintain and display a current Class I permit. The permit holder
for this permit must be the pharmacy the individual pharmacist is employed by or
contracted with;
2. Routine inspections for in-state pharmacies shall be arranged ahead of time.
Notification by the inspector to the permit holder will be provided a minimum of seventy-
two (72) hours ahead of the scheduled inspection. The permit holder must arrange for a
designated representative to be present that is not a resident of the location under inspection;
3. A pharmacy located outside the state must maintain a pharmacist-in-charge with a
current and active pharmacist license with the state of Missouri;
4. The audits required in paragraph (10)(B)3. shall be available for review during the
inspection; and
5. The pharmacy shall provide copies of inspections completed by the state in which
they are located if such inspections are required within seven (7) business days of the
inspection date.

AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and sections 338.010
and 338.210, RSMo Supp. 2007.*
MEAL BREAKS AND REST BREAKS

ALABAMA:

AL BReg 680-X-2-.28.
Temporary Absences of Pharmacists During Break and Meal Period

(1) This rule is to allow pharmacists to have breaks and meal periods without unreasonably impairing the ability of a pharmacy to remain open.

(2) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy area or department, temporarily, for breaks and meal periods without closing the pharmacy and removing interns/externs and technicians from the pharmacy, if the pharmacist reasonably believes that the security of the controlled substances will be maintained in his or her absence.

(a) If, in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should be closed during his or her absence, then the pharmacist shall close the pharmacy area or department and remove all interns/externs and technicians from the pharmacy during his or her absence.

(3) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a new or refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.

(4) During such times that the pharmacist is temporarily absent from the pharmacy area or department, the interns/externs and technicians may continue to perform the non-discretionary duties authorized to them by any applicable law or rule. However, any duty performed by an intern/extern or technician shall be reviewed by a pharmacist upon his or her return to the pharmacy.

(5) The temporary absence authorized by this rule shall be limited to thirty (30) minutes. The pharmacist shall remain within the facility during the break period and be available to handle all emergency situations.

(6) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy area or department during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of interns/externs and technicians, the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the Board or its designee at all times during business hours.
CALIFORNIA:

BReg 1714.1.
Pharmacy Operations During the Temporary Absence of a Pharmacist.

This section is to ensure that pharmacists are able to have duty free breaks and meal periods to which they are entitled under Section 512 of the Labor Code and the orders of the Industrial Welfare Commission, without unreasonably impairing the ability of a pharmacy to remain open.

(a) In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for breaks and meal periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence.

If in the professional judgment of the pharmacist, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during his or her absence.

(b) During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked, released for furnishing to the patient and was determined not to require the consultation of a pharmacist.

(c) During such times that the pharmacist is temporarily absent from the pharmacy, the ancillary staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.

(d) During the temporary absence of a pharmacist as authorized by this section, an intern pharmacist may not perform any discretionary duties nor otherwise act as a pharmacist.

(e) The temporary absence authorized by this section shall be limited to the minimum period authorized for pharmacists by section 512 of Labor Code or orders of the Industrial Welfare Commission and any meal shall be limited to 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period.

(f) The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the board or its designee at all times during business hours.

(g) For the purposes of this section, ancillary staff includes: an intern pharmacist, a pharmacy technician, non-licensed personnel as defined in Section 1793.3 of Title 16 of the California
CALIFORNIA (cont.):

Code of Regulations and a pharmacy technician trainee as defined in Section 4115.5(a) of the Business and Professions Code.

FLORIDA:

FL BReg 64B16-27.1001.
Practice of Pharmacy.

(6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:

(a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.

(b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.

(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

MASSACHUSETTS:

Policy 2000-03
Policy on Pharmacy Operations during the Temporary Absence of a Pharmacist

Board Regulations at 247 CMR § 6.02(9)(a) state:
"A registered pharmacist shall be on duty and shall be present at all times when non-pharmacist personnel have unrestricted access to the pharmacy department"
This requirement shall not apply during the temporary absence of a pharmacist as set forth below
MASSACHUSETTS (cont.):

provided that the following requirement is strictly adhered to at all times during the temporary absence of the pharmacist.

This policy is adopted to ensure that pharmacists are able to have necessary and appropriate duty free breaks and meal periods without unreasonably impairing the ability of a pharmacy to remain open.

a. In any pharmacy that is staffed by a single pharmacist, the pharmacist may leave the pharmacy temporarily for necessary and appropriate breaks and meal periods without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence.

If in the professional judgment of the pharmacist, for reasons of security or otherwise, the pharmacist determines that the pharmacy should close during his or her absence, then the pharmacist shall close the pharmacy and remove all ancillary staff from the pharmacy during his or her absence.

b. During the pharmacist's temporary absence, no prescription medication may be provided to a patient or to a patient's agent unless the prescription medication is a refill medication that the pharmacist has checked; and determined not to require the consultation of a pharmacist; prior to being released for furnishing to the patient.

A new prescription which has been previously prepared, visibly checked by a pharmacist and had a drug utilization performed by a pharmacist, may be picked up by a patient provided that a log, including the patients phone number, of all such transactions is kept.

The pharmacist, upon return from break, and within a reasonable time, shall call the patient to review any pertinent counseling deemed appropriate.

c. During such times that the pharmacist is temporarily absent from the pharmacy, the pharmacy technical support staff may continue to perform the non-discretionary duties authorized to them by pharmacy law. However, any duty performed by any member of the ancillary staff shall be reviewed by a pharmacist upon his or her return to the pharmacy.

d. Pharmacist managers, at their discretion, may develop a written policy for allowing Pharmacy Technician Certification Board ("PTCB") and/or Board approved certified technicians and pharmacy interns to receive telephone prescription orders from practitioners, unless otherwise prohibited by law.

e. In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the pharmacy is not left without a pharmacist for a temporary period.

f. The temporary absence authorized by this section shall not exceed 30 minutes. The pharmacist who is on break shall not be required to remain in the pharmacy area during the break period, however the pharmacist shall be required to remain on the premises, licensed by the Board. The total temporary absence shall not exceed more than 30 minutes absence during any work period of at least six consecutive hours.
MASSACHUSETTS (cont.):
g. The pharmacy shall have written policies and procedures regarding the operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the Board or its designee at all times during business hours.

A pharmacist who temporarily leaves the pharmacy for a break or meal period in compliance with this section shall not be subject to Massachusetts Board of Registration in Pharmacy disciplinary action or for acts that he or she did not authorize and that he or she, by the exercise of reasonable care, could not have prevented during his or her absence.

MISSISSIPPI:

MS BReg 30-20-3001:VII.
Responsibility of Pharmacist-In-Charge (PIC).

(4) That all staff should have the opportunity to take periodic breaks and/or meal periods to relieve fatigue and mental and physical stress. Nothing in this paragraph suggests closing the pharmacy; and

MONTANA:

MT BReg 24.174.411.
Pharmacist meal/rest breaks

(1) In any pharmacy staffed by a single pharmacist, the pharmacist shall take a meal/rest break for a period of up to 30 minutes per shift without closing the pharmacy and removing support personnel, provided the pharmacist reasonably believes that the security of prescription drugs will be maintained in the pharmacist's absence.

(2) The time of the meal/rest break will be conspicuously posted in clear view of patients approaching the prescription area.
(3) In the pharmacist's absence a sign indicating that no pharmacist is on duty will be conspicuously displayed in clear view of patients approaching the prescription area.

MONTANA (cont.)

(4) The pharmacist will remain on the premises if the prescription area is to remain open, and be available for emergencies.

(5) When authorized by the pharmacist, only registered technicians directly involved in the process of filling prescriptions may remain in the prescription department to perform nondiscretionary duties as delineated by the pharmacist.

(6) Upon returning, the pharmacist shall review any work performed in the pharmacist's absence.

(7) In the pharmacist's absence there may be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor may counseling be provided.

(8) At the discretion of the pharmacist, previously checked medication refills may be handed to patients or their agents by registered technicians in the pharmacist's absence, and the technicians must offer the patient counseling by the pharmacist. If the patient desires counseling, the patient may wait for the pharmacist to return or may leave a telephone number for the pharmacist to call upon return.

(9) Telephoned new prescriptions must not be accepted by support personnel in the pharmacist's absence.

(10) New hardcopy prescriptions may be accepted and processed by registered technicians in the pharmacist's absence. These prescriptions may not be dispensed until the pharmacist has performed prospective drug review and completed the final check.

(11) If two or more pharmacists are on duty, the pharmacists shall stagger their breaks so that the prescription department is not left without a pharmacist on duty.

(12) The pharmacist-in-charge shall develop written policies and procedures for operation of the prescription department in the temporary absence of the pharmacist.

NORTH CAROLINA:

NC BReg 2512.
Pharmacist work conditions.

A permit holder shall not require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than six continuous hours per work day shall be allowed during that time period to take a 30 minute meal break and one additional 15 minute break.
NEW JERSEY:

**NJ BReg 13:39-6.4. Meal or restroom breaks.**

(a) A sole pharmacist on duty may take restroom breaks and 30-minute meal breaks while working in a pharmacy consistent with the following requirements:

1. The pharmacist shall remain in the pharmacy or, in the case of a pharmacy department, in the pharmacy department building, and shall be accessible for emergencies or for counseling, if requested;

2. The pharmacy shall remain open during the restroom or meal breaks, provided a pharmacy employee remains present in the pharmacy, for patient related services, which include, but are not limited to, the following:

   i. The receipt of new written prescriptions; and

   ii. The dispensing of prescription medications which have been checked by the pharmacist; and

3. A sign shall be posted in the prescription dispensing area stating “Pharmacist on break, but available for emergencies and counseling.”

OREGON:

**OR BReg 855-041-1170**

**Grounds for Discipline**

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:

(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.
TENNESSEE:

TN BReg 1140-03-.07.
Temporary absence of pharmacist.

A pharmacist is permitted one (1) temporary absence for a period not exceeding one (1) hour per day. During the absence of a pharmacist from the pharmacy practice site, a sign containing the words “pharmacist not on duty” must be conspicuously displayed in the pharmacy practice site. It shall be unlawful to fail or refuse to display the required sign in a conspicuous place when a pharmacist is absent. No medical or prescription order may be compounded or dispensed during the absence of a pharmacist. Additionally, during the absence of the pharmacist the prescription department shall be closed off by physical barrier from floor to ceiling.

VERMONT:

VT BReg 20-4-1400:9.21.
Pharmacist Meal/Rest Breaks

(a) Whenever the prescription department is staffed by a single pharmacist, the pharmacist may take a meal/rest break for a period of up to 30 minutes without closing the pharmacy and removing support personnel from the pharmacy, provided that the pharmacist reasonably believes that the security of the prescription drugs will be maintained in the pharmacist's absence.

(b) No pharmacist shall work more than 8 hours without a meal/rest break. Breaks should be scheduled as close as possible to the same time each day, so that patients may become familiar with the approximate time of the breaks.

(c) The pharmacist shall remain on the premises of the drug outlet during the meal/rest break and shall be available for emergencies.

(d) If two or more pharmacists are on duty in the prescription department, the pharmacists shall stagger their meal/test breaks so that the prescription department is not left without a pharmacist on duty.

(e) Whenever the pharmacist temporarily leaves the prescription department for a meal/rest break, a sign indicating that there is no pharmacist on duty shall be conspicuously displayed. The sign shall also indicate the time when the pharmacist will return.
VERMONT (cont.):

(f) Only support personnel directly involved in the prescription dispensing process and authorized by the pharmacist on duty may remain in the prescription department while the pharmacist is on a meal/rest break.

(g) When the pharmacist is temporarily absent from the prescription department, support personnel authorized by the pharmacist on duty may continue to perform non-discretionary duties as delineated by the pharmacist. All such duties performed by support personnel shall be reviewed by the pharmacist upon return from the meal/rest break.

(h) When a pharmacist is not in the prescription department, there shall be no dispensing of new prescriptions that the pharmacist has checked and that are waiting to be picked up, nor shall counseling be provided by support personnel.

(i) New, written prescriptions presented by the patient or the patient's agent may be accepted by support personnel. The processing of such prescriptions, up to the final check, may occur in the absence of the pharmacist. However, no prescription may be dispensed until the final check is completed by the pharmacist after return to the prescription department.

(j) New prescriptions conveyed by telephone shall not be accepted by support personnel. The caller should be instructed to call back, or a telephone number should be obtained for the pharmacist to call upon return to the prescription department.

(k) During the pharmacist's absence, prescription refills which have been previously prepared and checked by a pharmacist may be picked up by the patient or the patient's agent. Support personnel must offer the patient counseling by the pharmacist. If the patient has no questions, dispensing may proceed as usual, with the patient signing for the counseling refusal. If the patient desires counseling, the patient should be asked to wait for the pharmacist to return from the meal/rest break. Alternatively, the patient may be asked to leave a telephone number for the pharmacist to call later the same day.

(l) Telephone refill orders and refill requests presented in person by the patient or the patient's agent may be accepted by support personnel. Such refill orders may be processed by support personnel up to the final check. However, no such refill orders shall be dispensed until the final check is completed by the pharmacist after return from the meal/rest break.

(m) Under this rule, the pharmacist-manager remains responsible for the direct management, supervision, and control of the prescription department.

(n) If, for security reasons or otherwise, the pharmacist determines that the prescription department should close during the pharmacist's absence, the pharmacist shall close the prescription department and remove all support personnel from the prescription department.
during the pharmacist's absence. A sign informing the public of the pharmacist's temporary absence and time of return shall be conspicuously posted.

VERMONT (cont.):

(o) Using this rule as a guide, the pharmacist-manager, in conjunction with the pharmacy license holder, should develop written policies and procedures regarding operation of the prescription department while the pharmacist is temporarily absent on a meal/rest break.

(1) The policies and procedures should include authorized duties of support personnel and should define the pharmacist's responsibilities for checking all work performed by support personnel and for maintaining security of the prescription department. The pharmacist-manager should review the policies and procedures with support personnel.

(2) After review, each support person should be requested to initial the policies and procedures to indicate that the policies and procedures are understood.

WASHINGTON D.C.:

BReg 1901.
General operating standards.

1901.2 A licensed pharmacist shall be on duty at all times that a pharmacy is open for business. Where only one pharmacist is on duty, the pharmacy shall be closed for business during the pharmacist's meal period and breaks.
20 CSR 2220-2.015 Termination of Business as a Pharmacy

PURPOSE: This rule establishes guidelines for the termination of business as a pharmacy.

(1) A licensed pharmacy who plans to terminate business activities shall file a written notice with the State Board of Pharmacy. The written notice shall be submitted to the State Board of Pharmacy in person or by registered or certified mail within fifteen (15) days after the date of termination. This notice shall be made on a form provided by the board or in letter form from the licensee and shall include the following information:

(A) The name, address, license (permit) number and effective date of closing;

(B) The name, address, and license (permit) number of the entity to which any of the stock/inventory will be transferred;

(C) The name and address of the location to which records, required to be maintained by law, have been transferred.

1. Any records that are transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board.

2. Any records that are transferred to a licensed (permitted) pharmacy or licensed drug distributor must be maintained in accordance with record requirements as set forth in section 338.100, RSMo.

(2) The licensee (permit holder) terminating business may transfer all drugs and records in accordance with the following:

(A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the pharmacy terminating business and as the initial inventory of the licensed entity to which the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee or permit holder involved in the transfer.

(B) A pharmacy terminating business shall not transfer misbranded, outdated or adulterated drugs, except for purposes of proper disposal; and

(C) Upon the actual termination of business, the license (permit) of the pharmacy shall be returned to the State Board of Pharmacy for cancellation either in person or by registered or certified mail.

(3) A one (1)-time transfer of drugs and devices due to a termination of business that is in compliance with this rule will not require a pharmacy to seek licensure as a drug distributor under sections 338.330 and 338.333, RSMo.

(4) The requirements of this rule are not intended to replace or be in conflict with any other laws or regulations governing the appropriate licensure, change of ownership or change of location of a pharmacy.
(5) The termination date is the date on which the permit holder ceases to practice pharmacy as defined in sections 338.010 and 338.210, RSMo, at the permitted location.
PURPOSE: This rule is to establish guidelines for the operation and temporary relocation of a pharmacy during a declared disaster.

(1) Declared disaster areas are defined as specified geographical counties within the state that have been designated by the governor or federal authorities as counties that have been adversely affected by a natural or man-made disaster and requires extraordinary measures to provide adequate, safe and effective health care for the affected population.

(2) In cases where a disaster as defined in section (1) has been declared, any pharmacy located within the disaster area may arrange to move to a temporary location to better serve the public or provide pharmacy services from a mobile unit that is under the control and management of the pharmacist-in-charge.

(A) The following constitutes requirements for maintaining temporary or mobile facilities:

1. Temporary or mobile pharmacy facilities shall only be located within the disaster area or adjacent county;

2. Temporary facilities may be maintained by a pharmacy operation for a period of up to six (6) months without applying for a change of location. Any pharmacy wishing to maintain a temporary site for more than six (6) months or desires to remain permanently at the temporary site, must apply for a change of location as outlined in 4 CSR 220-2.020(4);

3. Mobile pharmacy operations must cease services once the immediate disaster is over;

4. Temporary or mobile pharmacy facilities must inform the board of their location and provide an estimate of the time period for which the temporary or mobile pharmacy operation will be needed; and

5. The executive director shall have the authority to approve or disapprove temporary or mobile pharmacy facilities and shall make arrangements for appropriate monitoring and inspection of the pharmacy on a case by case basis.

   A. Approval of this type of operation will be based on the need, type and scope of disaster, as well as the ability of the pharmacy to comply with state and federal drug laws in addition to section 338.240, RSMo.

   B. Temporary or mobile pharmacy facilities shall cease operations under the provisions of this rule if any previous approval is withdrawn.

   C. Any decision made concerning the approval of a temporary or mobile pharmacy shall not interfere with any rights or privileges of a pharmacy permit holder at the original location of operation or prevent a permit holder from applying for a change of location as outlined in 4 CSR 220-2.020(4).

20 CSR 2220-2.020 Pharmacy Permits

PURPOSE: This rule outlines the requirements for obtaining and maintaining a pharmacy permit.

(1) All permits for the operation of a pharmacy shall expire on the date specified by the director of the Division of Professional Registration pursuant to 4 CSR 230-2.031.

(2) A pharmacy permit may be issued on the application of the owners. If the owner is a corporation, an officer of the corporation must sign the application as the applicant. If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability company, a member must sign the application as the applicant. In the case where a pharmacy is owned and operated by a person(s) who is a licensed pharmacist and in active charge of the pharmacy, the application for permit can be made by either party.

(A) An application for a pharmacy permit will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.

(3) When a pharmacy changes ownership, the original permit becomes void on the effective date of the change of ownership. Before any new business entity resulting from the change opens a pharmacy for business, it must obtain a new permit from the board. A temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license shall be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.

(A) A change of ownership of a pharmacy owned by a sole proprietor is deemed to have occurred when—

1. The business is sold and the sale becomes final;
2. The proprietor enters into a partnership with another individual or business entity; or
3. The proprietor dies; provided, however, that the proprietor’s estate may continue to operate the pharmacy under the licensed pharmacist in good standing in this state, but in no case for a period of more than one (1) year and only so long as appropriate pharmacy permit fees are paid.
(B) If a corporation owns a pharmacy, it is not necessary to obtain a new license if the
owners of the stock change. If a limited liability partnership or a limited liability company
owns a pharmacy, it is not necessary to obtain a new license if the partners or members of
the company change, as long as the partnership or company is not dissolved by that change.
It is necessary to file written notice with the State Board of Pharmacy within ten (10) days
after a change occurs in partners in a limited liability partnership, or in members in a limited
liability company. This notification must be in writing and certified. However, when a
corporation, limited liability partnership, or limited liability company begins ownership of a
pharmacy or transfers ownership of a pharmacy, a new license must be obtained regardless
of the relationship between the previous and subsequent owners.

(C) All individuals or business entities owning twenty-five percent (25%) or more of the
ownership of any entity owning a pharmacy must notify the board within thirty (30) days of
acquiring the percentage.

(4) If an individual or business entity operating a pharmacy changes the location of the
pharmacy to a new facility (structure), the pharmacy shall not open for business at the new
location until the board or its duly authorized agent has inspected the premises of the new
location and approved it and the pharmacy as being in compliance with section 338.240,
RSMo and all other provisions of the law. Upon the approval and receipt of a change of
location fee, the board shall issue a permit authorizing operation of a pharmacy at the new
location and the permit shall bear the same number as the previous pharmacy permit.
However, the permit remains valid if the pharmacy address changes, but not the location
and an amended permit will be issued without charge under these circumstances.

(A) Remodeling of a licensed pharmacy within an existing structure shall be deemed to
have occurred when any change in the storage conditions of the Schedule II controlled
substances is made or new connections to water/sewer resources are made or any changes in
the overall physical security of drugs stored in the pharmacy as defined in 4 CSR 220-
2.010(1)(H) are made. Remodeling as defined within this section will not require the
initiation of any change of location procedures. Satisfactory evidence of plans for any
remodeling of a pharmacy must be provided to the board office thirty (30) days in advance
of commencing such changes along with an affidavit showing any changes to the pharmacy
physical plant and the projected completion date for any remodeling.

(5) Permits, when issued, will bear an original number. Permits must be posted in a
conspicuous place in the pharmacy to which it is issued.

(6) No pharmacy permit will be issued unless the pharmacy area is under the direct
supervision of a licensed pharmacist in good standing with the Missouri State Board of
Pharmacy, who meets the requirements of 4 CSR 220-2.090.
If the owner/applicant is not the licensed pharmacist-in-charge, then the pharmacist-in-
charge must meet the requirements of 4 CSR 220-2.090 and complete the pharmacist-in-
charge affidavit of the permit application and have it notarized.

The names of all pharmacists regularly working in a pharmacy shall be clearly displayed
on the premises of every establishment having a pharmacy permit.

The following classes of pharmacy permits or licenses are hereby established:

(A) Class A: Community/Ambulatory. A pharmacy that provides services as defined in
section 338.010, RSMo to the general public;

(B) Class B: Hospital Outpatient Pharmacy. A pharmacy operated by and located within
a hospital that provides services as defined in section 338.010, RSMo to patients other than
to the hospital’s inpatient population;

(C) Class C: Long-Term Care. A pharmacy that provides services as defined in section
338.010, RSMo by the dispensing of drugs and devices to patients residing within long-term
care facilities. 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;

(D) Class D: Non-Sterile Compounding. A pharmacy that provides services as defined in
section 338.010, RSMo and provides a non-sterile compounded product as defined in 20
CSR 2220-2.400(1) and meets the following criteria:

1. Any product made from any bulk active ingredient in a batch quantity as defined in
20 CSR 2220-2.400(3).

(E) Class E: Radiopharmaceutical. A pharmacy that is not open to the general public and
provides services as defined in section 338.010, RSMo limited to the preparation and
dispensing of radioactive drugs as defined by the Food and Drug Administration (FDA) to
health care providers for use in the treatment or diagnosis of disease and that maintains a
qualified nuclear pharmacist as the pharmacist-in-charge;

(F) Class F: Renal Dialysis. A pharmacy that is not open to the general public that
provides services as defined in section 338.010, RSMo limited to the dispensing of renal
dialysis solutions and other drugs and devices associated with dialysis care;

(G) Class G: Medical Gas. A pharmacy that provides services as defined in section
338.010, RSMo through the provision of oxygen and other prescription gases for
therapeutic uses;

338.010, RSMo through the provision of oxygen and other prescription gases for
therapeutic uses;

(H) Class H: Sterile Product Compounding. A pharmacy that provides services as defined
in section 338.010, RSMo and provides a sterile pharmaceutical as defined in 20 CSR 2220-
2.200(11)(I) and (AA). Pharmacies providing sterile pharmaceuticals within the exemptions
outlined in 20 CSR 2220-2.200(25) shall not be considered a Class H pharmacy;
(I) Class I: Consultant. A location where any activity defined in section 338.010, RSMo is conducted, but which does not include the procurement, storage, possession or ownership of any drugs from the location;

(J) Class J: Shared Service. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations and therapeutic interventions; and

(K) Class K: Internet. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the receipt, review, preparation, compounding, dispensing or offering for sale any drugs, chemicals, medicines or poisons for any new prescriptions originating from the Internet for greater than ninety percent (90%) of the total new prescription volume on any day. A prescription must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient.

(10) Pharmacy applications for initial licensure or renewals of a license shall accurately note each class of pharmacy that is practiced at the location noted on the application or renewal thereof. The permit (license) issued by the board shall list each class of licensure that the pharmacy is approved to engage in. Whenever a change in service classification occurs at a pharmacy the permit must be sent to the board with a notarized statement explaining any additions or deletions of pharmacy classes that are to be made.

(11) Prescriptions processed by any classification of licensed pharmacy must be provided by a practitioner licensed in the United States authorized by law to prescribe drugs and who has performed a sufficient physical examination and clinical assessment of the patient. A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.
20 CSR 2220-2.025 Nonresident Pharmacies

PURPOSE: This rule establishes licensure guidelines for nonresident pharmacies.

(1) Nonresident pharmacies shall not ship, mail or deliver prescription drugs into Missouri without first obtaining a pharmacy license from the Missouri Board of Pharmacy. An exemption to licensure is allowed when a nonresident pharmacy provides a prescription drug in an emergency situation or supplies lawful refills to a patient from a prescription that was originally filled and delivered to a patient within the state in which the nonresident pharmacy is located or provides medications upon receipt of a prescription or physician order for patients in institutional settings and the nonresident pharmacy is not recognized as a primary provider.

(2) To obtain a license as a pharmacy, a nonresident pharmacy must comply with each of the following:
   (A) Maintain a license in good standing from the state in which the nonresident pharmacy is located;
   (B) Submit an application as provided by the Missouri Board of Pharmacy for licensure in compliance with 4 CSR 220-2.020(2) and (3);
   (C) Pay all appropriate licensing fees;
   (D) Submit a copy of the state pharmacy license from the state in which the nonresident pharmacy is located; and
   (E) Submit a copy of the state and federal controlled substance registrations from the state in which it is located, if controlled substances are to be shipped into Missouri.

(3) When requested to do so by the Missouri Board of Pharmacy, each nonresident pharmacy shall supply any inspection reports, warning notices, notice of deficiency reports or any other related reports from the state in which it is located concerning the operation of a nonresident pharmacy for review of compliance with state and federal drug laws.

(4) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state that licenses and regulates nonresident pharmacies for the purpose of investigating complaints against pharmacies located in Missouri or the sharing of information and investigative reports, as long as the other state will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.


PURPOSE: This rule establishes requirements for utilizing an electronic data-processing system in a pharmacy.

(1) In lieu of a non-electronic (manual) record-keeping system, a pharmacy may elect to maintain an electronic data processing (EDP) record keeping-system. All information concerning the compounding, dispensing, or selling by a pharmacy of any drug, device, or poison pursuant to a lawful prescription which is entered into an EDP system at any pharmacy shall be entered only by a licensed pharmacist or by a technician or intern pharmacist under the direct supervision and review of a licensed pharmacist. Prior to dispensing, a pharmacist shall personally verify the accuracy of prescription data entered into the EDP for each original prescription. The EDP system shall comply with all applicable state and federal controlled substance laws and regulations.

(2) EDP systems shall comply with the requirements of section 338.100, RSMo, and shall be capable of storing and retrieving the following information concerning the original filling or refilling of any prescription:

(A) A unique, sequential prescription label number;
(B) If applicable, a unique readily retrievable identifier;
(C) Date the prescription was prescribed;
(D) The date the prescription was initially filled and the date of each refill;
(E) Patient’s full name, or if an animal, the species and owner’s name;
(F) Patient’s address or animal owner’s address when a prescription prescribes a controlled substance;
(G) Prescriber’s full name;
(H) Prescriber’s address and Drug Enforcement Administration (DEA) number when a prescription specifies a controlled substance;
(I) Name, strength and dosage of drug, device or poison dispensed and any directions for use;
(J) Quantity originally dispensed;
(K) Quantity dispensed on each refill;
(L) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;
(M) Identity of the pharmacist responsible for reviewing the final product prior to dispensing on each original and refill prescription, if different from the pharmacist verifying prescription data;
(N) The number of authorized refills and quantity remaining;
(O) Whether generic substitution has been authorized by the prescriber;
(P) The manner in which the prescription was received by the pharmacy (e.g., written, telephone, electronic, or faxed); and
(Q) Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.

(3) The information specified in section (2) shall be required and recorded in the EDP system prior to dispensing by a pharmacist or pharmacy.

(4) Except as otherwise provided by 20 CSR 2220-2.083, prescription hard copies must be maintained and filed by either the sequential prescription label number or by a unique readily retrievable identifier. For verbal, telephone, or electronic data transmission prescriptions, a hard copy representation of the prescription shall be made and filed which contains all of the information in section (2). Prescription hard copies must be retrievable at the time of inspection, except as otherwise provided by 20 CSR 2220-2.010(1)(J). For purposes of this subsection an “electronic data transmission prescription” shall be defined as provided in 20 CSR 2220-2.085.

(5) If additional refills are authorized and added to a prescription, a notation indicating the method and source of the authorization must be a part of the EDP record or hard copy, in that case the expiration date of the original prescription shall remain the same.

(6) Any hospital pharmacy using an EDP system licensed by the board, as described in section (1), for outpatient prescriptions, employee prescriptions, and take-home prescriptions shall conform to all sections of this rule.

(7) Any EDP system must be capable of producing the record required by this rule and said records shall be readily retrievable online. Readily retrievable is defined as providing EDP records immediately or within two (2) hours of a request by an inspector or by making a computer terminal available to the inspector for immediate use.

(8) An auxiliary record-keeping system shall be established for the documentation of refills if the EDP system is inoperative for any reason. The auxiliary system shall ensure that all refills are authorized by the original prescription or prescriber. When this EDP system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the EDP system within seven (7) working days. However, nothing in this section shall preclude the pharmacist from using his/her professional judgment for the benefit of a patient’s health and safety.

(9) If a prescription is transferred from a pharmacy using an EDP system, a notation or deactivation must be made on the transferred record to preclude any further dispensing. If the same prescription is transferred back into the original pharmacy, it shall be treated as a new record, showing the original date written and expiration date.
Prior to or simultaneously with the purging of any EDP system, the permit holder shall make certain that a record of all prescription activity being erased exists in readable form, either on paper, microfiche, or electronic media storage. A pharmacy that desires to discard hard copy prescriptions that are more than three (3) years old must maintain all prescription information on microfiche or electronic media. Any process utilizing microfiche must ensure that all data is available and in readable form. Any pharmacy opting for the utilization of microfiche records must also maintain a microfiche reader so that records may be reviewed on-site by pharmacy personnel or board inspectors. Electronic media storage is defined as any medium such as a computer, floppy disk or diskette, compact disk (CD), or other electronic device that can reproduce all prescription information as required by section 338.100, RSMo, and this rule and is retrievable within three (3) working days.

If coded information exists in the electronic EDP, the board inspector may request the definitions of the codes from the pharmacist on duty for immediate review.

The EDP system shall be able to provide a listing of drug utilization for any drug for a minimum of the preceding twenty-four- (24-) month period. Drug utilization information shall be available by date(s), specific drug product, patient name, or practitioner. If requested to do so, the pharmacy shall have three (3) working days to provide the report.

The provisions of this rule shall not conflict with any federal laws or regulations. If any part of this rule is declared invalid by a court of law, that declaration shall not affect the other parts of the rule.

Licensees shall also comply with all state and federal controlled substance record keeping requirements, including, any required daily log books or printouts.


PURPOSE: The purpose of this rule is to establish requirements and guidelines for maintaining prescription hard copies in an electronic record-keeping system.

(1) In lieu of maintaining the original prescription hard copy or a hard copy representation as required by 20 CSR 2220-2.018 or 20 CSR 2220-2.080, a pharmacy shall be authorized to maintain an exact digitized image of the prescription in an electronic record-keeping system (ERS). For purposes of this rule, an electronic record-keeping system is defined as a system maintained by the pharmacy that provides input, storage, processing, communications, output, and control functions for digitized images of original prescriptions. Any alterations to the digitized original prescription shall be documented as required by 20 CSR 2220-2.018 or 20 CSR 2220-2.080, as applicable.

(2) Controlled substance hard copy prescriptions shall be maintained as required by applicable state and federal law.

(3) Digitized prescription images shall be readily retrievable by the pharmacy. Readily retrievable shall be defined as providing records immediately or within two (2) hours of a request of the inspector or by making a computer terminal available to the inspector for immediate use. An ERS system shall be capable of printing and retrieving the digitized prescription image at the time of inspection, including the reverse side of the prescription if applicable. Any printout of a digitized prescription image provided by a licensee/registrant to the patient or the patient’s representative shall be conspicuously marked with the statement “Copy Only – Not Valid for Dispensing Purposes.”

(4) Pharmacies maintaining an ERS shall establish written policies and procedures for the use of the ERS which shall include policies and procedures for reviewing compliance with the requirements of this rule and for storing, retrieving, and recovering digitized images. The policy and procedure manual shall be reviewed annually and shall be available to representatives of the board upon request.

(5) All digitized images in the ERS shall be stored, copied, or saved onto secure storage media on a regular basis in a manner that will allow image recovery in the event of a disaster, system interruption, or system failure.

PURPOSE: This rule defines the term pharmacist-in-charge, sets the requirements and standards for this title, and defines the term full-time pharmacy.

(1) A pharmacist may be a pharmacist-in-charge of a licensed pharmacy; provided, that s/he complies with all provisions of this rule.

(2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:
   (A) The management of the pharmacy must be under the supervision of a Missouri-licensed pharmacist at all times when prescriptions are being compounded, dispensed or sold;
   (B) The traffic in the prescription area must be restricted to authorized personnel only so that proper control over the drugs can be maintained at all times;
   (C) All required signs are displayed in the appropriate places when there is no pharmacist on duty;
   (D) The licenses of all pharmacists employed are conspicuously displayed in the pharmacy;
   (E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws;
   (F) Any excessive or suspicious requests, or both, for the dispensing of controlled substances be verified prior to dispensing;
   (G) All labeling requirements are complied with according to section 338.059, RSMo, federal laws where required and board regulations governing auxiliary labeling of drugs and devices;
   (H) The prescription files are maintained according to the requirements of this board and the other state and federal controlled substance laws and regulations;
   (I) The Missouri Revised Negative Drug Formulary and state laws governing drug substitution be complied with when generic substitution takes place;
   (J) If exempt narcotics are sold, complete records be kept of all exempt narcotics in a bound exempt narcotic register;
   (K) If poisons are sold, the pharmacy maintain a poison register;
   (L) The pharmacy maintain and have on file at all times the required reference library;
   (M) The pharmacy be kept in a clean and sanitary condition;
   (N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;
   (O) All Missouri and federal licenses are kept up-to-date;
   (P) Policies and procedures are in force to insure safety for the public concerning any action by pharmacy staff members or within the pharmacy physical plant;
   (Q) All equipment, as prescribed through regulation, is available and in good working order;
(R) Security is sufficient to insure the safety and integrity of all legend drugs located in the pharmacy;
(S) Any changes of the following are appropriately carried out:
  1. Pharmacy permit transfer of any type or manner;
  2. Regulation requirements completed satisfactorily when a change of pharmacist-in-charge occurs;
  3. Change of pharmacist’s own address as it appears on his/her license;
(T) When the board-recognized pharmacist-in-charge is changed at that licensed facility, an appropriate documented inventory of controlled substances must be taken;
(U) Assure that the appropriate handling and disposal of controlled substances is done and verified through appropriate documentation and when necessary that controlled substances be disposed of through appropriate procedures involving the Missouri Board of Pharmacy or the Bureau of Narcotics and Dangerous Drugs;
(V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items;
(W) Assure full compliance with all state and federal drug laws and rules;
(X) Compliance with state and federal requirements concerning drug samples;
(Y) Assure that all state and federal laws concerning drug distribution and control are complied with and that no violations occur that would cause a drug or device or any component thereof to become adulterated or misbranded;
(Z) Maintain compliance with all state and federal laws governing drug distributor activities and assure that appropriate licensure as a drug distributor is secured if lawful thresholds for unlicensed drug distributions are exceeded;
(AA) Assure overall compliance with state and federal patient counseling requirements;
(BB) Maintain a current list of all personnel employed by the pharmacy as pharmacy technicians. The list shall include the name, registration number or a copy of an application for registration that has been submitted to the board and a description of duties to be performed by each person contained on the list;
(CC) Maintain written standards setting out the responsibilities of registered pharmacy technicians as well as the procedures and policies for supervision of registered pharmacy technicians, as required by 4 CSR 220-2.700(1). Said standards shall be available to the board and its designated personnel for inspection and/or approvals;
/DD) Any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis in a pharmacy shall be required to register with the board as a pharmacy technician. The determination of whether or not an individual must register as a pharmacy technician will be the responsibility of the pharmacist-in-charge; and
(EE) Maintain compliance of automated dispensing and storage systems with applicable board rules and regulations.

PURPOSE: This rule defines the requirements for pharmacy technician registration.

(1) A pharmacy technician is defined as any person who assumes a supportive role under the direct supervision and responsibility of a pharmacist and who is utilized according to written standards of the employer or the pharmacist-in-charge to perform routine functions that do not require the use of professional judgement in connection with the receiving, preparing, compounding, distribution, or dispensing of medications.

(A) No person shall assume the role of a pharmacy technician without first registering with the board in accordance with the requirements in section 338.013, RSMo and this rule. Nothing in this rule shall preclude the use of persons as pharmacy technicians on a temporary basis as long as the individual(s) is registered as or has applied to the board for registration as a technician in accordance with 338.013.1 and .2, RSMo.

(B) A person may be employed as a technician once a completed application and the required fee is received by the board. The board will provide either a registration certificate that shall be conspicuously displayed or a letter of disqualification preventing the applicant’s employment within a pharmacy.

(C) Information required on the application shall include, but is not limited to—

1. The name, phone number, and residential address of the applicant;
2. Full-time and part-time addresses where the applicant will be employed as a technician;
3. Information concerning the applicant’s compliance with state and federal laws, as well as any violations that could be considered grounds for discipline as outlined in section 338.013.5, RSMo;
4. One (1) two-inch by two-inch (2” × 2”) frontal view portrait photograph of applicant; and
5. Proof of fingerprinting as required by 20 CSR 2220-2.450.

(D) A copy of the application must be maintained by the applicant at the site(s) of employment during and until notice of registration or disqualification is received by the applicant and must be readily retrievable for review by the board of pharmacy or the board’s representatives.

(2) Registered technicians as well as applicants for registration as a technician are responsible for informing the board in the case of a changed residential address. Any mail or communications returned to the board office marked unknown, incorrect address, and the like will not be mailed a second time until the correct address is provided.

(3) Registered technicians as well as applicants for registration as a technician shall inform the executive director of the board of any change in their employment address. The notification of an employment change must be provided in writing to the board no later than fifteen (15) days following the effective date of the change.
(4) Any person whose name appears on the board of pharmacy employment disqualification list shall be barred from employment as a pharmacy technician except as provided in section (5) of this rule.

(A) Information on the disqualification list shall include, at a minimum, the name and last known residential address of the person disqualified, as well as any previous registration number, the date on which the person’s name was entered on the list and the date at which time the person will again become eligible for employment in a pharmacy. The board may place a person on the disqualification list for an indefinite period of time if the disqualified person fails to maintain a current mailing address with the board or fails to communicate with the board on a timely basis when contacted in writing by the board.

(B) Once the board has made a determination to place a person’s name on the disqualification list, the board shall notify the person in writing by mailing the notification to the person’s last known address. The disqualification notice shall include:

1. The name, address of residence and, if already registered as a technician, the registration number;
2. The reasons for being placed on the disqualification list;
3. The consequences of the person’s name appearing on the list;
4. The time period of disqualification;
5. Any alternative restrictions or provisions for conditional employment, if provided by the board; and
6. The right to appeal the decision of the board as provided in Chapter 621, RSMo.

(5) Any person whose name appears on the disqualification list may be employed as a pharmacy technician subject to any restrictions or conditions ordered by the board. As an alternative to barring an individual from employment in a pharmacy, the board may consider restricted forms of employment or employment under special conditions for any person who has applied for or holds a registration as a pharmacy technician. Special conditions may include participation in the board’s Well-Being Program, as provided in 20 CSR 2220-2.175. Any registered technician subject to restrictions or conditions who violates any portion of the restrictions or conditions may be further restricted in employment or have additional conditions placed on their registration. The board may also implement full disqualification on a registrant who has violated any restrictions or conditions.

(6) The letter of notice of intent to disqualify and the disqualification list shall be considered an open record of the board as well as any notice of appeal or litigation that pertains to the disqualification and/or conditional registration as a pharmacy technician.

TO: Board Members

FROM: Kimberly Grinston, Executive Director

RE: Future Class-N (Automated Dispensing System) Rule

DATE: December 23, 2016

Section 338.220 was revised in 2014 to add a Class-N Automated Dispensing System (Health Care Facility) pharmacy permit and a Class-O Automated Dispensing System (Ambulatory Care) pharmacy permit. The Board previously expressed interest in promulgating a rule that would allow the use of an automated dispensing system in a physician’s office or other medical care clinic/unit. Licensees have also asked the Board to promulgate a similar rule. Although the Board has authority to promulgate both a Class-N and a Class-O rule, we began working on a Class-N rule concept to address the most recent concerns/requests.

The agenda includes the current automated dispensing system rule (20 CSR 2220-2.900) as well as a discussion draft for a future Class-N rule. The included language is not a formal staff recommendation. Instead, we attempted to create a general framework to help guide the Board’s discussion. Staff would like specific Board direction on what should be included in the rule. Additionally, staff has the following specific questions/notes:

1. Where can a Class-N system be operated? The statute references a “health care facility.” How would the Board like to define that term? For example, would a “health care facility include a physician’s office, a hospital or maybe a public health clinic?

2. How should Class-N systems be licensed? Should a license be issued for the machine or Should it be issued to another pharmacy to operate the system at a specified location? Some states provide that only a licensed pharmacy can apply to operate an automated dispensing system.

3. Should a Class-N system be available for public use?

4. What should be required for electronic/remote verification?

5. How should the rule apply to long-term care dispensing?
PURPOSE: This rule establishes guidelines for the use of automated dispensing and storage systems.

(1) Automated dispensing and storage systems (hereafter referred to as automated system or system) are hereby defined to include, but are not limited to, mechanical systems that perform operations or activities, relative to the storage, packaging or dispensing of medications, and which collect, control, and maintain all transaction information. Such systems may be used in pharmacies and where a pharmacy permit exists, for maintaining patient care unit medication inventories or for a patient profile dispensing system, provided the utilization of such devices is under the supervision of a pharmacist. A pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist. In order to supervise the system within an ambulatory care setting, the pharmacist must maintain constant visual and auditory communication with the site and full control of the automated system must be maintained by the pharmacist and shall not be delegated to any other person or entity. Supervision of an automated refill patient self-service device requires that a pharmacist employed by the pharmacy by which the device is owned and operated be available at all times during operating hours of the pharmacy.

(A) Documentation shall be maintained by the owner/operator of an automated system for the type of equipment, locations where all systems are located, identification of all persons accessing the automated system, the identity of persons stocking or restocking the system and the pharmacist responsible for checking the accuracy of medications stocked.

(B) Automated systems that are used within licensed health care facilities shall be used only in settings that ensure medication orders are reviewed by a pharmacist in accordance with established policies and procedures and laws governing the practice of pharmacy. A pharmacist shall control all operations of the automated system and approve the release of the initial dose of a prescription drug order. Subsequent doses from an approved prescription drug order may be removed from the automated system after this initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.
(C) In ambulatory care settings, a pharmacist must input all information from a prescription or prescription drug order into the electronic data system utilized for the initiation of the dispensing of a drug at a remote site and maintain proper oversight over the entire dispensing process. A pharmacist shall be accessible at all times to respond to patient’s or other health professionals’ inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. No prescription shall be prepared or dispensed from a remote automated system unless it is from a prescriber providing clinical services at the same location. Labeling of drug containers must be in accordance with section 338.059, RSMo, and application of labels to containers must occur prior to release of the prepared prescription drug from the automated system. Labels shall contain both the name, address and phone number of the supervising pharmacy and the remote dispensing site.

(D) When automated systems are located at remote sites the central pharmacy responsible for the operation and supervision of a remote site must maintain separate and readily retrievable records of all transactions and prescriptions processed by each remote automated system. Remote automated sites must provide the name, address and toll free telephone number of the supervising pharmacy displayed on the automated dispensing system in a prominent location.

(E) Automated systems shall maintain adequate security systems and procedures to prevent unauthorized access or use and shall at all times maintain compliance with all state and federal drug laws including all controlled substance requirements and patient confidentiality laws.

1. Any remote automated system that stocks controlled substances must maintain a perpetual inventory from each site.

2. Automated systems in ambulatory care settings must be located in an area that will provide adequate space for private consultations to occur and must only be installed within the same area utilized by the prescriber for the provision of clinical services.

3. Automated refill patient self-service devices must be physically attached to the pharmacy so that access to areas used to restock the device are only accessible through the pharmacy physical plant by pharmacy personnel.

(F) Restocking of automated systems shall be done by registered technicians under the supervision of a pharmacist or by a pharmacist.

(G) All events involving access to the contents of the automated system must be recorded electronically.

(H) No medication or device shall be returned directly to the system for reissue or reuse by a person not licensed or registered by the board of pharmacy.

(I) Quality assurance documentation for the use and performance of the automated systems shall be maintained for a minimum period of two (2) years and shall include at a minimum the following:

1. Breach of security of the automated system;
2. Failure of the system to operate correctly along with the frequency of any failures and
the necessary repairs completed;
3. Tests completed to measure the effectiveness and accuracy of the system. every six
(6) months and whenever any upgrade or change is made to the system.

(J) Drugs that are repackaged for use in automated systems at remote locations must
comply with 20 CSR 2220-2.130 Drug Repackaging requirements. Automated refill patient
self-service devices must comply with all labeling and dispensing laws governing the
provision of medication refills to patients. Products that are considered temperature
sensitive or products that require further manipulation in order to be ready for use by a
patient shall not be provided through patient self-service devices, unless the device has the
capability to provide storage conditions in compliance with Food and Drug Administration
(FDA) requirements.

(K) If an automated system uses removable cartridges or containers to hold drugs, the
prepackaging of the cartridges or containers must occur at the pharmacy where the original
inventory is maintained unless provided by a FDA approved repackager and who is licensed
as a drug distributor. The prepackaged cartridges or containers may be sent to the automated
system at remote locations to be loaded into the machine by registered technicians under the
supervision of a pharmacist or by a pharmacist provided that—
1. A pharmacist has verified the container has been properly filled and labeled;
2. The individual containers are transported to the automated system in a secure,
tamper-evident container; and
3. The automated system utilizes technologies to ensure that the containers are
accurately loaded in the automated system.

(L) Any pharmacy that maintains an automated system for remote dispensing to
ambulatory patients must maintain a video camera and audio system to provide for effective
communication between pharmacy personnel and consumers. It must be a system that will
allow for the appropriate exchange of oral as well as written communications to facilitate
patient counseling as provided in 20 CSR 2220-2.190 and other matters involved in the
correct transaction or provision of drugs.
1. Video monitors used for the proper identification and communication with persons
receiving prescription drugs shall be a minimum of twelve inches (12”) wide and provided
at both the pharmacy and remote location for direct visual contact between pharmacist and
patient.
2. Both the video monitor and the audio system must be in good working order or
operations utilizing the automated system shall cease until appropriate corrections or repairs
are made to the system(s).
3. Backlighting or other factors that may inhibit video or audio performance must be
taken into account when using such systems to identify recipients of prescription drugs.
Positive identification of recipients must be made before any drug is delivered.
(2) Each automated system shall maintain a manual of policies and procedures that, at a minimum, shall include the following:

(A) System operations that include specific and measurable accountability for safety, security, accuracy, patient confidentiality, access, data retention and retrieval, downtime procedures, emergency first dose or refill patient self-service procedures, inspection of systems by pharmacy personnel, installation requirements, maintenance, medication security, quality assurance, inventory levels and control, staff education and training and system set-up and malfunction.

(B) Documentation by the automated system at remote locations for on-site patient administration and remote dispensing of medications that includes specific identification of patients, medications used along with dates and times the system is utilized.

(C) Effective procedures for securing and accounting for wasted medications or discarded medications.

(D) Access to and limits on access (security levels) to the automated system must be defined and must comply with applicable state and federal laws and regulations.

(3) The pharmacist-in-charge is responsible for the overall compliance of the automated system in the same manner as other pharmacy operations as outlined in 4 CSR 220-2.090. In addition, responsibilities will also include:

(A) Establishment of a quality assurance program prior to implementation of an automated system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of the automated system, which is evidenced by written policies and procedures developed by the pharmacy;

(B) Assign, discontinue or change access to the automated system;

(C) Assure that the automated system is in good working order and accurately provides the correct strength, dosage form and quantity of a drug prescribed while maintaining appropriate record keeping and security safeguards.

(D) Procedures used for notifying the board on a timely basis and other state and federal agencies, when warranted, of any breach of security which results in the unauthorized removal of drugs.

(4) Except where otherwise noted in this rule, all records specified must be retained as a part of the dispensing record of the pharmacy and in accordance with section 338.100, RSMo and board regulations governing the proper maintenance and retrieval of records.

(5) Pharmacies that maintain automated sites for dispensing drugs to ambulatory patients shall maintain a Class J: Shared Service classification on each pharmacy permit involved in such activity.
(6) The supervising pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more than three (3) remote sites that are simultaneously open to provide services. An exception to the supervision limit may be granted by the board in situations where the provider has documented a need for a pharmacist to supervise additional remote sites and has demonstrated that appropriate safeguards are in place to assure proper supervision of each remote site.


This draft has not been approved by the Board and is not being proposed or suggested by Board staff. The included language is intended solely for discussion purposes and to assist the Board in developing a future Class-N rule.

20 CSR 2220-2.850 Class-N Automated Dispensing Systems (Health Care Facilities)

PURPOSE: This rule establishes guidelines for the use of automated dispensing and storage systems.

(1) Definitions.

(A) Automated Dispensing System: A mechanical/automated system that is used to store, package and dispense medication for patient use or administration. An automated dispensing system does not include a mechanical/automated system used for compounding or administering medication or an automated filling system governed by 20 CSR 2220-2.950.

(B) Dispense/Dispensing - The provision of medication by a Missouri licensed pharmacy or pharmacist pursuant to a legally valid prescription or medication order for the ultimate user.

(C) “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 dispensed and labeled by, or loaded into, an automated dispensing system.

(D) Health Care Facility-

1. A location other than a pharmacy or a licensed health care facility where healthcare services are provided to patients by a Missouri licensed healthcare practitioner at the same location; 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.

(E) Licensed Health Care Practitioner- A Missouri licensed healthcare practitioner authorized to prescribe or a Missouri licensed dentist, licensed practical nurse, optometrist, pharmacist, physician, physician assistant, podiatrist, registered nurse, surgeon or veterinarian.

(F) “Manufacturer Unit of Use Package”- A drug dispensed in the manufacturer’s original and sealed packaging, or in the original and sealed packaging of a repackager registered with the United States Food and Drug Administration (FDA), without additional manipulation or preparation by the pharmacy except for application of the required pharmacy label.

(G) Medication Order: A medication order as defined by § 338.165.1(5), RSMo.
(2) Authorized Activities. A Class-N automated dispensing system may be operated in a healthcare facility to dispense medication that will be provided or administered to a patient by a licensed healthcare practitioner at or within the healthcare facility. A Class-N automated dispensing system shall not be used to dispense medication that will be used by or administered to the patient outside of the healthcare facility. Medication shall not be deemed to have been dispensed for offsite patient use/administration if administration is initiated onsite of the healthcare facility by a licensed healthcare professional but continued offsite by a parenteral infusion method, including, but not limited to, a subcutaneous, intrathecal or intravenous method or via an implanted device, port, catheter or pump.

(3) Licensure. Applicants for a Class-N pharmacy permit shall submit an application in a form and manner approved by the Board along with the required application fee. The application must identify the address where the automated dispensing system will be operated and shall identify a supervising Missouri licensed pharmacy that is responsible for managing system operations. [Some states mandate that only a licensed pharmacy can apply for an automated dispensing license. Should this be included in Missouri’s rule?]

(A) A Class-N automated dispensing system must successfully pass a Board inspection prior to issuance of the permit. Once approved, a Class-N permit will be issued for the specific location inspected by the Board. A Change of Location application must be filed with the board if the system is moved to a different facility or address. Operation of the system must cease until the Change of Location application has been approved by the board and a new pharmacy permit issued.

(B) A Class-N permit may only be used to perform authorized Class-N pharmacy services. An additional pharmacy permit is required to provide other pharmacy services authorized by Chapter 338, RSMo.

(C) Remodeling plans for a Class-N system must be submitted to the Board in advance for review and approval. Remodeling will be deemed to have occurred if the automated dispensing machine or system is changed or replaced, moved to a different room within the approved facility/site or fastened to a new or different permanent structure than initially approved or if the overall physical security of drugs stored in the system is changed as defined in 20 CSR 2220-2.010. Remodeling plans must be provided to the board office thirty (30) days prior to commencing the proposed change along with an affidavit showing any physical changes to the automated dispensing site, structure or location and the projected remodel completion date.

(D) An Out-of-Business Notification form must be filed with the Board within fifteen (15) days of discontinuing service or closing a Class-N system.
(4) Standards of Operation. Class-N automated dispensing systems must be maintained and operated in compliance with applicable state and federal drug laws, including, all controlled substance and patient confidentiality requirements. The system must be maintained in good working order and must properly and accurately function at all times the system is in operation. A pharmacist shall not be required to be physically present on site when the automated dispensing system is in operation if the system is operated in compliance with this rule.

(A) Except as otherwise authorized by law, medication may only be dispensed from a Class-N automated dispensing system pursuant to a patient-specific prescription or a patient-specific medication order.

(B) Prior to initial operation, the system must be tested by a properly qualified pharmacy designee to ensure the system is functioning properly. Additional testing must occur if any modification to the automated dispensing system occurs that changes or alters the dispensing or electronic verification process. Testing dates and results must be documented in the pharmacy’s system.

(C) All transactions regarding the automated dispensing system must be tracked and documented in writing, including, the placement, removal and dispensing of medication into and out of the system.

(D) Medication stocked in an automated dispensing system must be maintained under proper temperature and storage conditions in compliance with Food and Drug Administration (FDA) requirements and manufacturer guidelines. The system must be equipped with an effective temperature measuring device. At a minimum, temperatures must be recorded and documented daily. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that are reviewed daily or if the system provides alerts of improper temperature deviations that are promptly reviewed by a pharmacist. Documentation of the required temperature review or any temperature alerts must be maintained in the pharmacy’s records or otherwise accessible to the pharmacy.

(E) Controlled substances shall be handled and dispensed in compliance with all state and federal controlled substance laws.

(F) Long Term Care. The provisions of 20 CSR 2220-2.140 shall be applicable to a remote dispensing system used in a long-term care facility for emergency dispensing (e.g., an e-kit). All other long-term care dispensing via an automated dispensing system shall comply with the provisions of this rule.

(5) Except as otherwise provided in section (6), a pharmacist shall review and approve all medication dispensed by the automated dispensing system prior to release. A pharmacist may electronically verify medication contents and labels from a remote location if:
1. The entire dispensing process is fully automated from the time the process is initiated until a completed and properly labeled manufacturer unit of use package or medication container is produced that is ready for dispensing;

2. A pharmacist reviews and verifies the prescription or medication order and the patient/medication information used to initiate the dispensing process prior to dispensing;

3. An electronic verification system is used to verify the correct medication and medication strength, dosage form and quantity have been dispensed; and

4. The pharmacist electronically views and verifies the final medication package or container for accuracy prior to dispensing using video or electronic technology. The pharmacist must be able to view and verify the actual package/container, including, the label and medication contents.

(6) Medication may be removed [by a licensed healthcare practitioner] from a Class-N automated dispensing system when a pharmacist is not physically present if:

1. The medication will be used or administered as authorized by section (2) of this rule;

2. The identity of the individual/healthcare practitioner accessing the system is electronically recorded and verified before dispensing using a password or other unique identifier;

3. A pharmacist reviews and approves the initial prescription or medication order. Subsequent refills/doses may be removed from the automated system for the specific patient without additional pharmacist review/approval of the prescription or medication order, however, any change in the prescription or medication order shall require new approval from a pharmacist;

4. The automated dispensing system uses an electronic verification system to verify the correct medication is dispensed;

5. A pharmacist is available to respond to inquiries in the event of an emergency; and

6. A pharmacist operating on behalf of the pharmacy reviews [all] medication dispensed by the system and the applicable prescription/medication order on a [random basis/sample size/weekly/monthly basis] to ensure proper dispensing and compliance with the requirements of the rule. The identity of the reviewing pharmacist, the date of review and the review results must be documented in writing and maintained in the pharmacy’s records for two (2) years.

(C) The final pharmacist prescription/medication order verification requirements of 20 CSR 2220-2.010 shall be deemed satisfied if a pharmacist complies with the requirements of this section.
(7) Labeling. Medication must be 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. Multi-med paks must comply with 20 CSR 2220-2.145 and must be labeled with the following:

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 if any, contained in the prescription order for each drug product therein;
5. Any storage instructions or cautionary statements required by the official compendia;
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); and
7. Any other information, statements, or warnings required for any of the drug products contained therein.

(8) Stocking Medication. Automated dispensing systems may only be stocked by a Missouri licensed pharmacist or by a Missouri licensed intern pharmacist or registered technician. Individuals authorized to stock medication must be trained on system use and operations as appropriate for the tasks performed. A list of individuals authorized to stock the system must be maintained by the pharmacy and available on request of the Board or the Board’s authorized designee.

(A) Medication must be transported to the automated dispensing system in a secure, tamper-evident container. No outdated, expired, misbranded or adulterated medication may be stocked or stored in the system;

(B) The pharmacy must maintain a record of all medication stocked into or removed from the system. At a minimum, the pharmacy’s records must maintain written documentation of the date and time medication is stocked into or removed from the system, the identity of individuals stocking or removing medication and the type of medication stocked/removed.

(C) Automated dispensing systems may be stocked by an intern pharmacist or a pharmacy technician without a pharmacist present if:

1. 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 prepackaged and labeled. The identity of the verifying pharmacist must be documented in the pharmacy’s records; and
2. An electronic verification system or other mechanical system is used to ensure medication and prepackaged containers/cartridges are correctly stocked or loaded into the system.

(D) Medication may be returned and reused as authorized by 20 CSR 2220-3.040 or as authorized by 20 CSR 2220-2.145 governing multi-med dispensing.

(E) Prepackaging must comply with 20 CSR 2220-2.130

(9) Prescription/Medication Order Records. The pharmacy must maintain records of all prescriptions or medication orders dispensed by the automated dispensing system. Prescriptions must be maintained as required by section 338.100, RSMo, and the rules of the Board. For medication orders, the pharmacy’s records must include the dispensing date, patient name, authorized prescriber and the name, strength, dosage form and quantity of medication dispensed. Except as otherwise required by law, prescription and medication order records may be included in a patient medical record maintained by the healthcare facility, provided the records must be retrievable by the pharmacy on request of the Board or the Board’s authorized designee. Prescriptions and medication orders must be assigned a sequential number or other unique identifier that allows individual retrieval of the dispensing record.

(10) Security. Adequate security systems and procedures must be maintained to prevent unauthorized access to or movement of the automated dispensing system and to prevent medication loss, diversion or theft.

(A) Automated dispensing systems must be securely placed inside of a licensed pharmacy or health care facility. The system must be securely fastened to a permanent structure and shall not be located in or near exit doors or accessible to the public.

(B) Automated dispensing systems must be locked by key, combination or other mechanical or electronic means. The system must consist of a substantially constructed container and shall be maintained and operated in a manner that will prevent system theft, tampering or unauthorized use/access. The system must be equipped with an alarm or other monitoring system that notifies or alerts the pharmacy in the event of a security breach or other unauthorized access.

(C) A written list must be maintained of all individuals or entities authorized to access an automated dispensing system. The pharmacist-in-charge must have authority to assign, initiate, modify and deny access to the automated dispensing system as deemed necessary or appropriate. System access must be promptly terminated or revoked if access authorization is revoked or rescinded.
(D) All access to the automated dispensing system must be manually or electronically documented, including, the date and time the system was accessed, the identity of individuals accessing the system and the name, strength, quantity and dosage form of medication placed in or removed from the system.

(E) Any theft or diversion of or from an automated dispensing system 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.

(F) [The pharmacy must reconcile medication inventory for each automated dispensing system every six ??? months.] A perpetual inventory must be maintained for any automated dispensing system that stocks or provides controlled substances. [Controlled substance inventory must be reconciled every ?? months.] The required inventory and reconciliation must be documented in writing and retained for two (2) years. Should all inventory have to be reconciled?

(11) Quality Assurance. An initial and ongoing quality assurance program must be operated and established to objectively and systematically monitor the appropriate use and performance of all automated dispensing systems. The quality assurance program must include policies and procedures for detecting, evaluating and documenting system malfunctions and any breach of security.

(A) Quality assurance testing must be conducted [weekly/monthly/every six (6) months] for each automated dispensing system to measure system accuracy and operations. At a minimum, the required testing must include a physical inspection of drugs in the system and testing of the electronic verification system. Retesting must be performed whenever any upgrade or change is made to the system that may affect, alter or change system security, medication release/dispensing or the electronic verification system.

(B) As part of the quality assurance program, a pharmacist must review and investigate any verified or suspected dispensing or labeling error related to the automated dispensing system. The investigation dates and results must be documented in the pharmacy’s records. If a dispensing error is verified or substantiated, operation of the system must immediately cease until the system has been restored to proper functioning.

(C) Quality assurance documentation shall be maintained for two (2) years, including, documentation of quality assurance testing and testing results.
(12) Policies and procedures. The pharmacy shall establish and follow written policies and procedure to ensure the proper, safe, and secure functioning of all automated dispensing systems. Policies and procedures shall be reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy’s records for a minimum of two (2) years. The required annual review shall be documented in the pharmacy’s records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for—

(A) Maintaining the automated dispensing system and any accompanying electronic verification system in good working order;
(B) Ensuring accurate filling, loading, and stocking of the system;
(C) Monitoring and ensuring accurate dispensing;
(D) Reporting, investigating, and addressing known or suspected errors and system malfunctions;
(E) Testing the accuracy of the automated dispensing system and any accompanying electronic verification system;
(F) Training persons with system access on proper equipment use and operations;
(G) Tracking, documenting and investigating medication errors;
(H) Conducting routine and preventive maintenance and, if applicable, calibration;
(I) Removing expired, adulterated, misbranded, or recalled drugs;
(J) Preventing unauthorized access to the system, including, assigning, discontinuing, restricting or changing security access as deemed necessary or appropriate;
(K) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements;
(M) Maintaining the quality assurance program required by section (10) of this rule;
(N) Securing and accounting for wasted or discarded medications;
(O) Providing any required notifications to the board or other state or federal agency; and
(P) Emergency procedures in the event of a disaster or power outage that affects system functioning, including, procedures for system recovery.
20 CSR 2220-2.950 Automated Filling Systems

PURPOSE: This rule establishes standards for automated filling systems.

(1) Definitions. The following definitions shall be applicable for purposes of this rule:

(A) “Automated filling system”—An automated system used by a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An “automated filling system” shall not include automated devices used solely to count medication, vacuum tube drug delivery systems governed by 20 CSR 2220-2.800, or automated dispensing and storage systems governed by 20 CSR 2220-2.900 used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to the patient;

(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 dispensed and labeled by, or loaded into, an automated filling system;

(C) “Manufacturer unit of use package”—A drug dispensed in the manufacturer’s original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label;

(D) “Repackager”—A repackager registered with the United States Food and Drug Administration; and

(E) “Repacked”—Any drug that has been removed from the original packaging of the manufacturer or a repackager’s packaging and is placed in a container for use in an automated filling system.

(2) Medication Stocking. Automated filling systems (hereinafter “system”) may be stocked or loaded by a pharmacist or by an intern pharmacist or pharmacy technician under the direct supervision of a pharmacist. Pharmacy repacked medication, cartridges, or containers shall comply with 20 CSR 2220-2.130.

(3) Verification. Except as provided herein, a licensed pharmacist shall inspect and verify the accuracy of the final contents of any medication filled or packaged by an automated filling system, and any label affixed thereto, prior to dispensing, as required by 20 CSR 2220-2.010(1)(B).

(4) The pharmacist verification requirements of section (3) shall be deemed satisfied if—

(A) The pharmacy establishes and follows a policy and procedure manual that complies with section (5) of this rule;
(B) The filling process is fully automated from the time the filling process is initiated until a completed, labeled, and sealed prescription is produced by the automated filling system that is ready for dispensing to the patient. No manual intervention with the medication or prescription may occur after the medication is loaded into the automated filling system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(C) A pharmacist verifies the accuracy of the prescription information used by or entered into the automatic filling system for a specific patient prior to initiation of the automatic fill process. The name, initials, or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy’s records and maintained for five (5) years after dispensing;

(D) A pharmacist verifies the correct medication, repacked container, or manufacturer unit of use package was properly stocked, filled, and loaded in the automated filling system prior to initiating the fill process. Alternatively, an electronic verification system may be used for verification of manufacturer unit of use packages or repacked medication previously verified by a pharmacist;

(E) The medication to be dispensed is filled, labeled, and sealed in the prescription container by the automated filling system or dispensed by the system in a manufacturer’s unit of use package or a repacked pharmacy container;

(F) An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication, repackaged container, or manufacturer unit of use package for the correct patient; and

(G) Daily random quality testing is conducted by a pharmacist on a sample size of prescriptions filled by the automated filling system. The required sample size shall not be less than two percent (2%) of the prescriptions filled by the automated system on the date tested or two percent (2%) of the prescriptions filled by the automated system on the last day of system operation, as designated in writing by the pharmacist-in-charge. Proof of compliance with this subsection and random quality testing date(s) and results shall be documented and maintained in the pharmacy’s records.

(5) Policies and Procedures. Pharmacies verifying prescriptions pursuant to section (4) of this rule shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy’s records for a minimum of two (2) years. The required annual review shall be documented in the pharmacy’s records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for—

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

(B) Ensuring accurate filling, loading, and stocking of the system;

(C) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;
(D) Reporting, investigating, and addressing filling errors and system malfunctions;
(E) Testing the accuracy of the automated filling system and any accompanying electronic verification system. At a minimum, the automated filling system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the automated filling system or electronic verification system that changes or alters the filling or electronic verification process;
(F) Training persons authorized to access, stock, restock, or load the automated filling system in equipment use and operations;
(G) Tracking and documenting prescription errors related to the automated filling system that are not corrected prior to dispensing to the patient. Such documentation shall be maintained for two (2) years and produced to the board upon request;
(H) Conducting routine and preventive maintenance and, if applicable, calibration;
(I) Removing expired, adulterated, misbranded, or recalled drugs;
(J) Preventing unauthorized access to the system, including, assigning, discontinuing, or changing security access;
(K) Identifying and recording persons responsible for stocking, loading, and filling the system;
(L) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements; and
(M) Maintaining an ongoing quality assurance program that monitors performance of the automatic fill system and any electronic verification system to ensure proper and accurate functioning.

(6) Recordkeeping. Except as otherwise provided herein, records required by this rule shall be maintained in the pharmacy’s records electronically or in writing for a minimum of two (2) years. When the verification requirements of subsection (4)(D) of this rule are completed by a pharmacist, the name, initials, or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy’s records and maintained for five (5) years after dispensing. Records shall be made available for inspection and produced to the board or the board’s authorized designee upon request.


#D3 Draft Rule Discussion

- 20 CSR 2220-6.050 (Administration of Vaccines Per Protocol)
- 20 CSR 2220-2.650 (Standards of Operation for a Class J: Shared Services Pharmacy)
20 CSR 2220-6.050 Administration of Vaccines Per Protocol

PURPOSE: This rule establishes the procedures for pharmacists to administer vaccines per written protocol with a physician.

(1) A pharmacist may administer vaccines authorized by Chapter 338, RSMo, pursuant to a written protocol authorized by a physician licensed pursuant to Chapter 334, RSMo, who is actively engaged in the practice of medicine. Unless otherwise restricted by the Board or the governing protocol, pharmacists authorized to immunize pursuant to this rule may administer immunizations at any Missouri licensed pharmacy. Immunizations may be provided at a non-pharmacy location if authorized by the governing protocol.

(A) Vaccines must be administered in accordance with current treatment guidelines established by the Centers for Disease Control (CDC) and in accordance with manufacturer’s guidelines, provided that CDC guidelines shall control in the event of a conflict with manufacturer guidelines. Vaccines shall not be administered to persons under twelve (12) years old unless otherwise authorized by law.

(B) Vaccine administration must comply with all state and federal laws, including, all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) Vaccines must be stored at all times in accordance with CDC guidelines/recommendations and within the manufacturer’s labeled requirements, including, when administering outside of a pharmacy.

(D) A pharmacist may not delegate the administration of vaccines to another person, except to a pharmacist intern who has met the qualifications under subsections (4)(B) and (C) and is working under the direct supervision of a pharmacist qualified to administer vaccines. Intern pharmacists must maintain proof of compliance with subsections (4)(B) and (C) for a minimum of two (2) years.

(2) The authorizing physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.

(3) Pharmacist Qualifications. A pharmacist who is administering a vaccine authorized by Chapter 338, RSMo, by protocol must:
(A) Hold a current Missouri pharmacist license;

(B) Hold a current cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification issued by the American Heart Association or the American Red Cross or an equivalent organization. The qualifying BLS or CPR certification program must have included a live/in-person CPR skills assessment;

(C) Have successfully completed a certificate program in administering vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE) or a similar health authority or professional body approved by the State Board of Pharmacy. To be approved, non-ACPE programs must include a live/in-person training component and include instruction in:
   1. Current CDC guidelines and recommendations for vaccines authorized by Chapter 338, RSMo, including, recommended immunization schedules;
   2. Basic immunology and vaccine protection;
   3. Physiology and techniques for vaccine administration which must include hands-on training in common routes of vaccine administration, including, intramuscular, intradermal, subcutaneous and nasal routes of administration;
   4. Pre- and post- vaccine screening or assessment; and
   5. Identifying and treating adverse immunization reactions;

(D) Have filed a Notification of Intent with the Board of Pharmacy attesting that the pharmacist has complied with sections (4)(A) to (4)(C) of this rule. Notifications of Intent must be filed on the Board’s website or on a form approved by the Board; and

(E) Have a current written protocol with an authorizing physician that complies with this rule.

(4) Protocol Requirements.

(A) Pharmacists administering vaccines pursuant to this rule must enter into a written protocol with a Missouri licensed physician for the administration of vaccines as authorized by Chapter 338, RSMo. The written protocol may be valid for a time period not to exceed one (1) year and must be renewed annually. The protocol must include the following:
   1. The identity of the participating pharmacist and physician, including signatures;
   2. Time period of the protocol;
   3. The identification of the vaccines which may be administered;
   4. The identity of the patient or groups of patients to receive the authorized vaccine(s);
   5. The identity of the authorized routes and anatomic sites of administration allowed;
6. A provision to create a prescription for each administration under the authorizing physician’s name;

7. A provision establishing a course of action the pharmacist shall follow to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks;

8. A provision establishing the length of time the pharmacist shall observe an individual for adverse events following an injection;

9. A provision establishing the disposal of used and contaminated supplies;

10. The street addresses of any non-pharmacy locations at which the pharmacist may administer the authorized vaccine;

11. Record-keeping requirements and any required notification procedures; and

12. A provision that allows for termination of the protocol at the request of any party to it at any time.

(B) The protocol, and any subsequent amendments or alterations, shall be manually or electronically signed and dated by the pharmacist and authorizing physician prior to its implementation, signifying that both are aware of its content and agree to follow the terms of the protocol. The authorizing physician and pharmacist shall each maintain a copy of the protocol from the beginning of implementation to a minimum of eight (8) years after termination of the protocol.

(C) Additional pharmacists or immunization locations may be added to an existing protocol, if the amendment is signed and dated by the authorizing physician(s) and, if applicable, any newly added pharmacist(s). Other participating pharmacists shall not be required to re-sign the protocol unless other protocol terms or provisions are changed.

(5) Record Keeping.

(A) A pharmacist administering vaccines pursuant to this rule must maintain a record of each administration which shall include:

1. The patient’s name, address, and date of birth;

2. The date, route, and anatomic site of the administration;

3. The name, dose, manufacturer, lot number, and expiration date of the vaccine;
4. The name and address of the patient’s primary health care provider, as identified by the patient;
5. The identity of the administering pharmacist or intern pharmacist;
6. The nature of any adverse event or reaction and who was notified, if applicable;
7. Documentation that pharmacist interns administering vaccines under the pharmacist’s supervision have complied with section (2) of this rule; and
8. Documentation that any notifications required by this rule have been sent.

(B) If the vaccine was administered on behalf of a pharmacy, the pharmacist shall ensure the records required by subsection (6)(A) of this rule are promptly delivered to the pharmacy.

(C) Within seventy-two hours (72) hours after administration of a vaccine, the administering pharmacist shall obtain a prescription from the authorizing physician for the drug dispensed or shall create a prescription, as authorized by protocol documenting the dispensing of the drug. Notwithstanding any other provision of this rule, prescription records shall be maintained as provided by Chapter 338, RSMo, and the rules of the board.

(D) The records required by this rule must be maintained securely and confidentially at all times.

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the administering pharmacist shall ensure that all records required by this rule are maintained at the pharmacy separate from the pharmacy’s prescription files.

2. If the vaccine is not administered on behalf of a pharmacy, records shall be maintained securely and confidentially by the administering pharmacist at an address that must be identified in the protocol prior to administering the vaccine; and

3. Records shall be maintained for two (2) years from the date of such record and shall be made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives. Records maintained at a pharmacy must be produced during an inspection or investigation by the Missouri State Board of Pharmacy and/or their authorized representatives. Records not maintained at a pharmacy must be produced within three (3) business days after a request from the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts and/or their authorized representatives. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.
(6) Notification of Immunizations. Notification of vaccine administration must comply with all state and federal law. All pharmacists provided immunizations must be reported to the Missouri immunization registry operated by the Missouri Department of Health and Senior Services (ShowMeVax). Additionally, pharmacists must comply with the following:

(A) Pharmacists shall notify the protocol physician after administering a vaccine as required by the governing protocol. Notification of vaccine administration must also be provided to the patient’s primary care provider as required by Chapter 338, RSMo.

(B) Pharmacists shall notify the patient’s primary health care provider and, if different, the protocol physician, within twenty-four (24) hours after learning of any adverse event or reaction experienced by the patient. Adverse events or reactions must also be reported to the Vaccine Adverse Event Reporting System (VAERS) or its successor, within thirty (30) days.

(C) Unless otherwise provided by the governing protocol, notification may be made via a common electronic medication record that is accessible to and shared by both the physician and pharmacist. Proof of notification must be maintained in the pharmacist’s records as required by section (6) of this rule.

(7) Notification of Intent Renewal. A Notification of Intent (NOI) to immunize by protocol must be renewed biennially with the immunizing pharmacist’s Missouri pharmacist license. The NOI must be submitted on the Missouri Board of Pharmacy’s website or in a form approved by the Board. To renew a NOI, pharmacists must:

(A) Have a current Missouri pharmacist license;

(B) Have a current cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification that complies with section (4)(B) of this rule; and

(C) Have completed a minimum of two (2) hours of continuing education (0.2 CEU) related to administering vaccines or CDC immunization guidelines in a course provided by the Board or an ACPE accredited continuing education provider. Alternatively, continuing education may be provided by a governmental entity, healthcare professional organization or educational institution approved by the Board in advance. Approval requests for non-ACPE programs must be submitted in accordance with 20 CSR 2220-7.080. To be approved, non-ACPE programs must provide instruction in one or more of the following:
1. Current CDC guidelines and recommendations for vaccines authorized by Chapter 338, RSMo, including, recommended immunization schedules;
2. Basic immunology and vaccine protection;
3. Physiology and techniques for vaccine administration;
4. Pre- and post- vaccine screening or assessment; or
5. Identifying and treating adverse immunization reactions.

(D) The required continuing education may be used to satisfy the pharmacist’s biennial continuing education requirements.
TO:       Board Members

FROM:     Kimberly Grinston,
          Executive Director

RE:       20 CSR 2220-2.650 (Class-J: Shared Services Pharmacy)

DATE:     January 5, 2017

The Board has asked to review the Class-J: Shared Services Pharmacy rule which is included in the agenda. In addition to a general rule review, the Board has previously asked to discuss the following Class-J issues:

1. Should the common electronic database requirement be revised or removed from the rule?

2. Does the rule need to be revised to better accommodate hospitals/healthcare facilities that may be dispensing outpatient medication for hospital-owned or affiliated clinics (e.g., infusion centers)? Should a Class-J permit be required in these instances? The Board previously discussed that sharing a common database may not be feasible for some of these entities.

3. Which pharmacy should be included on the prescription label under a Class-J arrangement- the dispensing pharmacy, the filling pharmacy or both?

4. Should the rule address which pharmacist/pharmacy is responsible for the DUR or Rx review in a Class-J arrangement?

These questions were gathered from previous Board notes and may not be exhaustive. How would the Board like to proceed?
20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy

PURPOSE: The purpose of this rule is to establish minimum standards of operation for Class J: Shared Services Pharmacy, in compliance with House Bill 567 of the 91st General Assembly.

(1) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(A) A pharmacy may perform or outsource centralized prescription processing services provided the parties:
   1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;
   2. Maintain separate licenses for each location involved in providing shared services; and
   3. Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(B) There must be record keeping systems between shared service pharmacies with real time on-line access to shared services by both pharmacies. Transfer of prescription information between two (2) pharmacies that are accessing the same real-time, on-line database pursuant to the operation of a shared service pharmacy operation shall not be considered a prescription transfer and, therefore, is not subject to the requirements of 4 CSR 220-2.120.

(C) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes, but is not limited to, the following:
   1. A description of how the parties will comply with federal and state laws and regulations;
   2. The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;
   3. The maintenance of a mechanism for tracking the prescription drug order during each step in the process;
   4. The provision of adequate security to protect the confidentiality and integrity of patient information;
   5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems.
DISCUSSION REQUESTED: The Board asked to review the yellow highlighted language in the Class-B Hospital Guidance document at the January meeting. The Hospital Advisory Committee will be meeting after the January meeting and has not reviewed the highlighted language.
MISSOURI BOARD OF PHARMACY

CLASS-B HOSPITAL PHARMACY GUIDANCE

*** THIS DRAFT HAS NOT BEEN REVIEWED OR APPROVED BY THE BOARD AND MAY NOT REFLECT THE BOARD’S CURRENT POSITION/ GUIDANCE***
CLASS-B
Hospital Pharmacy Guidance

This guidance document is being provided by the Missouri Board of Pharmacy to provide compliance information for Class-B Hospital pharmacies. **This guidance is not applicable to pharmacy services regulated by and under the jurisdiction of the Missouri Department of Health and Senior Services (DHSS).**

**OVERVIEW**

In 2014, the Missouri General Assembly enacted SB 808 which officially established a Class-B Hospital pharmacy permit for pharmacies located in Missouri licensed hospitals and also hospital clinics and facilities. Prior to the new law, only Missouri licensed hospitals were eligible for a Class B permit. As healthcare delivery models have evolved, Missouri hospitals indicated pharmacy services were increasingly being delivered via hospital owned clinics or satellite pharmacies that were not part of the licensed hospital. The Board was informed its general pharmacy rules conflicted or hindered compliance with accreditation and other reimbursement requirements, particularly for clinics/facilities not engaged in traditional “prescription” dispensing.

The Board subsequently convened a Hospital Pharmacy Advisory Group comprised of hospital representatives to assist the Board in addressing these concerns. The Advisory Group recommended establishing a single Class-B permit class for both hospitals and hospital related clinics and facilities along with enhanced distribution/dispensing standards for Class-B pharmacies under common control or ownership.

SB 808 was subsequently enacted which officially established the current Class-B Hospital Pharmacy permit classification. SB 808 also:

- Created additional dispensing and distribution allowances for Class-B pharmacies;
- Granted DHSS and the Board of Pharmacy authority to collaborate on rules governing medication distribution and medication therapy services performed by a pharmacist at or within a hospital. This allowance does not change DHSS’ current jurisdiction over hospital pharmacy but allows the agencies to collaborate on rulemaking, and
- Established a standing Hospital Advisory Committee to advise the Board. The Advisory Committee consists of hospital representatives designated by DHSS, the Missouri Hospital Association, the Missouri Society of Health System
Pharmacists and the Missouri Pharmacy Association and a Board appointed pharmacist with experience in hospital pharmacy.

**CLASS-B PERMIT REQUIREMENTS**

Section 338.220, RSMo, defines a “Class-B Hospital Pharmacy” as:

- A pharmacy owned, managed, or operated by a hospital as defined by § 197.020, or
- A hospital clinic or facility under common control, management or ownership of the same hospital or hospital system. [§ 338.165.1(3); § 338.220.6].

Eligible clinics/facilities may be located within a Missouri licensed hospital or separately operated at an offsite location. For example, offsite facilities such as infusion clinics, physician clinics, long-term care facilities, ambulatory surgical centers or other healthcare facilities may be licensed as a Class-B pharmacy, provided the clinic/facility meets the common ownership/operation requirements *(this list is not exhaustive)*. The governing hospital or hospital system is not required to be licensed with the Board unless the hospital/hospital system is also providing pharmacy services under the Board’s jurisdiction.

Applicants should consult with legal counsel to determine if a hospital clinic/facility is under “common control, management or ownership of the same hospital or hospital system.” The Board cannot provide legal advice.

Once approved, a Class-B permit will be issued for a specific location/address. Applicants may choose to license all or portions of a building under a Class-B permit (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. For example, a Class-B permit may include drug rooms that are located on different floors within the same building, however, each area and pharmacy activity would be required to comply with Board requirements. A separate Class-B permit would be required for facilities located at different addresses.

Class-B applications and related fees are available on the Board’s website. *Note: Applicants must apply for and hold any required classification for specialty pharmacy services regulated by the Board (e.g., Class D-Non-sterile Compounding, Class H- Sterile Compounding, Class J- Shared Services).*

**CLASS-B LICENSURE FOR MISSOURI HOSPITALS**

Under Chapter 197, RSMo, DHSS has regulatory jurisdiction over pharmacy services provided within the “licensed premises” of a Missouri hospital. A Class-B Hospital Pharmacy permit is not required for hospitals “solely providing services within the practice of
pharmacy under the jurisdiction of, and the licensure granted by” DHSS. [§ 338.220.6, RSMo]. Hospitals solely providing pharmacy services under DHSS’ jurisdiction may choose to be licensed as a Class-B pharmacy although not required.

Section 197.052, RSMo, defines the hospital premises as: “tracts of property which are adjacent but for a common street or highway, as defined in section 300.010, and its accompanying public right-of-way.” DHSS has provided the following examples of facilities considered “adjacent but for a common street or highway” to a hospital:

According to DHSS, buildings or areas that do not meet the above definition/requirements would not qualify as part of the hospital’s premises even though the building/area may be:
- Part of the hospital’s campus
- Under the same CMS Certification Number (CCN), or
- Under the same ownership

Inclusion in the hospital premises is not automatic. Instead, buildings/areas must be officially designated with DHSS as part of the hospital’s license. According to DHSS, this may be done in the hospital’s initial DHSS license application or hospitals may separately notify DHSS to amend their license. Hospitals should contact DHSS to verify that all desired buildings/areas have been properly designated, including, any newly added facilities. Pharmacy services provided in buildings/areas that have not been officially included as part of the DHSS licensed hospital premises would be regulated by the Board.

DHSS has advised that the hospital premises may include more than just “inpatient” areas. For example, other hospital areas such as emergency departments, infusion clinics, urgent care facilities, ambulatory surgery centers, physical therapy departments or other “outpatient” service areas may be included, provided the facility or department meets the hospital premises definition above. Note: Additional DHSS regulatory requirements may apply (e.g., DHSS construction standards/life safety requirements).
Examples of pharmacy services under DHSS’ jurisdiction would include, but are not limited to:

- Dispensing or distributing medication for use or administration to patients within the same DHSS licensed premises regardless of billing status (“inpatient” vs. “outpatient”). This includes dispensing or distributing to clinics or other hospital departments included within the DHSS licensed premises,
- Compounding medication within the DHSS licensed hospital premises for use or administration within the same licensed premises;
- Counseling or providing other non-dispensing pharmacy services for patients located or receiving treatment within the DHSS licensed hospital premises (e.g., DUR, medication reconciliation, order review/approval),
- Administering medication within the DHSS licensed hospital premises, and
- Initiating, modifying or dosing medication for use or administration within the DHSS licensed hospital premises (a Board Certificate of Medication Therapeutic Plan Authority would still be required as described below).

The Board has jurisdiction over pharmacy services provided outside of the licensed DHSS hospital premises. Examples would include, but are not limited to:

- Dispensing or distributing medication that will be used or administered outside of the DHSS licensed premises (e.g., “take-home” meds)
- Pharmacy services provided under a pharmacy’s Class-B permit
- Compounding for use or administration outside of the DHSS licensed hospital premises or compounding medication outside of the DHSS licensed hospital premises regardless of patient location
- Counseling or providing other non-dispensing pharmacy services for patients located or receiving treatment outside of the DHSS licensed hospital premises (DUR, medication reconciliation, order review/approval)
- Administering medication outside of the licensed hospital premises,
- Modifying or initiating drug therapy that will be dispensed, distributed or administered outside of the DHSS licensed premises, and
- Pharmacy services provided at a clinic or facility that is not part of the DHSS licensed hospital premises. This would include any clinic/facility that has not been officially designated with DHSS as part of the hospital’s license even if located within the hospital’s building or on the hospital campus.

The Board has determined that “take-home” medication would not include a self-contained medication therapy course where administration is initially started within the DHSS licensed hospital premises and will leave with the patient. Examples would include intrathecal or 5-FU pumps that are started within the DHSS licensed hospital premises. The Board has also determine that medication sent with a patient to be used during an emergency transfer to
another facility would not be considered a “take home” medication. These services may be provided under DHSS’ jurisdiction; additional Board licensure is not required.

Additionally, DHSS rules allow licensed hospitals to send a limited supply of medication home with the patient from the hospital when pharmacy services are not reasonably available. A Board pharmacy permit is not required for these activities as authorized by DHSS rules.

All pharmacists, technicians and interns practicing in Missouri must hold an individual pharmacist, technician or intern license/registration issued by the Board regardless of practice setting. Pharmacist, technicians and interns practicing within a DHSS licensed hospital must be licensed with/registered by the Board.

**Dually Regulated Entities**

The Board is aware of dually operating Class-B pharmacies providing pharmacy services under DHSS’ jurisdiction and pharmacy services under the Board’s jurisdiction at the same location. Class-B pharmacies may share pharmacy space with a DHSS regulated hospital; the Board does not require physical separation of facilities or drug inventory. However, proper security must be maintained over drug stock at all times. Additionally, pharmacy services under the Board’s jurisdiction must comply with all applicable Board statutes/rules.

DHSS licensed hospitals may choose to license all or a portion of the hospital as a Class-B pharmacy (e.g., a designated room or floor). Additionally, multiple areas at the same address may be included under a single permit. The Board would only have jurisdiction over and regulate the Class-B pharmacy services.

**Non-Dispensing Activities**

Missouri law authorizes pharmacists to perform non-dispensing activities outside of a Missouri licensed pharmacy. Specifically, 20 CSR 2220-6.055 provides a pharmacist may perform the following activities at a non-pharmacy location:

1. Administering medication or biologicals
2. Obtaining patient history/information
3. Reviewing patient records/medical reconciliation
4. Patient assessment/evaluation
5. Insurance billing and claims
6. Drug utilization review
7. Pharmacy compliance audits/evaluations
8. Peer review/peer consultations
9. Managing drug inventory, including purchasing and ordering
(10) Consulting with other health care professionals
(11) Patient referrals
(12) Medication therapy management/medication therapy services, and
(13) Prescription order entry/review, provided a pharmacist can only accept a prescription on the premises of a Missouri licensed pharmacy [§ 338.095.5]

A Class-B pharmacy permit would not be required for allowed non-dispensing activities, unless technicians will be assisting at the non-pharmacy location.¹

The Board has been asked if pharmacists can maintain or monitor drug storage areas/units that are located in hospital areas/facilities that are not licensed with the Board or located in other unlicensed healthcare facilities such as a private physician’s office, ambulatory surgical center or an infusion clinic. Class-B pharmacies cannot store medication outside of the licensed pharmacy area, except as allowed by 20 CSR 2220-2.900 for automated dispensing systems. However, 20 CSR 2220-6.055 would allow pharmacists to monitor/maintain medication or drug storage areas belonging to other unlicensed entities without a Board pharmacy permit. This would include non-dispensing activities such as checking drug storage, inventoring medication, performing drug utilization reviews, medication reconciliation and counseling patients (this list is not exhaustive).

SCOPE OF CLASS-B ACTIVITIES

Once licensed by the Board, sections 338.165.5 and .6, RSMo, grant two new allowances to Class B Hospital pharmacies. Specifically, Class-B Hospital pharmacies may:

1) Dispense medication by prescription or by medication order, and
2) Distribute medication to other hospital clinics or facilities that are under common control, management or ownership of the same hospital or hospital system without a Missouri drug distributor license.

Dispensing by Prescription/Medication Order

Class-B pharmacies may dispense medication pursuant to a patient-specific prescription or a patient-specific medication order. Prescriptions must comply with all state and federal requirements, including, the required two-line format for Missouri prescribers.

A “medication order” is defined as an order for a legend drug or device that is:

¹ A Board pharmacy permit would not be required if technicians are only assisting with administering vaccines. 20 CSR 2220-6.055(6).
1. Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee, and

2. To be distributed or administered to a patient by a health care practitioner or lawfully authorized designee at a hospital or a “hospital clinic or facility” that is under the “common control, management or ownership of the same hospital or hospital system.” Section 338.165.1, RSMo

Significantly, medication orders can only be used to dispense medication that will be distributed or administered at a hospital or at a qualifying “hospital clinic or facility.” A qualifying hospital clinic or facility could include offsite physician clinics, urgent-care centers, long-term care facilities, infusion clinics, physical therapy units or other healthcare facilities, provided the clinic or facility is under common control, management or ownership of the same hospital or hospital system.

The Board has been asked if a medication order may be used to dispense a self-contained medication therapy course that will be initially administered onsite but later sent home/transferred with a patient to complete/continue administration (e.g., intrathecal and 5-FU pumps). The Board has determined that a medication order may be used in these instances provided administration to the patient initially begins at the hospital or at a qualifying hospital clinic or facility.

Medication orders do not have to be in two-line format, however, orders must comply with all state/federal controlled substance requirements. Missouri law is silent on the pharmacist’s authority to perform generic or biosimilar substitution on a medication order. Please consult an attorney for guidance.

**Drug Distribution by Class-B Pharmacies**

Section § 338.165.6 provides a Class B Hospital pharmacy may distribute medication to a “hospital clinic or facility” for patient care or treatment without a Missouri drug distributor license. Once again, a “hospital clinic or facility” is defined as a clinic or facility under common control, management or ownership of the same hospital or hospital system.

The following chart provides examples of distributions that are authorized for Class-B pharmacies without an additional Missouri drug distributor license:
Under federal law, a pharmacy may still be required to register with the DEA as a controlled substances distributor if the total dosage units of all controlled substances distributed by the pharmacy exceeds five-percent (5%) of all controlled substances dispensed by the pharmacy during the previous calendar year.

Significantly, a Class B pharmacy may not distribute compounded preparations to other entities or distribute repackaged medication to other practitioners without being registered with the FDA. Licensees distributing non-patient specific medication may also be required to register with the FDA as a section 503(b) drug outsourcer. Licensees should consult with legal counsel to ensure compliance with state and federal law.

Class-B Labeling Requirements

Section 338.059, RSMO, provides a written label must be affixed to each prescription container dispensed to a consumer indicating:

1) The date the prescription was filled;
2) A prescription number or other unique identifier;
3) The patient's name;
4) The prescriber's directions for usage;
5) The prescriber's name;
6) The pharmacy's name and address;
7) The exact name and dosage of the drug dispensed, and;
8) If a generic substitution is made, the manufacturer must be identified on the label or in the pharmacy's records by name or abbreviation. [§ 338.059].

For controlled substance prescriptions issued by an advanced practice registered nurse (APRN) or a physician assistant (PA), the required label must also include the names of the prescribing mid-level practitioner and their supervising or collaborating physician. [§ 195.100, RSMo].

If a unique identifier is used in lieu of a prescription number, the identifier must be able to retrieve the patient’s specific medication order/prescription. Board inspectors have observed instances where a unique identifier could retrieve the patient’s medical record but not the specific medication order/prescription. In some cases, the same identifier was used

2 Section 338.059, RSMo, does not apply to internal drug orders for hospital in-patients.
for multiple patients. Unique identifiers should be formatted to allow retrieval of the specific dispensing record for each individual patient (e.g. a unique identifier/order #).

The Board has been asked about labeling requirements for Class-B pharmacies dispensing medication to a healthcare provider for onsite administration to a patient. The Board understands labeling may be a particular issue for hospital-owned clinics/satellite pharmacies that may not use prescriptions or have software to print a traditional “outpatient” prescription label.

The Board intends on addressing this issue by rule in the future. In the interim, Board Inspectors will not cite Class-B pharmacies for violations of § 338.059’s labeling requirements if:

1) Medication is given to a healthcare practitioner for use or administration to a patient onsite of a Class-B pharmacy or within the licensed premises of a DHSS licensed hospital, and

2) The medication/prescription container labeling is accurate and complies with DHSS’ medication labeling requirements [see generally 19 CSR 30-20.100(21) which requires patient name, drug name, strength, expiration date, lot number when applicable and other pertinent information], and

3) The medication/prescription container is not “given to the patient for use/administration” offsite. The Board will not consider medication to have been given to the patient for offsite use/administration if medication administration is initiated onsite but continued offsite by a parenteral infusion method, including, but not limited to, a subcutaneous, intrathecal or intravenous method or via an implanted device, port or catheter. The Board will not consider medication to have been given to the patient for offsite use/administration if medication administration is initiated onsite but continued offsite via a locked, pre-programmed external or implanted medication delivery device that does not require programming by the patient or caregiver.

Sterile Compounding

Class-B pharmacies engaged in sterile compounding must also have a Class-H Sterile Compounding pharmacy permit. All sterile compounding for use or administration to patients outside of the DHSS licensed hospital premises must comply with the Board’s sterile compounding rules (20 CSR 2220-2.200, 20 CSR 2220-2.400). Class-B pharmacies may share sterile compounding space/equipment with a DHSS hospital (e.g., the same clean room). However, the sterile compounding area will be inspected for compliance with Board requirements.

3 Radiopharmaceuticals must also comply with 19 CSR 30-20.100(18)
Licensees are reminded that Class-B pharmacies may only dispense compounded sterile preparations pursuant to a patient-specific prescription or a patient-specific medication order.

**Allowed Technician Activities**

Generally, a Missouri pharmacy technician registration is required for any person who has independent access to a pharmacy on a routine basis or who assists a pharmacist in the practice of pharmacy. Given the nature of hospital practice, the Board has determined that technician registration is not required for nurses and other healthcare practitioners who access Class-B pharmacy space or drug inventory that is shared with a DHSS regulated hospital pharmacy as part of their non-pharmacy job duties.

Pharmacy technicians may assist in any area of pharmacy practice that does not require the use of professional judgment by a pharmacist. [20 CSR 2220-2.700(1).] Technicians assisting in Class B pharmacy practice may not work independently and must be under the direct supervision and responsibility of a Missouri licensed pharmacist at all times. [20 CSR 2220-2.700]. All prescriptions prepared or compounded by a technician in a Class-B pharmacy must be finally verified/checked by a pharmacist, including, reconstituted products.

**Medication Therapy Services**

Under Missouri law, all pharmacists providing medication therapy services (MTS) must obtain a certificate of medication therapeutic authority from the Board, regardless of practice setting. [§ 338.010.4] Licensees should review the Missouri Pharmacy Practice Guide for additional MTS requirements.

As explained in the Practice Guide, an MTS certificate is not required to perform traditional pharmacist functions such as medication reconciliation or medication therapy management. A MTS certificate is only required if a pharmacist will be modifying drug/device therapy which includes:

- Selecting a new, different or additional medication or device (including initiating therapy);
- Discontinuing any current medication/device;
- Selecting a new, different or additional strength, dose, dosage form or dosage schedule; or
- Selecting, adding or changing a new or different route of administration.
Generally, pharmacists who are dosing, modifying or initiating medication that will be dispensed, distributed or administered outside of the DHSS licensed premises would be regulated by the Board and required to comply with the Board’s MTS rules and requirements. DHSS would regulate dosing, modifying or initiating medication within the DHSS licensed hospital premises (a Board MT certificate would still be required). Note: This is a general guideline. A determination of DHSS/Board jurisdiction would depend on the specific facts.

The Board has issued the following additional guidance for pharmacists performing MT services under the Board’s jurisdiction:

1. Pharmacists must have a MT protocol with a Missouri physician that complies with 20 CSR 2220-6.080. A hospital protocol may be used to provide MT services if the protocol includes all information required by 20 CSR 2220-6.080(4) and authorizes the pharmacist to perform the services provided. A separate protocol would not be required. In lieu of individual signatures, 20 CSR 2220-6.080 allows the pharmacist and authorizing physician(s) to sign and date a statement agreeing to be governed by the hospital’s protocol.

2. Pharmacists are required to notify the protocol physician within twenty-four (24) hours of modifying drug therapy or within 24-hours of an adverse event, adverse medical reaction or an adverse needle stick. The Board has determined that notifications may be maintained in an electronic medical record (EMR) that is required to be maintained by state or federal law, provided the EMR is accessible to and shared by both the physician and pharmacist.

3. In addition to a MT protocol, pharmacists performing MT services under the Board’s jurisdiction must also have a prescription order from a physician authorizing them to provide MT services for the specific patient. The Board has determined that a protocol approved by a hospital’s clinical care committee, pharmacy and therapeutics committee or an equivalent hospital reviewing body/committee may be used to initiate pharmacist MT services, provided the protocol is not restricted or limited to MT services within the DHSS licensed premises.4 By statute, the prescription order/protocol must be initiated or issued by the physician and not a nurse or physician assistant. [§ 338.010.2]

4. Generally, the authorizing physician must review the pharmacist’s MT services at least once every three (3) months. For pharmacists providing MT services for, or on behalf of, a licensed hospital, the required review may be conducted by the clinical care committee, the pharmacy and therapeutics committee or by an equivalent hospital reviewing body that includes a Missouri-licensed physician (e.g., the medical staff committee).4

4 Note: This allowance would also apply to pharmacists providing MT services for, or on behalf of, a state or federally licensed hospice facility, ambulatory surgical center, nursing home, long-term care facility,
The above requirements are for services provided under the Board’s jurisdiction. Please consult DHSS requirements for services provided under their jurisdiction.

**Immunization/Administration of Medication**

Pharmacists immunizing or administering medication outside of the DHSS licensed premises must file a Notification of Intent to immunize and/or administer medication by prescription order with the Board and comply with rules 20 CSR 2220-6.040 and 20 CSR 2220-6.050.

Pharmacists immunizing by protocol are required to notify the authorizing protocol physician within seventy-two (72) hours after immunizing and notify the patient’s primary care provider within fourteen (14) days after vaccination, if different. Additionally, pharmacists must notify the protocol physician within twenty-four (24) hours of an adverse event/reaction. Pending future Class-B rules, the Board has determined the required notifications may be documented in a common EMR that is accessible to both the pharmacist and physician. Proof of documentation/notification must be produced on inspection or as requested by the Board.

Licensees should review the Missouri Pharmacy Practice Guide for additional immunization/administration compliance information. The Board also has an Immunization/Administration Checklist available online at [http://pr.mo.gov/pharmacists-faq-compliance.asp#immunization](http://pr.mo.gov/pharmacists-faq-compliance.asp#immunization). Pharmacists immunizing or administering medication within the DHSS licensed hospital premises must comply with DHSS requirements.

**Class-J Shared Services**

Class-B pharmacies engaged in shared services with another Board licensed pharmacy must also have a Class-J pharmacy permit, in addition to their Class-B permit. A Class-J permit is required if a pharmacy will be using, or assisting another pharmacy with:

- Filling or refilling a prescription drug order, or
- Performing or assisting in the performing of any function associated with the dispensing process. This would include drug utilization review (DUR), claims adjudication, refill authorizations and therapeutic interventions for another pharmacy.

Pharmacies may participate in a Class-J shared services arrangement if both pharmacies:

1. Have the same owner or have a written contract outlining the shared services to be provided by, and the responsibilities of, each party participating in the contract; and
2. Maintain separate pharmacy licenses for each shared services location; and

residential care facility, assisted living facility, intermediate care facility, skilled nursing facility or a habilitation center.
3) Share a common electronic file that allows access to sufficient information necessary or required to fill/refill a prescription drug order. The pharmacies must share a record keeping system that provides real time, on-line access to shared services by both pharmacies.

Class-J pharmacies must also maintain a policy and procedure manual that describes/includes procedures for: (a) how the parties will comply with state/federal requirements (b) identifying the pharmacist responsible for dispensing and counseling, (c) tracking the prescription drug order during each step in the process, (d) maintaining adequate security to protect the confidentiality and integrity of patient information and (e) maintaining a quality assurance program for pharmacy services that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care and resolve identified problems.

Once again, a Class-J permit is required for both pharmacies engaged in shared services. For example, a Class-B chemotherapy infusion pharmacy receives and fills a patient’s prescription from a specialty mail order pharmacy (i.e., a manufacturer’s indigent program). A Class-J permit would be required for both the Class-B chemotherapy infusion pharmacy and the specialty mail order pharmacy. Pharmacies may add a classification by filing a Pharmacy Classification Change Application with the applicable fee.

Transferring prescription information between Class-J pharmacies in a shared services arrangement that share a real-time, on-line database are not considered “prescription transfers” under, and are not subject to the requirements of, 20 CSR 2220-2.120. Other controlled substance laws may apply.

Record-Keeping

As a licensed pharmacy, Class-B pharmacies must comply with all Board record-keeping requirements applicable to pharmacies. Licensees should review Missouri law and the Missouri Practice Guide for specific requirements. The Board has determined that Class-B pharmacies may maintain dispensing, distribution and administration records in the same electronic or manual system used by the hospital or other hospital clinics/facilities (e.g., a common EMR), provided the records must be readily retrievable on inspection or if requested by the Board.5

Future Rules

5 Controlled substance records must still be separately maintained/retrievable as required by state/federal law.
The Board will be consulting with the Hospital Advisory Committee to develop future Class-B pharmacy rules. Interested parties should monitor the Board’s website for meeting information; public comments are welcomed.

Questions

Questions regarding activities under DHSS’ authority should be addressed to DHSS’ Division of Hospital Licensure and Regulation at (573). Questions regarding the Board’s rules or requirements may be addressed to your Inspector or e-mailed to compliance@pr.mo.gov.
Hospital Advisory Committee Update
#D5  **DQSA Implementation/FDA Compounding Guidance**
- Prescription Requirement Under Section 503(A) of the Federal Food, Drug and Cosmetic Act
- Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities
- Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities
- Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification
Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

December 2016
Compounding and Related Documents
Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:
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U.S. Department of Health and Human Services
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December 2016
Compounding and Related Documents
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Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION AND SCOPE

This guidance sets forth the FDA’s policy concerning certain prescription requirements for compounding human drug products for identified individual patients under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act). It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use (or office stock).

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

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1 This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER), in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

2 This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For proposed policies pertaining to compounding drug products from bulk drug substances for use in animals, see FDA’s draft guidance, Compounding Animal Drugs from Bulk Drug Substances. For proposed policies pertaining to mixing, diluting, and repackaging biological products, see FDA’s draft guidance, Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application. For proposed policies pertaining to repackaged drug products, see FDA’s draft guidance, Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities. FDA guidances are available on the FDA website at http://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
II. BACKGROUND

A. Overview

1. Compounding Under the FD&C Act

Sections 503A and 503B of the FD&C Act address human drug compounding.

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act in 1997, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act:

- section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements);
- section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and
- section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

A list of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A of the FD&C Act appears in the guidance, Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.

New section 503B, added to the FD&C Act by the Drug Quality and Security Act in 2013, created a new category of compounders called outsourcing facilities. Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act:

- section 502(f)(1);
- section 505; and
- section 582 (concerning drug supply chain security requirements).

In contrast to drug products compounded under section 503A of the FD&C Act, drug products compounded by outsourcing facilities under section 503B are not exempt from CGMP requirements in section 501(a)(2)(B). Outsourcing facilities are also subject to FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that help to mitigate the risks of the drug products they compound.

The guidance, For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act, lists the conditions that are set forth in section 503B of the FD&C Act.

2. Compounding, Generally
Contains Nonbinding Recommendations

Compounded drug products can serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, or an elderly patient or a child who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form that is not otherwise available, or for appropriate pediatric or weight-based dosing. Drug products for identified individual patients can be compounded consistent with section 503A by licensed pharmacists in State licensed pharmacies and Federal facilities, or by licensed physicians. Drug products can also be compounded by outsourcing facilities under section 503B of the FD&C Act.

In general, when a compounded drug product is clinically necessary for a patient, a prescriber writes a prescription for a compounded drug product, and the patient brings the prescription to a pharmacy, where a licensed pharmacist fills the prescription. In an inpatient setting, such as in a hospital, a prescriber may write an order for a compounded drug product on a patient’s health record (e.g., chart). In an office setting, a physician may make an entry or order in a patient’s health record that the physician compounded a drug in the office for administration to his or her patient after the patient presents at the physician’s office with a clinical need for the compounded drug.

In other cases, based on a history of receiving prescriptions for identified individual patients, in the context of an established relationship with the patient or the practitioner who writes the prescription, a pharmacist may compound a drug product before receipt of a prescription for an identified individual patient in anticipation of receiving such a prescription. The pharmacist then provides the drug product to a patient or a prescriber upon receipt of a prescription. Similarly, based on the amount of the compounded drug that the physician has historically administered or dispensed to his or her patients, a physician may compound a drug product to hold in his or her office in anticipation of patients in his or her practice presenting with a need for the compounded drug. The physician then administers or dispenses the compounded drug to his or her patients after making an entry in the patients’ health records.

Sometimes, it is necessary for health care practitioners in hospitals, clinics, offices, or other settings to have certain compounded drug products on hand that they can administer to a patient who presents with an immediate need for the compounded drug product. For example, if a patient presents at an ophthalmologist’s office with a fungal eye infection, timely administration of a compounded antifungal medication may be critical to preventing vision loss. In such a case, the ophthalmologist may need to inject the patient with a compounded drug product immediately, rather than writing a prescription and waiting for the drug product to be compounded and shipped to the prescriber.3

In other cases, compounded drug products may need to be administered by a health care practitioner in his or her office because it would not be safe for the patient to take the drug home for self-administration, and it would be more convenient for the physician to have the drug in his

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3 Such compounding would be subject to all of the conditions of section 503A or 503B, including provisions concerning compounding drug products that are essentially copies of commercially available drug products (section 503A(b)(1)(D)) or drug products that are essentially copies of approved drugs (section 503B(a)(5)).
or her office to administer immediately upon diagnosis, rather than asking the physician to order the drug and have the patient return to the health care practitioner for administration.

3. Risks Associated with Compounded Drug Products

Although compounded drugs can serve an important need, they pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not subject to CGMP requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products they compound (see section 3, below) because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint such as a report of a serious adverse event or visible contamination.

In 2012, contaminated injectable drug products that a compounding pharmacy shipped to patients and health care practitioners across the country caused a fungal meningitis outbreak that resulted in more than 60 deaths and 750 cases of infection.4 This was the most serious of a long history of outbreaks associated with contaminated compounded drugs. Since the 2012 fungal meningitis outbreak, FDA has investigated numerous other outbreaks and other serious adverse events, including deaths, associated with compounded drugs that were contaminated or otherwise compounded improperly. For example, patients have been hospitalized after receiving compounded non-sterile drugs that were hundreds or even thousands of times their labeled strength.5

FDA has also identified many pharmacies that compounded drug products under insanitary conditions whereby the drug products may have been contaminated with filth or rendered injurious to health, and that shipped, sometimes in large amounts, the compounded drug products made under these conditions to patients and health care providers across the country.6 The longer a compounded sterile drug product that has been contaminated is held by a pharmacist or physician before distribution, 7 or held in inventory in a health care facility before administration, the greater the likelihood of microbial proliferation and increased patient harm. Because of these and other risks, the FD&C Act places conditions on compounding that must be met for compounded drugs to qualify for the exemptions in section 503A. These conditions include:

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5 See, for example, http://www.fda.gov/Drugs/DrugSafety/ucm474552.htm
6 See FDA actions, including warning letters and injunctions, related to insanitary conditions at compounding facilities, on FDA’s website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm
7 Distribution means that the compounded drug has left the facility in which it was compounded. As used in this guidance, distribution includes dispensing a drug directly to a patient.
Contains Nonbinding Recommendations

- compounding is for an identified individual patient,
- drugs compounded in advance of receiving prescriptions are compounded only in limited quantities, and
- drugs are distributed pursuant to a valid patient-specific prescription.

These conditions are meant to help ensure that compounding under section 503A is based on individual patient needs, and that entities purportedly operating under section 503A are not actually operating as conventional manufacturers.

B. The Prescription Requirement in Section 503A(a) of the FD&C Act

A compounded drug product may be eligible for the exemptions under section 503A of the FD&C Act only if it is, among other things, “compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient.” To qualify for the exemptions under section 503A, the drug product must also be compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or by a licensed physician (section 503A(a)).

Section 503A(a) describes two situations in which a drug product can be compounded: (1) based on the receipt of a valid prescription order for an identified individual patient (section 503A(a)(1)); or (2) in limited quantities before the receipt of a valid prescription order for an identified individual patient (section 503A(a)(2)). As discussed further in section III.C of this guidance document, section 503A does not provide for distributing a compounded drug product before receiving a valid prescription order for an identified individual patient.

The prescription requirement under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved, are not subject to the requirement that labeling bear adequate directions for use, and are not subject to CGMP requirements, are provided to a patient only based on individual patient need.

The prescription requirement is also an important factor that distinguishes compounding by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or by a licensed physician under section 503A from compounding by an outsourcing facility under section 503B of the FD&C Act. Section 503B states that an outsourcing facility may or may not obtain prescriptions for identified individual patients (section 503B(d)(4)(C)). Outsourcing facilities, which are subject to CGMP requirements and other important conditions, can compound drug products to fulfill the needs described in section II.A.2 for health care practitioners to have drug products on hand that are not compounded for identified individual patients.

1. Compounding After Receipt of a Valid Prescription Order

As described in section II.A.2, a prescriber may write a prescription for an identified individual patient who needs a compounded drug product. In most cases, either the prescriber or the patient...
will then bring or send the prescription to the pharmacy, where the pharmacist will compound the drug product for the patient and provide it to the prescriber or patient according to the prescription. For a patient in an inpatient setting, a prescriber may place an order in the patient’s health record (e.g., chart) for a compounded drug product, which will likely be provided by the health care facility pharmacy. In an office setting, a physician may compound a drug after making a notation in the health record of a patient in his practice who presents with a need for the compounded medication. These types of compounding are covered under section 503A(a)(1) of the FD&C Act, which provides for compounding by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order for an individual patient made by a licensed physician or other licensed practitioner authorized by state law to prescribe drugs.

2. Compounding Before Receipt of a Valid Prescription Order

Sometimes, based on a history of receiving prescriptions for a particular drug product to be compounded for an identified individual patient, and in the context of an established relationship with a particular prescriber or patient, a pharmacist or physician will compound a batch of drugs in anticipation of receiving another patient-specific prescription. The compounder then provides the drugs to a patient or health care provider when a prescription for an identified individual patient is received. This is known as anticipatory compounding. Section 503A(a)(2) of the FD&C Act provides for compounding by a licensed pharmacist or licensed physician in “limited quantities before the receipt of a valid prescription order for such individual patient” if:

- The compounding is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product;

and

- The orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order.

Anticipatory compounding can be beneficial because larger batch sizes can increase efficiency and reduce the likelihood of human error that is associated with compounding many small batches of a drug product after the receipt of individual prescriptions for the same drug. However, anticipatory compounding also has risks. For example, if a problem occurs during compounding, such as contaminating a drug product that is supposed to be sterile, or producing subpotent or superpotent sterile or non-sterile drugs, it could affect numerous patients, and not just one. Because drug products compounded in accordance with section 503A are exempt from CGMP requirements, there is an inherently greater chance of a production mistake or

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8 If applicable state and federal requirements are met, outsourcing facilities can also compound drug products pursuant to prescriptions for identified individual patients under section 503B of the FD&C Act. However, that is not the subject of this guidance document.
contamination. Restricting anticipatory compounding to limited quantities serves to limit the number of patients likely to be affected if there are drug product mix-ups or contamination.

The limitations on anticipatory compounding in section 503A (i.e., compounding must be in “limited quantities” and based on an “established relationship”) help to protect patients from product quality issues.

These limitations on anticipatory compounding also help to distinguish licensed pharmacists or licensed physicians compounding drug products under section 503A for individual patients from conventional manufacturers, who generally produce larger quantities of drugs that are distributed without a prescription.

The anticipatory compounding limitations also differentiate licensed pharmacists and licensed physicians compounding under section 503A from compounders registered as outsourcing facilities under section 503B of the FD&C Act. As explained above, outsourcing facilities are subject to increased Federal oversight and quality standards, including CGMP requirements, which reduce the risks of quality problems such as production mistakes or contamination. Under section 503B, an outsourcing facility can distribute compounded drug products to health care facilities and health care practitioners without first receiving prescriptions for identified individual patients.

With these principles in mind, FDA sets forth its policy with regard to the prescription requirement in section 503A.

III. POLICY

A. Receipt of a Valid Prescription Order or a Notation Approved by the Prescriber Under Section 503A

For purposes of section 503A(a), a valid prescription order for a compounded drug product means a valid prescription order from a licensed physician or other licensed practitioner authorized by state law to prescribe drugs (prescriber). It also includes a valid order or notation made by a prescriber in a patient’s health record (e.g., chart) in an inpatient setting, and a valid order or notation by a physician who compounds a drug for his or her own patient documented in that patient’s health record.9

To meet the prescription requirement, a prescription must identify the patient for whom the drug has been prescribed. If the identity of the patient is not given or is not clear, it will not satisfy

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9 Prescription orders that are not valid would not satisfy the prescription requirement in section 503A and cannot serve as the basis for anticipatory compounding. See, in addition, section 301(ccc)(2), which states that, with respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable, is a prohibited act.
Contains Nonbinding Recommendations

this requirement. For example, a prescription would not satisfy the requirement if it is written for the prescriber, when the prescriber is not also the patient.10

B. When a Drug Can Be Compounded Under Section 503A

1. Compounding After Receipt of a Valid Prescription Order

Unless a drug product is compounded in limited quantities before the receipt of a valid prescription order under the conditions described in section 503A(a)(2) of the FD&C Act, which are also described in section III.B.2 of this guidance, to qualify for the exemptions under section 503A, the drug product must be compounded after the licensed pharmacist or licensed physician receives a valid prescription order for an individual patient. We understand this to be compounding “on” the receipt of a valid prescription order, as provided in section 503A(a)(1).11

2. Compounding Before Receipt of a Valid Prescription Order

If a drug product is not compounded after the receipt of a valid prescription order for an identified individual patient as described in section 503A(a)(1) of the FD&C Act and section III.B.1 of this guidance, the drug product can be compounded under section 503A of the Act by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient (section 503A(a)(2)(A)), if all of the conditions of section 503A are met, including the following conditions:

- The compounding is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product; and

- The orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the prescriber who will write such prescription order12 (see section 503A(a)(2)(B)).

This means that anticipatory compounding under section 503A is done in limited quantities, based on an expectation that the licensed pharmacist or licensed physician will receive a patient-specific prescription for the particular drug product, written for a patient or by a prescriber with whom the compounder has a relationship.

10 In addition, for a notation to serve as a basis for compounding under section 503A, the notation must document the prescriber’s determination that a compounded drug is necessary for the identified patient (section 503A(a)). FDA intends to describe its policies regarding this provision in a future policy document.

11 This includes a physician compounding a drug for his or her own patient after writing a prescription order (e.g., an order written in the patient’s chart) for the compounded drug.

12 When a physician compounds drugs for his or her own patients, FDA considers the “established relationship” provision of section 503A(a)(2) to have been satisfied because the licensed physician and the “prescriber who will write such prescription order” are the same individual.
At this time, as an interim compliance policy, we do not intend to consider whether a compounder has exceeded the limited quantity condition in section 503A(a)(2) if:

- The compounder holds for distribution no more than a 30-day supply of a particular compounded drug product (i.e., units of a compounded drug product that the compounder believes it will distribute over a 30-day period) to fill valid prescriptions it has not yet received; and

- The amount of the supply of a particular compounded product is based on the number of valid prescriptions that the compounder has received for identified individual patients in a 30-day period over the past year that the compounder selected.

Under this policy, if a compounder does not exceed the quantities described above, FDA does not intend to determine whether anticipatory compounding was based on the expectation that the compounder would receive another prescription for the drug product for the same patient or from the same prescriber with whom the compounder has a history. FDA also contemplates that a compounded drug product might be distributed to any patient or prescriber who presents a valid prescription for an identified individual patient for the compounded drug product.

The following examples illustrate FDA’s policy on anticipatory compounding under section 503A(a)(2):

- A compounder regularly receives valid prescription orders from a particular prescriber or prescribers, or for a particular patient or patients, for compounded drug X. The highest number of units of drug X for which the compounder has received valid patient-specific prescriptions in a 30-day period in the last year is 500 units. Compounding up to 500 units of drug X in advance of receiving prescriptions for the drug, and holding no more than that amount to fill new valid patient-specific prescriptions as the compounder receives them, would be consistent with this policy.

- A compounder regularly receives valid prescription orders from a particular prescriber or prescribers, or for a particular patient or patients, for compounded drug

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13 The limited quantities policy, which relates to the amount of inventory held by the compounder, does not alter the product’s BUD. For example, if the BUD for the product is 9 days, the compounder should not produce more units than can be distributed pursuant to valid prescriptions and used within 9 days.

14 A drug product for distribution does not include drug product that is being held pending receipt of the results of release testing such as sterility testing.

15 For example, in an inpatient setting, the “established relationship” may be between the prescriber who writes an order for a compounded drug product in a patient’s health record, and the compounder who produces the drug product.

16 In this example, it would be consistent with FDA’s policy if, after distributing 200 units of drug X pursuant to valid patient-specific prescriptions, the compounder produces up to 200 additional units of drug X so that the total number of units that the compounder is holding for distribution returns to 500 units.
X. As of August 1, 2016, the highest number of units of drug X for which the compounder has received such valid patient-specific prescriptions in a 30-day period between August 1, 2015, and August 1, 2016, is 500 units, which were received between July 1, 2016, and July 30, 2016. Based on this 30-day reference period, the compounder produces 500 units of drug X in advance of receiving prescriptions for the drug, and holds no more than that amount to fill new patient-specific prescriptions as the compounder receives them. However, between July 15, 2016, and August 15, 2016, the compounder receives valid patient-specific prescriptions for 750 units of compounded drug X. Therefore, based on this new reference period, on August 16, 2016, the compounder produces up to 750 units of drug X in advance of receiving prescriptions for the drug, and holds no more than that amount to fill new valid patient-specific prescriptions as the compounder receives them. This would be consistent with FDA’s policy on anticipatory compounding.

• A physician who compounds drugs for his or her own patients routinely sees patients who need compounded drug X. The highest number of units of drug X that the physician has dispensed or administered to patients after making a notation in the patients’ charts in a 30-day period in the last year is 500 units. Compounding up to 500 units of drug X in advance of making such notations in patients’ charts (i.e., before patients present at the physician’s office with a need for the compounded drug), and holding no more than that amount to dispense or administer to patients, would be consistent with this policy.

C. When a Compounded Drug Product Can Be Distributed Under Section 503A

Compounding under section 503A(a) must be “for an identified patient based on the receipt of a valid prescription order” – either “on the receipt of a prescription order for such individual patient” or, under certain conditions, “before the receipt of a valid prescription order for such individual patient.” This means that for each drug compounded under section 503A, the compounder must obtain a valid patient-specific prescription order. We therefore understand that the compounder can distribute compounded drugs under section 503A only pursuant to such a valid patient-specific prescription (i.e., the compounder receives a valid patient-specific prescription before the compounded drug product leaves the compounding facility). We recognize that some state boards of pharmacy may authorize the writing of prescriptions that do not include individual patient names. Such prescriptions, however, do not meet the requirement of a patient-specific prescription in section 503A. Under section 503B, outsourcing facilities can fill such prescriptions if they meet the requirements of applicable state and Federal laws.

D. Compounding Office Stock/ Compounding for Office Use

As discussed in section II.A.2 of this guidance, some compounded drug products are kept as office stock/ for office use by hospitals, clinics, or health care practitioners to administer to patients who present with an immediate need for a compounded drug product. Hospitals, clinics, and health care practitioners can obtain non-patient-specific compounded drug products from
outsourcing facilities registered under section 503B.\textsuperscript{17} Outsourcing facilities, which are subject to CGMP requirements, FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that provide greater assurance of the quality of their compounded drug products, may, but need not, obtain prescriptions for identified individual patients prior to distribution of compounded drug products (section 503B(d)(4)(C)).\textsuperscript{18} Therefore, outsourcing facilities can compound and distribute sterile and non-sterile\textsuperscript{19} non-patient-specific drug products to hospitals, clinics, and health care practitioners for office use.\textsuperscript{20}

Section 503A(a)(2) provides a pathway for anticipatory compounding in limited quantities. A licensed pharmacist or licensed physician can compound a drug product in advance of receiving a valid prescription order for an identified individual patient, in accordance with the conditions described in section 503A(a)(2) of the FD&C Act, to have a supply of the drug product ready to provide to a patient or prescriber (or, in the case of a physician, to administer to a patient) when a patient-specific prescription order is presented for the compounded drug product. This can reduce the time it would take for a compounded drug product to be made available to a patient upon receipt of a valid prescription order for that patient.

\textsuperscript{17} See also FDA’s draft guidance, \textit{Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act}, which, when final, will describe FDA’s policies regarding the application of section 503A of the FD&C Act to drug products compounded for use within a hospital or health system.

\textsuperscript{18} Although an outsourcing facility may send prescription drugs to health care facilities without obtaining prescriptions for identified individual patients, drugs produced by outsourcing facilities remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a prescription drug to a patient without a prescription.

\textsuperscript{19} Section 503B defines outsourcing facility, in part, as a facility that is engaged in the compounding of sterile drugs (section 503B(d)(4)(A)(i)). Therefore, an entity that only compounds non-sterile drugs does not meet the definition of outsourcing facility. An outsourcing facility may engage in non-sterile compounding provided that it also engages in the compounding of sterile drugs, and provided that it compounds all of its drugs (both sterile and non-sterile) in accordance with the conditions of section 503B.

\textsuperscript{20} Distribution of compounded drug products by outsourcing facilities is subject to the limitations described in section 503B(a)(8), among other conditions.
Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document, contact Edisa L. Gozun, CDER Office of Unapproved Drugs and Labeling Compliance (OUDLC) at 301-796-3110.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

December 2016
Compounding and Related Documents
Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities

Guidance for Industry

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Guidance for Industry

Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION AND SCOPE

This guidance sets forth the FDA’s policy regarding the compounding and repackaging of radiopharmaceuticals for human use by State-licensed nuclear pharmacies and Federal facilities that are not registered as outsourcing facilities.

Under current law, radiopharmaceuticals that are compounded by entities that are not registered with FDA as outsourcing facilities, and radiopharmaceuticals that are repackaged, are subject to all applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) related to the production of drugs. Because Congress explicitly excluded radiopharmaceuticals from section 503A of the FD&C Act, compounded radiopharmaceuticals are not eligible for the exemptions under section 503A from section 505 (concerning new drug approval requirements), section 502(f)(1) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements). In addition, Congress did not exempt repackaged radiopharmaceuticals from any provisions of the FD&C Act.

FDA is issuing this guidance to describe the conditions under which the Agency does not intend to take action for violations of sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act when

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1 This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

2 Outsourcing facility refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the FD&C Act.

3 Section 503A of the FD&C Act describes the conditions that must be met for drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act. Section 503A(d)(2) of the FD&C Act states that “this section shall not apply to . . . radiopharmaceuticals.”
This guidance does not address the following:

- Mixing, reconstituting, combining, diluting, or repackaging of a radiopharmaceutical, or other such acts, performed in accordance with directions contained in the FDA-approved labeling.
- Production of positron emission tomography (PET) drugs.
- Drug products that are not radiopharmaceuticals.
- Radioactive biological products that are subject to licensure under section 351 of the Public Health Service (PHS) Act.
- Radiopharmaceuticals for use in animals.
- Compounding or repackaging of radiopharmaceuticals by entities that are not State-licensed nuclear pharmacies or Federal facilities.
- Compounding or repackaging of radiopharmaceuticals by outsourcing facilities. See FDA’s draft guidance document, Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.
- This guidance does not alter FDA’s current regulations and guidances addressing investigational new drugs.

In May 1984, FDA issued guidance for industry on Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment to describe activities of a nuclear pharmacy that would require the pharmacy to register as a drug establishment under section 510 of the FD&C Act. When finalized, this guidance will supersede the May 1984 guidance, and FDA intends to withdraw the May 1984 guidance in the Federal Register notice announcing the availability of the final version of this guidance.

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.
II. BACKGROUND

A. Radiopharmaceuticals, Generally

Radiopharmaceuticals are radioactive sterile and non-sterile drugs that are used in nuclear medicine procedures to diagnose, monitor, and treat diseases. Radiopharmaceuticals are used in diagnostic procedures and for therapeutic purposes. For example, during certain diagnostic procedures involving radiopharmaceuticals, the body is exposed to small amounts of radiation to observe organ function. Radiopharmaceuticals used for therapeutic purposes are generally administered in larger amounts to ensure that therapeutic doses of radiation are delivered to specific disease sites.

Some radiopharmaceuticals are produced by a conventional manufacturer and shipped in hot (radioactive) multi-dose containers directly to an imaging center or hospital for patient administration. The imaging center or hospital’s nuclear pharmacy transfers the radiopharmaceuticals from the multi-dose containers into unit-dose, patient-ready containers, and sometimes manipulates the radiopharmaceuticals in other ways, such as by diluting or pooling them. Other radiopharmaceuticals are produced at the nuclear pharmacy by combining radioactive materials eluted from a generator with non-radioactive cold kits. The nuclear pharmacy prepares the radiopharmaceutical product using the components of the kit and adding radioactive material eluted from a generator for administration to a patient.

Because radioactive drugs generally have short half-lives (e.g., minutes, hours, or up to a few days), they must reach the patient for administration soon after they are produced. Therefore, hospitals and imaging centers often place orders with a nuclear pharmacy for delivery of radiopharmaceutical unit-doses for procedures scheduled for the following day or in anticipation of unscheduled nuclear medicine procedures that might take place during the evening or weekend when the nuclear pharmacy is closed.

There are legal restrictions as to who is permitted to obtain, transport, manipulate, and use radioactive drugs. At the Federal level, the Nuclear Regulatory Commission (NRC) has established rules to protect the general public, patients, and radiation workers from unnecessary exposure to radiation. The NRC and those States that have entered into certain agreements with

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6 As used in this guidance, radiopharmaceutical and radioactive drug have the same meaning and refer to a drug that meets the definition in 21 CFR 310.3(n): “any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term ‘radioactive drug’ includes a ‘radioactive biological product’ as defined in 600.3(ee) of this chapter.” Radioactive biological product is defined in 21 CFR 600.3(ee) as “a biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.” As stated previously, this guidance does not apply to radioactive biological products.

7 See 10 CFR parts 19, 20, and 35.
the NRC (Agreement States)\textsuperscript{8} issue radioactive materials (RAM) licenses that describe who is licensed to possess radioactive materials and the type of radioactive material that may be possessed under the license. An authorized nuclear pharmacist, as defined by the NRC,\textsuperscript{9} must be identified on a RAM license issued to a nuclear pharmacy where radiopharmaceuticals are prepared. Transport of radioactive materials is regulated by the NRC or the Agreement State and the U.S. Department of Transportation.\textsuperscript{10}

Separate from the RAM licenses issued by the NRC or an Agreement State, State boards of pharmacy may issue pharmacy permits to holders that receive, prepare, repackage, and/or dispense radioactive drugs. Certain States specifically recognize a separate category of pharmacists who practice as nuclear pharmacists and issue credentials specific for this practice.

\section*{B. Terminology}

\subsection*{1. Compounding}

In this guidance, FDA regards \textit{compounding} as the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

In some cases, State-licensed nuclear pharmacies compound a radiopharmaceutical from an FDA-approved drug product with one or more minor deviations (as described below) that are necessary to accommodate circumstances not contemplated in the FDA-approved labeling, such as the rate of radioactive decay or geographical distance from the patient.

For purposes of this guidance, FDA regards a \textit{minor deviation} as a change from the approved labeling in radioactivity, volume, and/or the step-by-step procedures made when compounding the radiopharmaceutical from an FDA-approved drug product in a patient-ready dose. For example:

- A minor deviation in radioactivity may include the addition of a supplemental amount of Tc-99m sodium pertechnetate to an FDA-approved kit already containing that ingredient, so that the radiopharmaceutical can be provided to a geographically distant patient with a later use time.

- A minor deviation in volume may include the use of an additional quantity of normal saline to reduce the concentration of the radiopharmaceutical in cases in which a supplemental amount of Tc-99m sodium pertechnetate has been added, as described above. In such cases, the additional radioactivity may necessitate a corresponding increase in volume so that the quantity of the radiopharmaceutical to be drawn up into a unit-dose syringe can be more precisely measured.

\textsuperscript{8} The NRC defines an Agreement State in part as one that has entered into an agreement with the NRC under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021).

\textsuperscript{9} See 10 CFR 35.2

\textsuperscript{10} See 10 CFR 71.5, 49 CFR parts 107, 171 through 180, and 390 through 397.
• A minor deviation in the step-by-step procedures for preparation may be one that results in the same finished radiopharmaceutical, but incorporates improvements in technology, enhanced quality control procedures, or decreased radiation exposure to pharmacy personnel.

In other circumstances, manipulations of a radiopharmaceutical involve more significant deviations from the directions in FDA-approved labeling, or a radiopharmaceutical might be produced from a bulk drug substance. For example, to meet the needs of an identified individual patient, such as a patient with an allergy to a particular ingredient, a nuclear pharmacist might compound a radiopharmaceutical that differs from an FDA-approved radiopharmaceutical in its inactive ingredients, dosage form, or mass dose.

There are also circumstances in which nuclear pharmacists compound radiopharmaceuticals from bulk drug substances when the FDA-approved radiopharmaceutical is discontinued or appears on the FDA drug shortage list.

2. Repackaging

FDA regards repackaging as the act of removing an FDA-approved radiopharmaceutical from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a radiopharmaceutical is manipulated in any other way, including if it is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.

III. POLICY

As stated above, radiopharmaceuticals are generally not exempt from provisions of the FD&C Act related to the production of drugs.\(^\text{11}\) For example, radiopharmaceuticals are subject to the premarket approval, misbranding and adulteration provisions of the FD&C Act, including section 505, section 502(f)(1), and section 501(a)(2)(B).

FDA recognizes that, although radiopharmaceuticals are not eligible for the exemptions in section 503A of the FD&C Act, there are circumstances in which State-licensed nuclear pharmacies and Federal facilities compound or repackage radiopharmaceuticals to meet patient needs. FDA has developed this guidance to explain the conditions under which it does not intend to take action regarding violations of certain requirements of the FD&C Act when radiopharmaceuticals are compounded or repackaged by State-licensed nuclear pharmacies or Federal facilities that are not outsourcing facilities.

\(^{11}\) But see section 503B of the FD&C Act. FDA has addressed compounding of radiopharmaceuticals by outsourcing facilities under section 503B of the FD&C Act in the draft guidance document, Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.
Although radiopharmaceuticals addressed by this guidance are subject to the adulteration, misbranding, and new drug approval provisions of the FD&C Act, FDA does not intend to take action for violations of sections 505, 502(f)(1), and 501(a)(2)(B) of the Act if a State-licensed nuclear pharmacy or a Federal facility that is not an outsourcing facility compounds or repackages radiopharmaceuticals in accordance with the conditions described in Section A or B below, whichever is applicable, and any other applicable requirements.  

A. Radiopharmaceutical Compounding That Involves Manipulation Other Than Minor Deviations

The conditions referred to above for compounding of a radiopharmaceutical other than minor deviations are as follows:

1. The radiopharmaceutical is compounded by or under the direct supervision of a licensed, authorized nuclear pharmacist in a State-licensed nuclear pharmacy or a Federal facility that holds a RAM issued by the NRC or by an Agreement State.

2. The radiopharmaceutical is distributed after the receipt of a valid prescription order for an identified individual patient (which includes an order or a notation in the patient’s health record (e.g., chart) in a health care setting).

3. If the radiopharmaceutical is compounded in advance of receipt of a valid patient-specific prescription, it is compounded in a quantity that does not exceed the expected demand for the radiopharmaceutical within the beyond use date (BUD) of the product, based on a history of receipt of prescriptions for the radiopharmaceutical for that time period. The radiopharmaceutical is not distributed before the receipt of a valid prescription for an identified individual patient.

4. If the radiopharmaceutical is compounded using bulk drug substance(s), the bulk drug substance(s) comply with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary (NF) monograph, if a monograph exists. If a monograph does not exist, the bulk drug substance(s) are components of a drug product approved under section 505 of the FD&C Act. For purposes of this condition, a bulk drug substance includes a radioisotope, a ligand, or other substance, such as a precursor that becomes an active ingredient.

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12 Applicable requirements include, for example, the requirement that manufacturers not adulterate a radiopharmaceutical by preparing, packing, or holding the drug product under insanitary conditions. See section 501(a)(2)(A) of the FD&C Act.

13 See definition of an authorized nuclear pharmacist at 10 CFR 35.2.

14 Distributed means that the compounded or repackaged radiopharmaceutical has left the facility in which it was compounded or repackaged.

15 FDA considers cold kits to be finished drug products. Therefore, a radiopharmaceutical compounded from the components of a cold kit is not subject to conditions of this guidance concerning bulk drug substances.
5. If the radiopharmaceutical is compounded using bulk drug substance(s), the original manufacturer of the bulk drug substance(s) and any subsequent manufacturers, including repackers, are establishments that are registered under section 510 of the FD&C Act (including a foreign establishment that is registered under section 510(i) of the FD&C Act), and each bulk drug substance is accompanied by a valid certificate of analysis. For purposes of this condition, original manufacturer means the entity that originally produced the bulk drug substance and not a subsequent packer, repacker, labeler, or distributor.

6. Radiopharmaceuticals may also contain other inactive ingredients such as a buffer, a stabilizer, or a preservative. If the radiopharmaceutical is compounded using ingredient(s) other than bulk drug substances, the ingredients comply with the standards of an applicable USP or NF monograph, if a monograph exists.

7. The radiopharmaceutical is compounded in compliance with the following USP Chapters:
   - If it is a non-sterile radiopharmaceutical, it is compounded in accordance with USP Chapter <795> (except for the BUD); or
   - If it is sterile radiopharmaceutical, it is produced in accordance with USP <797> (except for the BUD).

8. The compounded radiopharmaceutical does not appear on a list of drug products that have been withdrawn or removed from the market because they have been found to be unsafe or not effective. For purposes of this condition, refer to the “withdrawn or removed list” at 21 CFR 216.24.

9. The compounded radiopharmaceutical is not essentially a copy of a marketed FDA-approved radiopharmaceutical.

   FDA considers a compounded radiopharmaceutical to be essentially a copy of a marketed FDA-approved radiopharmaceutical if:

   - the compounded radiopharmaceutical has the same active ingredient(s) as the approved radiopharmaceutical;
   - the active ingredient(s) in the compounded radiopharmaceutical have the same or similar dosage strength (i.e., radioactive dose)\(^{16}\) as the active ingredient(s) in the approved radiopharmaceutical;
   - the approved radiopharmaceutical can be used by the same route of administration as prescribed for the compounded radiopharmaceutical;
   - the approved radiopharmaceutical is not on FDA’s drug shortage list (see section 506E of the FD&C Act) at the time of compounding and distribution; and
   - the approved product has not been discontinued and is currently marketed,

\(^{16}\) Similar strength means that the strength of the compounded radiopharmaceutical is within 10% of the strength of the approved radiopharmaceutical.
unless there is a change that produces for an identified individual patient a clinical
difference, as determined by the prescribing practitioner, between the compounded
radiopharmaceutical and the comparable FDA-approved radiopharmaceutical, and the
prescriber’s determination is documented in writing on the prescription or order by either
(1) the prescribing practitioner, or (2) the compounder, reflecting a conversation with the
prescribing practitioner.

If a compounder intends to rely on such a determination, the determination is documented
on the prescription. This condition will be satisfied provided that the prescription makes
clear that the prescriber identified the relevant change and the clinical difference
produced for the patient, regardless of format. For example, the following would be
sufficient for this condition:

- “No Dye X, patient allergy” (if the comparable approved drug contains the dye)

However, if a prescription identifies only a patient name and radiopharmaceutical
formulation, this would not be sufficient to establish that the prescriber made the
determination described in this condition. Note also that to satisfy this condition, the
clinical difference that the prescriber identifies must be produced by the change the
compounder will make to a radiopharmaceutical (i.e., a change in drug product
formulation). Other factors, such as a lower price, are not sufficient to establish that the
compounded radiopharmaceutical is not essentially a copy of the approved
radiopharmaceutical.

10. The radiopharmaceutical that is being compounded is not identified (directly or as part of
a category of drugs) on a list of drugs or categories of drugs that present demonstrable
difficulties for compounding that are reasonably likely to lead to an adverse effect on the
safety or effectiveness of the drug or category of drugs, taking into account the risks and
benefits to patients. For purposes of this condition, refer to the list in FDA regulations at
21 CFR part 216.17

11. The compounded radiopharmaceutical is not sold or transferred by an entity other than
the entity that compounded such radiopharmaceutical. For purposes of this condition, a
sale or transfer does not include administration of a compounded radiopharmaceutical in
a health care setting.

12. The compounded radiopharmaceutical is distributed only in States in which the
compounding of the radiopharmaceutical meets all applicable State requirements.

13. The radiopharmaceutical is compounded in accordance with all applicable requirements
of the NRC (e.g., labeling requirements18) in a facility that meets all applicable

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17 This list has not yet been developed.
18 See 10 CFR 20.1904.
requirements of the NRC, and the nuclear pharmacist who compounds or oversees the
compounding of the radiopharmaceutical meets all applicable NRC requirements.

B. Radiopharmaceutical Compounding that Constitutes Minor Deviations, and
Repackaging

The conditions referred to above for compounding of a radiopharmaceutical that is limited to
minor deviations, as defined above, or to the repackaging of a radiopharmaceutical, are as
follows:

1. The radiopharmaceutical is compounded or repackaged from a drug product approved
under section 505 of the FD&C Act.

2. No substances are added to the radiopharmaceutical unless they are specified in the FDA-
approved labeling for the radiopharmaceutical being compounded.

3. If the radiopharmaceutical is compounded (and not repackaged), the compounding
constitutes a minor deviation(s), as that term is defined above.

4. The radiopharmaceutical is compounded or repackaged by or under the direct supervision
of a licensed authorized nuclear pharmacist in a State-licensed nuclear pharmacy or a
Federal facility that also holds a RAM license issued by the NRC or an Agreement State.

5. The radiopharmaceutical is compounded or repackaged in compliance with the following
USP Chapters:
   • If it is a non-sterile radiopharmaceutical, it is compounded or repackaged in
     accordance with USP Chapter <795> (except for the BUD); or
   • If it is sterile radiopharmaceutical, it is compounded or repackaged in accordance
     with USP <797> (except for the BUD).

6. The radiopharmaceutical is compounded or repackaged in accordance with all applicable
requirements of the NRC (e.g., labeling requirements19) in a facility that meets all
applicable requirements of the NRC, and the nuclear pharmacist who compounds or
repackages, or who supervises the compounding or repackaging of the
radiopharmaceutical, meets all applicable NRC requirements.

7. The compounded or repackaged radiopharmaceutical is distributed only in States in
which the compounding or repackaging of the radiopharmaceutical meets all applicable
State requirements.

8. The compounded or repackaged radiopharmaceutical is not sold or transferred by an
entity other than the entity that compounded or repackaged such radiopharmaceutical.

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19 See 21 CFR 20.1904.
For purposes of this condition, a sale or transfer does not include administration of a compounded or repackaged radiopharmaceutical in a health care setting.

C. Establishment Registration and Drug Listing

Under section 510(b)(1) of the FD&C Act, between October 1 and December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs is required to register with FDA, and under section 510(j) of the FD&C Act, every person who registers with FDA under section 510(b) must list its drugs with the Agency. Pharmacies that compound or repackage radiopharmaceuticals may qualify for an exemption from registration and thus not be required to list. Specifically, under section 510(g)(1), the registration and listing requirements do not apply to:

- pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

With respect to entities that do not qualify for the exemptions from registration under section 510 of the FD&C Act, 20 FDA does not intend to take action under section 502(o) of the FD&C Act for failure to register and list radiopharmaceuticals that are compounded or repackaged in accordance with this guidance.

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20 See also, 21 CFR 207.10.
Compounding and Repackaging of Radiopharmaceuticals By Outsourcing Facilities

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact Sara Rothman, CDER Office of Unapproved Drugs and Labeling Compliance (OUDLC) at 301-796-3110.

U.S. Department of Health and Human Services
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Guidance for Industry

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Guidance for Industry

Compounding and Repackaging of Radiopharmaceuticals By Outsourcing Facilities

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I. INTRODUCTION AND SCOPE

This guidance sets forth the FDA’s policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). This guidance describes how FDA intends to apply section 503B of the FD&C Act to radiopharmaceuticals compounded by outsourcing facilities. It also describes the conditions under which FDA does not intend to take action for violations of sections 505 and 502(f)(1) of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals.

This guidance does not address the following:

- Mixing, reconstituting, combining, diluting, or repackaging of a radiopharmaceutical, or other such acts, performed in accordance with directions contained in the FDA-approved labeling.
- Positron emission tomography (PET) drugs.
- Drug products that are not radiopharmaceuticals.  
- Radioactive biological products that are subject to licensure under section 351 of the Public Health Service (PHS) Act.
- Radiopharmaceuticals for use in animals.

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1 This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER), in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

2 FDA has issued several guidance documents concerning its policies for compounding drug products that are not radiopharmaceuticals under sections 503B of the Act. See, for example, For Entities Considering Whether to Register Under Section 503B of the Federal Food, Drug, and Cosmetic Act.

All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.
Contains Nonbinding Recommendations
Draft — Not for Implementation

- Compounding or repackaging of radiopharmaceuticals by entities that are not registered with FDA as outsourcing facilities. See FDA’s draft guidance document, Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies and Federal Facilities.
- This guidance does not alter FDA’s current regulations and guidances addressing investigational new drugs.

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Radiopharmaceuticals, Generally

Radiopharmaceuticals are radioactive\(^3\) sterile and non-sterile drugs that are used in nuclear medicine procedures to diagnose, monitor, and treat diseases. Radiopharmaceuticals are used in diagnostic procedures and for therapeutic purposes. For example, during certain diagnostic procedures involving radiopharmaceuticals, the body is exposed to small amounts of radiation to observe organ function. Radiopharmaceuticals used for therapeutic purposes are generally administered in larger amounts to ensure that therapeutic doses of radiation are delivered to specific disease sites.

Some radiopharmaceuticals are produced by a conventional manufacturer and shipped in hot (radioactive) multi-dose containers directly to an imaging center or hospital for patient administration. The imaging center or hospital’s nuclear pharmacy transfers the radiopharmaceuticals from the multi-dose containers into unit-dose, patient-ready containers, and sometimes manipulates the radiopharmaceuticals in other ways, such as by diluting or pooling them. Other radiopharmaceuticals are produced at the nuclear pharmacy by combining radioactive materials eluted from a generator with non-radioactive cold kits. The nuclear pharmacy prepares the radiopharmaceutical product using the components of the kit and adding radioactive material eluted from a generator for administration to a patient.

\(^3\) As used in this guidance, radiopharmaceutical and radioactive drug have the same meaning and refer to a drug that meets the definition in 21 CFR 310.3(n): “any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term ‘radioactive drug’ includes a ‘radioactive biological product’ as defined in 600.3(ee) of this chapter.” Radioactive biological product is defined in 21 CFR 600.3(ee) as “a biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.” As stated previously, this guidance does not apply to radioactive biological products.
Because radioactive drugs generally have short half-lives (e.g., minutes, hours, or up to a few days), they must reach the patient for administration soon after they are produced. Therefore, hospitals and imaging centers often place orders with a nuclear pharmacy for delivery of radiopharmaceutical unit-doses for procedures scheduled for the following day or in anticipation of unscheduled nuclear medicine procedures that might take place during the evening or weekend when the nuclear pharmacy is closed.

There are legal restrictions as to who is permitted to obtain, transport, manipulate, and use radioactive drugs. At the Federal level, the Nuclear Regulatory Commission (NRC) has established rules to protect the general public, patients, and radiation workers from unnecessary exposure to radiation. The NRC and those States that have entered into certain agreements with the NRC (Agreement States) issue radioactive materials (RAM) licenses that describe who is licensed to possess radioactive materials and the type of radioactive material that may be possessed under the license. An authorized nuclear pharmacist, as defined by the NRC, must be identified on a RAM license issued to a nuclear pharmacy where radiopharmaceuticals are prepared. Transport of radioactive materials is regulated by the NRC or the Agreement State and the U.S. Department of Transportation.

Separate from the RAM licenses issued by the NRC or an Agreement State, State boards of pharmacy may issue pharmacy permits to holders that receive, prepare, repackage, and/or dispense radioactive drugs. Certain States specifically recognize a separate category of pharmacists who practice as nuclear pharmacists and issue credentials specific for this practice.

**B. Compounding and Repackaging of Radiopharmaceuticals by an Outsourcing Facility**

1. **Compounding**

In 2013, the Drug Quality and Security Act added a new section 503B to the FD&C Act, which describes a new category of compounders called *outsourcing facilities*. Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from the following three sections of the FD&C Act:

- Section 502(f)(1) (concerning labeling with adequate directions for use)
- Section 505 (concerning drug approval requirements)

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4 See 10 CFR parts 19, 20, and 35.

5 The NRC defines an Agreement State in part as one that has entered into an agreement with the NRC under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021).

6 See 10 CFR 35.2

7 See 10 CFR 71.5, 49 CFR parts 107, 171 through 180, and 390 through 397.

Section 582 (concerning drug supply chain security requirements)\textsuperscript{9}

A complete list of the conditions that must be met for a drug product to qualify for the exemptions in section 503B appears in the Appendix to this guidance document.

In contrast to drug products compounded under section 503A of the FD&C Act, drug products compounded by outsourcing facilities under section 503B cannot qualify for exemption from current good manufacturing practice (CGMP) requirements in section 501(a)(2)(B) of the FD&C Act. Outsourcing facilities are also subject to FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that help to mitigate the risks associated with the drug products they compound.

Section 503B of the FD&C Act defines \textit{compounding} as including “the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.”\textsuperscript{10} In contrast to section 503A of the FD&C Act, section 503B does not expressly exclude radiopharmaceuticals, so the conditions of section 503B of the FD&C Act apply to radiopharmaceuticals compounded by an entity that is registered with FDA as an outsourcing facility.

Because section 503B applies to the compounding of radiopharmaceuticals, an entity is eligible to become an outsourcing facility if some or all of its operations consist of compounding radiopharmaceuticals for human use, provided that the entity otherwise meets the definition of an \textit{outsourcing facility} in section 503B(d)(4) of the FD&C Act (e.g., the entity must engage in the compounding of at least some sterile products (radiopharmaceuticals and/or non-radiopharmaceuticals)).\textsuperscript{11}

\textbf{2. Repackaging}

FDA regards \textit{repackaging} as the act of taking a finished drug product, including a radiopharmaceutical, from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a radiopharmaceutical is manipulated in any other way, including if it is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.

\textsuperscript{9} In addition to the exemption in section 503B, the definition of \textit{product} in section 581(13) of the FD&C Act excludes radioactive drugs from the drug supply chain security requirements of the FD&C Act, including section 582.

\textsuperscript{10} See section 503B(d)(1).

\textsuperscript{11} See Section 503B(d)(4A)(i). Section 503B(d)(4) defines an \textit{outsourcing facility} as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of Section 503B. An outsourcing facility is not required to be a licensed pharmacy and may or may not obtain prescriptions for identified individual patients.
Drugs that are repackaged are not subject to section 503B of the FD&C Act. Therefore, repackaged radiopharmaceuticals are not eligible for the exemptions under section 503B. Additionally, an entity that only repackages drugs, including radiopharmaceuticals, does not meet the definition of an outsourcing facility in section 503B(d)(4) of the FD&C Act. If an entity that meets the definition of an outsourcing facility in section 503B(d)(4) also repackages radiopharmaceuticals, FDA does not intend to take action for violations of sections 505 and 502(f)(1) of the FD&C Act when the outsourcing facility repackages radiopharmaceuticals in accordance with the conditions of described below and any other applicable requirements. In addition, the outsourcing facility’s compounded drugs would be eligible for the exemptions in section 503B if they meet the conditions in that section. We describe our policies with respect to repackaged and compounded radiopharmaceuticals in section III.B of this guidance document.

III. POLICY

A. Compounding of Radiopharmaceuticals

1. General

Outsourcing facilities that compound radiopharmaceuticals must do so in accordance with the conditions of section 503B of the FD&C Act (see the Appendix to this guidance document). If an outsourcing facility fails to compound a drug in accordance with a condition of section 503B, none of the outsourcing facility’s compounded drugs, including radiopharmaceuticals and non-radiopharmaceuticals, would qualify for the exemptions in section 503B.12

In general, FDA’s policies regarding section 503B apply to the compounding of radiopharmaceutical drug products. However, we have developed the following specific policies, applicable only to the compounding of radiopharmaceuticals by outsourcing facilities:

• Bulk drug substances used in compounding radiopharmaceuticals under section 503B (see section III.A.2)

• Compounding radiopharmaceuticals that are essentially copies of approved drugs under section 503B when such compounding is limited to minor deviations, as defined below (see section III.A.3).

2. Bulk Drug Substances Used to Compound Radiopharmaceuticals Under Section 503B of the FD&C Act

One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for the exemptions provided by 503B is that the outsourcing facility does not compound drug products using a bulk drug substance unless: (1) the bulk drug substance appears on a list developed by FDA of bulk drug substances for which there is a clinical need (503B

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12 See sections 503B(a)(11) and 503B(d)(4) of the FD&C Act.
bulks list); or (2) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E of the FD&C Act (the FDA’s drug shortage list) at the time of compounding, distribution, and dispensing.

FDA solicited nominations for bulk drug substances for inclusion on the 503B bulks list, however, FDA’s request for nominations for the 503B bulks list reserved the question of compounded radiopharmaceutical products, and only one radiopharmaceutical was nominated for the 503B bulks list.

At this time, interested parties can nominate substances for inclusion on the 503B bulks list, and they will be evaluated as described in FDA’s guidance, *Interim Policy for Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.*

FDA intends to adopt a policy for bulk drug substances nominated for use in compounding radiopharmaceuticals under section 503B that is consistent with the policy described in *Interim Policy for Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.*

3. Compounded Radiopharmaceuticals that are Essentially Copies of Approved Drugs

Under section 503B(a)(5) of the Act, a compounded drug that is essentially a copy of one or more approved drugs is not eligible for the exemptions in section 503B.

In some cases, an outsourcing facility might receive a prescription or order for a radiopharmaceutical compounded from an FDA-approved radiopharmaceutical, with one or more minor deviations (see below) that are necessary to accommodate circumstances not contemplated in the FDA-approved labeling, such as the rate of radioactive decay or geographical distance from the patient.

For purposes of this guidance, FDA regards a minor deviation as a change from the approved labeling in radioactivity, volume, and/or the step-by-step procedures made when compounding the radiopharmaceutical from an FDA-approved drug product in a patient-ready dose. For example:

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14 Distribution means that the compounded or repackaged radiopharmaceutical has left the facility in which it was compounded or repackaged.

15 See Section 503B(a)(2)(A)(ii).


• A minor deviation in radioactivity may include the addition of a supplemental amount of Tc-99m sodium pertechnetate to an FDA-approved kit already containing that ingredient, so that the radiopharmaceutical can be provided to a geographically distant patient with a later use time.

• A minor deviation in volume may include the use of an additional quantity of normal saline to reduce the concentration of the radiopharmaceutical in cases in which a supplemental amount of Tc-99m sodium pertechnetate has been added, as described above. In such cases, the additional radioactivity may necessitate a corresponding increase in volume so that the quantity of the radiopharmaceutical to be drawn up into a unit-dose syringe can be more precisely measured.

• A minor deviation in the step-by-step procedures for preparation may be one that results in the same finished radiopharmaceutical, but incorporates improvements in technology, enhanced quality control procedures, or decreased radiation exposure to pharmacy personnel.

A compounded radiopharmaceutical that is prepared with *minor deviations* from the directions contained in FDA-approved labeling provided by the product’s manufacturer may meet the definition of *essentially a copy of an approved drug* under section 503B(d)(2). However, FDA recognizes that for practical reasons radiopharmaceuticals might be compounded with *minor deviations* from an approved radiopharmaceutical, including for the reasons listed above. After considering the risks associated with these practices we do not intend to focus enforcement on such compounding. Specifically, FDA does not intend to take action against an outsourcing facility for compounding a radiopharmaceutical that is essentially a copy of an approved drug in violation of section 503B(a)(5) of the FD&C Act, provided that the outsourcing facility:

• compounds the radiopharmaceutical from FDA-approved radiopharmaceuticals, and not using bulk drug substances;
• makes *minor deviations* from the approved product labeling, as defined above; and
• compounds all of its drugs in accordance with all of the other conditions of section 503B and all other applicable statutory and regulatory requirements.

**B. Repackaging of Radiopharmaceuticals**

Outsourcing facilities sometimes receive a prescription or order for a radiopharmaceutical product that differs from an approved radiopharmaceutical only in that it has been repackaged. Repackaged drug products are not eligible for the exemptions provided under section 503B of the Act. In addition, repackaged radiopharmaceuticals are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs, including the premarket

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18 See FDA’s draft guidance, *Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act*. Once finalized, this guidance will describe FDA’s current thinking on compounding drug products that are essentially copies of approved drugs under Section 503B.
approval, misbranding, and adulteration provisions of the FD&C Act, including sections 505, 502(f)(1), and 501(a)(2)(B).

Below, FDA describes the conditions under which it does not intend to take action regarding violations of certain requirements of the FD&C Act, in the context of radiopharmaceutical repackaging. Specifically, FDA does not intend to take action for violations of sections 505 and 502(f)(1) if an outsourcing facility repackages radiopharmaceuticals in accordance with all of the conditions described below, and any applicable requirements.

Conditions:

1. The radiopharmaceutical that is being repackaged is a drug product approved under section 505 of the FD&C Act.

2. The radiopharmaceutical is repackaged by or under the direct supervision of a licensed, authorized nuclear pharmacist in an outsourcing facility that holds a RAM license issued by the NRC or by an Agreement State.

3. The radiopharmaceutical is repackaged in accordance with applicable CGMP requirements.

4. The radiopharmaceutical being repackaged does not appear on a list of drug products that have been withdrawn or removed from the market for reasons of safety or effectiveness.

5. The repackaged radiopharmaceutical is not sold or transferred by an entity other than the entity that repackaged such radiopharmaceutical. For purposes of this condition, a sale or transfer does not include administration of a repackaged radiopharmaceutical in a health care setting.

6. The repackaged radiopharmaceutical is distributed only in States in which the production of the radiopharmaceutical meets all applicable State requirements.

But see U.S. v. Kaybel, 430 F.2d 1346 (3d Cir. 1970), holding that repackaging of approved Enovid (estrogen) tablets from large bottles into small bottles did not require pre-approval under Section 505 of the FD&C Act.

See footnote 8.

Applicable requirements include, for example, the requirement that manufacturers not adulterate a drug product by preparing, packing, or holding the drug product under insanitary conditions. See Section 501(a)(2)(A) of the FD&C Act.

See definition of an authorized nuclear pharmacist at 10 CFR § 35.2.

See FDA’s draft guidance, Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act. Once final, this guidance will describe FDA’s expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

7. The radiopharmaceutical is repackaged in accordance with all applicable requirements of the NRC (e.g., labeling requirements\textsuperscript{25}) by a facility that meets all applicable requirements of the NRC, and the nuclear pharmacist who repackages or supervises the repackaging of the radiopharmaceutical meets all applicable NRC requirements.

8. The label on the immediate container (primary packaging, e.g., the syringe) of the repackaged radiopharmaceutical includes the following:
   a. The statement “This radiopharmaceutical was repackaged by [name of outsourcing facility].”
   b. The address and phone number of the outsourcing facility that repackaged the radiopharmaceutical.
   c. The established name of the original, approved radiopharmaceutical that was repackaged.
   d. The lot or batch number of the repackaged radiopharmaceutical.
   e. The dosage form and radioactive dose of the repackaged radiopharmaceutical.
   f. A statement of either the quantity or volume of the repackaged radiopharmaceutical, whichever is appropriate.
   g. The date the radiopharmaceutical was repackaged.
   h. The BUD of the repackaged radiopharmaceutical.
   i. Storage and handling instructions for the repackaged radiopharmaceutical.
   j. The National Drug Code (NDC) number of the repackaged radiopharmaceutical, if available\textsuperscript{26}.
   k. The statement “Not for resale,” and, if the repackaged radiopharmaceutical is distributed by an outsourcing facility other than pursuant to a prescription for an individual identified patient, the statement “Office Use Only.”
   l. A list of the active and inactive ingredients, unless such information is included on the label for the container from which the individual units are removed, as described below in condition 9.a.

9. The label on the container from which the individual units are removed for administration (secondary packaging (e.g., the bag, box, or other package in which the repackaged products are distributed)) includes:
   a. The active and inactive ingredients, if the immediate drug product label is too small to include this information.
   b. Directions for use, including, as appropriate, radioactive dosage and administration, and the following information to facilitate adverse event reporting:
      
      \url{www.fda.gov/medwatch} and 1-800-FDA-1088.

10. The radiopharmaceutical is included on a report submitted to FDA each June and December identifying the drug products repackaged by the outsourcing facility during the previous 6-month period, and providing the active ingredient(s); source of the active

\textsuperscript{25} See 10 CFR 20.1904.

\textsuperscript{26} The NDC number of the original approved drug product should not be placed on the repackaged drug product.
ingredient(s); NDC number of the source ingredient(s), if available; the dosage form and
route of administration; the package description; the number of individual units
produced; and the NDC number of the final product, if assigned.27

11. The outsourcing facility reports serious adverse events to FDA that may be associated
with its repackaged radiopharmaceuticals.28

C. Establishment Registration and Drug Listing

Under section 510(b)(1) of the FD&C Act, between October 1 and December 31 of each year,
every person who owns or operates any establishment in any State engaged in the manufacture,
preparation, propagation, compounding, or processing of a drug or drugs is required to register
with FDA, and under section 510(j) of the FD&C Act, every person who registers with FDA
under section 510(b) must list its drugs with the Agency. Outsourcing facilities that are State-
licensed pharmacies that compound or repackage radiopharmaceuticals may qualify for an
exemption from registration and thus also not be required to list their drugs with FDA.
Specifically, under section 510(g)(1), the registration and listing requirements do not apply to:

- pharmacies which maintain establishments in conformance with any applicable local
  laws regulating the practice of pharmacy and medicine and which are regularly
  engaged in dispensing prescription drugs or devices, upon prescriptions of
  practitioners licensed to administer such drugs or devices to patients under the care
  of such practitioners in the course of their professional practice, and which do not
  manufacture, prepare, propagate, compound, or process drugs or devices for sale
  other than in the regular course of their business of dispensing or selling drugs or
  devices at retail.

With respect to outsourcing facilities that do not qualify for the exemptions from registration
under section 510 of the FD&C Act,29 FDA does not intend to take action under section 502(o)
of the FD&C Act for failure to register and list radiopharmaceuticals that are compounded or
repackaged in accordance with this guidance.

27 FDA has issued a draft guidance for industry, Electronic Drug Product Reporting for Human Drug Compounding
Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act, which describes how
outsourcing facilities are to submit drug product reports to FDA. Once finalized, that guidance will represent the
Agency’s current thinking on that topic. Although that guidance addresses reporting of compounded drug products,
outsourcing facilities should follow the same procedure to electronically report the radiopharmaceuticals they
repackaged.

28 FDA has issued a guidance for industry, Adverse Event Reporting for Outsourcing Facilities Under Section 503B
of the Federal Food, Drug, and Cosmetic Act, which describes how outsourcing facilities are to submit adverse
event reports to FDA and the content and format of the reports that they are required to submit. Although that
guidance addresses reporting of adverse events associated with compounded drug products, outsourcing facilities
should follow the same procedure to electronically report adverse events associated with the radiopharmaceuticals
they repackaged.

29 See also, 21 CFR 207.10.
APPENDIX

The following are the conditions of section 503B that must be met for a compounded drug, including a compounded radiopharmaceutical, to qualify for the exemptions in section 503B of the FD&C Act:

1. The outsourcing facility is in compliance with the registration and reporting requirements of section 503B(b). This includes submitting twice yearly reports regarding the drugs compounded by the outsourcing facility and submitting adverse event reports in accordance with section 503B(b)(5).30,31

2. If the outsourcing facility compounds drugs using one or more bulk drug substances, the bulk drug substances meet the requirements of 503B(a)(2). See the policy described in section II.A.2 of this guidance document.

3. If the outsourcing facility compounds using ingredients other than bulk drug substances, those ingredients must meet certain requirements.32

4. The outsourcing facility does not compound drugs that appear on a list published by FDA of drugs that have been withdrawn or removed from the market because the drugs or components of such drugs have been found to be unsafe or not effective.33,34

5. The outsourcing facility does not compound drugs that are essentially a copy of one or more approved drugs.35 See the policy described in section II.A.3 of this guidance document.

6. The outsourcing facility does not compound drugs that appear on a list published by FDA of drugs that present demonstrable difficulties for compounding.36

30 See section 301(ccc)(3) of the FD&C Act, which makes it a prohibited act for an entity that is registered in accordance with section 503B(b) to fail to report drugs or adverse events as required.


32 See section 503B(a)(3).

33 See section 503B(a)(4).

34 The list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective (the withdrawn-or-removed list) can be found at 21 CFR 216.24.


36 See section 503B(a)(6). This list has not yet been developed.
7. If the outsourcing facility compounds a drug that is the subject of a risk evaluation and mitigation strategy (REMS) approved with elements to assure safe use pursuant to section 505-1, or from a bulk drug substance that is a component of such drug, the outsourcing facility must demonstrate to FDA before beginning to compound that it will use controls comparable to the controls applicable under the REMS. 37

8. The outsourcing facility’s compounded drugs will not be sold or transferred by an entity other than that outsourcing facility. 38

9. The outsourcing facility has paid all applicable establishment and reinspection fees owed under section 744(k). 39,40

10. The outsourcing facility includes on the labels and labeling of its compounded drug products the information required under section 503B(a)(10). 41

11. All of the outsourcing facility’s compounded drugs are compounded in accordance with section 503B. 42,43

37 See section 503B(a)(7).
38 See section 503B(a)(8).
39 See section 503B(a)(9).
40 See also sections 744J and 744K of the FD&C Act, and guidance for industry, Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.
41 See section 503B(a)(10).
42 See section 503B(a)(11).

The portion of this guidance that describes when manufacturers should notify FDA if there is a high risk that a product is illegitimate, is being distributed for comment purposes only.

Comments and suggestions regarding this document should be submitted within 60 days of publication in the Federal Register of the notice announcing the availability of the guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

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See additional PRA statement in section V of this guidance.
Drug Supply Chain Security Act Implementation:
Identification of Suspect Product and Notification Guidance for Industry

Additional copies are available from:
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Food and Drug Administration
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Guidance for Industry

Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to aid trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) in identifying a suspect product as defined at section 581(21) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee(21)) and terminating notifications. It does not establish any rights for any person and, with the exception of section IV.B, it is not binding on FDA or the public. With respect to section IV.B, section 582 of the FD&C Act gives FDA authority to issue binding guidance on the process for terminating notifications of illegitimate product. Specifically, section 582(h)(2)(A) states that FDA “shall issue a guidance document to aid trading partners in the identification of a suspect product and notification termination. Such guidance document shall . . . set forth the process by which manufacturers, repackagers, wholesale distributors, and dispensers shall terminate notifications in consultation with the Secretary regarding illegitimate product . . . .”

As of January 1, 2015, a trading partner that determines a product in its possession or control is an illegitimate product as defined at section 581(8) of FD&C Act, must notify the Food and Drug Administration (FDA or Agency) and certain immediate trading partners under section 582 of

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1 This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research and the Office of Regulatory Affairs at the Food and Drug Administration.

2 Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product and products with a high risk of illegitimacy in consultation with FDA, it has binding effect. This is discussed further in the Introduction.

3 For this guidance, trading partner is defined in section 581(23)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 30eee(23)(A)), and refers to a manufacturer, repackager, wholesale distributor, or dispenser. For purposes of this guidance, trading partner does not refer to a third-party logistics provider (3PL) as defined in section 581(23)(B) of the FD&C Act (21 U.S.C. 360eee(23)(B)), though FDA encourages 3PLs to follow the recommendations in this guidance to the extent relevant to the 3PL’s operations.

4 Trading partners must be authorized as defined in FD&C Act section 581(2) and required under FD&C Act section 582(b)(3), (c)(3), (d)(3) and (e)(3).
the FD&C Act (21 U.S.C. 360eee-1), as added by the Drug Supply Chain Security Act (DSCSA). Manufacturers are additionally required under section 582 to notify FDA and certain immediate trading partners after the manufacturer determines or is notified by FDA or a trading partner that there is a high risk that a product is illegitimate.\(^5\) This guidance identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain; provides recommendations on how trading partners can identify a product and determine whether a product is a suspect product as soon as practicable; and sets forth the process by which trading partners should notify FDA of illegitimate product or products with a high risk of illegitimacy, and how they must terminate the notifications, in consultation with FDA.

This guidance does not address all provisions of the DSCSA related to suspect and illegitimate products. As FDA works to implement other provisions of the DSCSA, the Agency intends to issue additional information to support efforts to develop standards, issue guidance and regulations, establish pilot programs, and conduct public meetings.

FDA’s guidance documents, in general, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word \textit{should} in Agency guidances means that something is suggested or recommended, but not required. Insofar as section IV.B of this guidance sets forth the process by which trading partners must terminate notifications of illegitimate product and products with a high risk of illegitimacy in consultation with FDA, it has binding effect.\(^6\)

\section{II. BACKGROUND}

\subsection{A. Drug Supply Chain Security Act}

On November 27, 2013, the DSCSA (Title II of Public Law 113-54) was signed into law. Section 203 of the DSCSA added section 582(h)(2) to the FD&C Act, which requires FDA to issue guidance to aid trading partners in identifying a suspect product and terminating notifications. \textit{Suspect product} is defined in section 581(21) of the FD&C Act as a product for which there is reason to believe it (A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. Section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is a suspect product, to quarantine the product while they promptly conduct an investigation to determine whether the product is an illegitimate product. \textit{Illegitimate product} is defined in section 581(8) of the FD&C

\footnote{The portion of this guidance that describes when manufacturers should notify FDA of a high risk that a product is illegitimate is shaded in gray and is being distributed for comment purposes only.}

\footnote{See section 582(h)(2)(A) of the FD&C Act.}
Act as a product for which credible evidence shows that it is (A) counterfeit, diverted, or stolen; (B) intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.  

Section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is illegitimate, to notify FDA and all immediate trading partners (that they have reason to believe may have received the illegitimate product) not later than 24 hours after making the determination. Manufacturers are additionally required under section 582(b)(4)(B)(ii)(II) to notify FDA and immediate trading partners (that the manufacturer has reason to believe may possess a product manufactured by or purported to be manufactured by the manufacturer) not later than 24 hours after the manufacturer determines or is notified by FDA or a trading partner that there is a high risk that the product is illegitimate.

The DSCSA outlines critical steps to build an electronic, interoperable system over the next 10 years that will identify and trace certain prescription drugs as they are distributed within the United States. For many years, FDA has been engaged in efforts to improve the security of the drug supply chain to protect U.S. patients from unsafe, ineffective, and poor quality drugs. Since at least the formation of the first FDA Counterfeit Drug Task Force in 2003, FDA has strongly advocated for a multilayered approach to securing the supply chain. A key component of that approach has been to encourage heightened vigilance and awareness among supply chain partners. The electronic, interoperable system that will be established under the DSCSA will enhance FDA’s ability to help protect U.S. consumers by improving detection and removal of potentially dangerous drugs from the drug supply chain.

B. Scope of This Guidance

Pursuant to section 582(h)(2) of the FD&C Act, this guidance identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain; provides recommendations on how trading partners can identify such product and determine whether a product is a suspect product as soon as practicable; describes when manufacturers should notify FDA of a high risk that a product is illegitimate; and sets forth the process by which trading partners must terminate notifications in consultation with FDA regarding illegitimate product under section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the FD&C Act and the process for terminating notifications in consultation with FDA regarding products with a high risk of illegitimacy under section 582(b)(4)(B)(iv). This guidance also addresses how trading partners should notify FDA when they determine that a product in their possession or control is an illegitimate product under section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act, and how manufacturers should notify FDA regarding products with a high risk of illegitimacy under section 582(b)(4)(B)(ii)(II).

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7 For additional definitions applicable to this guidance, please refer to section 581 of the FD&C Act.
III. IDENTIFICATION OF SUSPECT PRODUCT AND, FOR MANUFACTURERS, PRODUCT WITH A HIGH RISK OF ILLEGITIMACY

Trading partners, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from the FDA (whereby FDA has made a determination that a product within the possession or control of the trading partner is a suspect product), must have systems in place that enable them to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, as applicable, to determine whether a suspect product is illegitimate.

As trading partners conduct business on a daily basis, they should exercise vigilance, maintain awareness about suspicious activity or potential threats to their supply chain, and devote attention and effort to detecting suspect product.

The next two sections of this guidance (A.) identify some specific scenarios that could significantly increase the risk of suspect products entering the pharmaceutical distribution supply chain and (B.) make recommendations to assist trading partners in identifying suspect product and making determinations about whether a product is suspect as soon as practicable. The scenarios contained in this guidance are based on Agency experience with suspect product in the drug supply chain. These examples are illustrative and should not be viewed as an exhaustive list of all potential scenarios that increase the likelihood that a suspect product could enter the pharmaceutical distribution supply chain. Trading partners should consider the surrounding circumstances of any particular scenario they may encounter in determining whether or not a product is suspect, including whether multiple scenarios are present in any given transaction.

A. Specific Scenarios That Could Significantly Increase the Risk of a Suspect Product Entering the Pharmaceutical Distribution Supply Chain

There may be situations involving trading partners where heightened vigilance would be appropriate. In addition, there could be identifiable characteristics of products that might increase the likelihood that they are suspect products. The following are examples of some specific scenarios that could significantly increase the risk of a suspect product entering the drug supply chain. Thus, trading partners should be particularly diligent when engaging in transactions that involve:

1. Trading Partners and Product Sourcing

   • Purchasing from a source new to the trading partner.
   
   • Receiving an unsolicited sales offer from an unknown source. Trading partners might receive unsolicited offers or advertisements through an email, a fax, a telephone call, or an in-person sales call from a person or entity with whom they do not have an established business relationship.
   
   • Purchasing on the Internet from an unknown source. Trading partners might be searching for a better price on the Internet or for a product that they cannot obtain
from their usual source, and might be tempted to turn to a person or entity with whom they do not have an established business relationship.

- Purchasing from a source that a trading partner knows or has reason to believe has engaged in questionable or suspicious business practices that could increase the risk of suspect product entering the supply chain, such as:
  - A trading partner that has been involved in business transactions where they sold or delivered illegitimate product.
  - A trading partner that has a history of problematic or potentially false transaction histories or pedigrees, such as those that contain misspelled words or incomplete information.
  - A trading partner that is reluctant to provide a transaction history associated with the product being purchased, or does not do so in a timely manner.
  - A trading partner that provides transaction information, a transaction statement, and/or transaction history that appears to be incomplete or suspicious.

2. Supply, Demand, History, and Value of the Product

- Product that is generally in high demand in the U.S. market.
- Product that is in higher demand because of its potential or perceived relationship to a public health or other emergency (e.g., antiviral drugs).
- Product that has a high sales volume or price in the United States.
- Product offered at a price that is “too good to be true.”
- Product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs).
- Product that has been previously or is currently the subject of a drug shortage (see a list of current drugs in shortage at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Shortages/default.htm and http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm for more information).
- Product that has been or is the subject of an illegitimate product notification under the DSCSA or other alert or announcement related to drug quality.
- Product that has been or is the subject of an FDA counterfeit or cargo theft alert
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3. Appearance of the Product

- Appearance of a package or a container used for transport (e.g., case or tote) that seems suspicious (e.g., it has a label that contains misspellings or appears different from the standard label for that product in color, font, images, or otherwise).

- Package that exhibits unusual or excessive adhesive residue.

- Package that contains foreign identification features (such as a different drug identification number where a National Drug Code (NDC) number would be expected).

- Package that is missing information, such as the lot number or other lot identification, or the expiration date.

- Package that is missing security or anti-counterfeiting technologies normally featured on the FDA-approved product that are easily visible to the eye, such as holograms, color shifting inks, neckbands, or watermarks.

- Finished dosage form that seems suspicious (e.g., it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints).

B. Recommendations on How Trading Partners Might Identify Suspect Product and Determine Whether the Product Is a Suspect Product as Soon as Practicable

The following are recommendations for trading partners on ways that they can expeditiously identify suspect product and determine whether the product is suspect (and, after investigation, whether it is illegitimate). In general, trading partners should exercise due diligence when conducting business and should confirm that all trading partners are authorized. Trading partners should discuss with each other any observations, questions, or concerns they have related to the status of a drug as a suspect product to aid them in determining whether the drug should be considered a suspect product. Trading partners should also contact regulatory authorities, law enforcement, the drug’s manufacturer, or other available resources to aid in that determination when additional expertise is called for to make an accurate assessment of the status of a drug as a suspect product. If a trading partner receives a product in a secured transport container or sealed homogenous case, trading partners should examine the appearance of that container as

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recommended below. If trading partners observe anything suspicious, they should take steps to ascertain whether the product inside the transport container is suspect. Strategies to identify suspect product include, but are not limited to, the following recommendations:

- Be alert for offers of product for sale at a very low price or one that is “too good to be true.”

- Closely examine the package and the transport container (such as the case or tote):
  - To look for signs that it has been compromised (e.g., opened, broken seal, damaged, repaired, or otherwise altered). If a trading partner receives a product in a secured transport container or sealed homogenous case, trading partners should examine the appearance of that container to see if anything about that appearance seems suspicious, such as shrink wrap that has unexpected markings, or a seal that is broken, torn, or repaired.
  - To see if the package or the transport container has changed since the last shipment of the same product type was received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received).
  - To see if product inserts are missing, do not correspond to the product, or are suspicious in some way.
  - For shipping addresses, postmarks, or other materials indicating that the product came from an unexpected foreign entity or source.

- Closely examine the label on the package, and the label on the individual retail unit, if applicable, for:
  - Any missing information, such as the lot number or other lot identification, NDC, or strength of the drug.
  - Any altered product information, such as smudged print or print that is very difficult to read.
  - Misspelled words.
  - Bubbling in the surface of a label.
  - Lack of an “Rx only” symbol.\(^8\)
  - Foreign language with little or no English provided.\(^9\)
  - Foreign language that is used to describe the lot number.\(^10\)

\(^8\) Or, for products distributed solely in the Commonwealth of Puerto Rico or any other territory where the predominant language is Spanish, “Solamente Rx” (21 CFR 201.16).

\(^9\) Except for products distributed solely in the Commonwealth of Puerto Rico or any other territory where the predominant language is one other than English (21 CFR 201.15 (c)(1)).

\(^10\) Except for products distributed solely in the Commonwealth of Puerto Rico or any other territory where the predominant language is one other than English (21 CFR 201.15(c)(1)).
- A product name that differs from the name that appears on the FDA-approved drug label or labeling.
- A product name that is the product name for a foreign version of the drug.
- A product that is transported in a case or tote, when not expected under the circumstances.
- Lot numbers and expiration dates on product that do not match the lot numbers and expiration dates of its outer container.

Again, under section 582 of the FD&C Act, trading partners must have systems in place that enable them, upon determining that a product in their possession or control is suspect or upon receiving a request for verification from the FDA that has made a determination that a product within the possession or control of the trading partner is a suspect product, to quarantine suspect product and promptly conduct an investigation, in coordination with other trading partners, as applicable, to determine whether a suspect product is illegitimate. In addition, trading partners must, as applicable, make the notifications described in section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B) of the FD&C Act related to illegitimate product determinations, and, for manufacturers, the notification of a high risk of illegitimacy described in section 582(b)(4)(B)(ii)(II).

C. For Manufacturers: High Risk of Illegitimacy Notifications

Section 582(b)(4)(B)(ii)(II) of the FD&C Act requires manufacturers to make notifications in certain circumstances for products that pose a high risk of illegitimacy. The provision states as follows:

(II) HIGH RISK OF ILLEGITIMACY.--A manufacturer shall notify the Secretary and immediate trading partners that the manufacturer has reason to believe may have in the trading partner’s possession a product manufactured by, or purported to be a product manufactured by, the manufacturer not later than 24 hours after determining or being notified by the Secretary or a trading partner that there is a high risk that such product is an illegitimate product. For purposes of this subclause, a ‘high risk’ may include a specific high risk that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain and other high risks as determined by the Secretary in guidance pursuant to subsection (h).

FDA interprets this provision to require manufacturers to notify (1) FDA and (2) the manufacturer’s immediate trading partners (that the manufacturer has reason to believe may have in the trading partner’s possession a product manufactured by, or purported to be a product manufactured by, the manufacturer) in three general scenarios:

(1) Within 24 hours after determining or being notified by FDA or a trading partner that there is a high risk that a product that the manufacturer has reason to believe is in an immediate trading partner’s possession is an illegitimate product.

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(2) Within 24 hours after determining or being notified by FDA or a trading partner that there is a specific high risk that could increase the likelihood that illegitimate product will enter the U.S. pharmaceutical distribution supply chain.

(3) Within 24 hours after determining or being notified by FDA or a trading partner that there exists an “other high risk” as determined by FDA in guidance pursuant to subsection 582(h).

FDA believes that Congress intended section 582(b)(4)(B)(ii)(II) to leverage the surveillance systems that many manufacturers already have in place to detect counterfeit and otherwise violative versions of their products. Manufacturers could learn about products with a high risk of illegitimacy from a variety of sources, including from within their own company, from their trading partners, from the FDA, or from other domestic and/or foreign regulatory authorities—even when a product may not be in the manufacturer’s possession or control.

Below are scenarios and examples in which a manufacturer should make a notification under section 582(b)(4)(B)(ii)(II).

1. **High Risk of Illegitimacy Notification for Products That the Manufacturer Has Reason to Believe Are in an Immediate Trading Partner’s Possession**

The first general scenario, described above, involves notifications for products that the manufacturer has reason to believe are in an immediate trading partner’s possession.

An example of this scenario might occur when the manufacturer is asked to coordinate a suspect product investigation by an immediate trading partner under section 582(c)(4)(B), 582(d)(4)(B), or 582(e)(4)(B), and the manufacturer determines that there is a high risk that the product is illegitimate. Some sample scenarios involving high risks of illegitimacy, in which a manufacturer should make a notification, include:

- A manufacturer learns from a trading partner that a suspect product purporting to be one produced by that manufacturer has been found in the U.S. pharmaceutical distribution supply chain. The manufacturer examines the suspect product and believes the product could be illegitimate but wants to take additional steps before determining that it is illegitimate. The manufacturer has reason to believe that additional illegitimate products are in the possession of immediate trading partners. For example, a wholesale distributor informs a manufacturer that it believes it has a counterfeit of that manufacturer’s product. The wholesale distributor sends the product to the manufacturer. The manufacturer examines the product and believes it could be counterfeit, but wants to perform a laboratory analysis or other analysis for confirmation.

- A manufacturer learns that its product has been stolen or diverted in the United States while not in its possession or control, and the manufacturer has reason to believe that an immediate trading partner might have the stolen or diverted product in its possession.

2. **Specific High Risks That Could Increase the Likelihood of an Illegitimate Product Entering the U.S. Pharmaceutical Distribution Supply Chain**
Section 582(b)(4)(B)(ii)(II) states that a high risk of illegitimacy may include a “specific high risk” that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain. In such cases, the product has not yet entered the pharmaceutical distribution supply chain, so no immediate trading partners would have it in their possession. Section 582(b)(4)(B)(ii)(II) thus would require the manufacturer to make a notification to FDA, but the manufacturer would not be required to notify immediate trading partners. To help ensure the integrity of the supply chain, however, FDA recommends that a manufacturer notify its immediate trading partners of such “specific high risk[s]” even if that manufacturer does not have reason to believe that its immediate trading partners may have the high risk product in their possession. Some examples involving specific high risks include:

- A manufacturer learns that a product with a high risk of illegitimacy (purporting to be one produced by that manufacturer) has been found in another country, and that such product is likely destined for a trading partner in the United States. For instance, the manufacturer learns from a foreign regulatory authority that one of its products has been counterfeited in another country, and that some of that product is on a cargo ship destined for the United States for delivery to a wholesale distributor.

- A manufacturer learns that its product was stolen or diverted in another country, and that such product is destined for the United States in a manner that leads the manufacturer to believe the product will likely enter the U.S. pharmaceutical distribution supply chain. For instance, the manufacturer learns from a foreign law enforcement agency that its product was stolen during transport in another country and is on a plane destined for the United States for delivery to a dispenser.

- A manufacturer learns that there is a high risk that its product has been intentionally adulterated in another country such that the product would result in serious adverse health consequences or death to humans, and that such product is likely destined for the United States in a manner that leads the manufacturer to believe the product will enter the pharmaceutical distribution supply chain. For instance, the manufacturer learns from its own investigation that there is a high risk that a contaminant that would result in serious adverse health consequences or death to humans was added to a product in another country and sent to a repackager in the United States.

As noted above, the scenarios given in sections 1 and 2 are examples, rather than an exhaustive list of circumstances in which trading partners should make notifications under section 582(b)(4)(B)(ii)(II).

3. Other High Risks as Determined by FDA: High Risk of Illegitimacy Notification Where a Manufacturer Has Reason to Believe the Product Has Entered the Pharmaceutical Distribution Supply Chain

Section 582(b)(4)(B)(ii)(II) of the FD&C Act permits FDA to determine, through guidance pursuant to section 582(h), “other high risks” that would trigger a notification under this provision. FDA believes that one “other high risk” not covered by the two general scenarios described above is when a manufacturer has reason to believe that an illegitimate product has
entered the pharmaceutical distribution supply chain, even though the manufacturer does not have reason to believe that an immediate trading partner possesses the high risk product. As with the second general scenario, described above, section 582(b)(4)(B)(ii)(II) would require the manufacturer to make a notification to FDA, but the manufacturer would not be required to notify immediate trading partners. To help ensure the integrity of the supply chain, however, FDA recommends that a manufacturer notify its immediate trading partners of this “other high risk,” even if that manufacturer does not have reason to believe that its immediate trading partners may have the high risk product in their possession.

A manufacturer could learn that a product with a high risk of illegitimacy that was manufactured by (or purported to be manufactured by) that manufacturer, may be in the possession of a trading partner, but that trading partner is not an immediate trading partner of the manufacturer. Some examples that involve this other high risk include:

- A manufacturer learns that a licensed health care practitioner is administering an oncology drug to patients that purports to have been manufactured by that manufacturer but the manufacturer determines that there is a high risk that the drug is a counterfeit. The licensed health care practitioner purchased the drug from a wholesale distributor, so he/she is not an immediate trading partner of the manufacturer. However, the manufacturer believes that the product has entered the pharmaceutical distribution supply chain.

- A manufacturer learns that its product has been stolen or diverted in the United States, and the manufacturer learns that a patient filled a prescription and received some of the stolen or diverted product. The patient suffers an adverse event, and FDA and the manufacturer are notified of that situation. Because the dispenser did not purchase the product from the manufacturer, it is not an immediate trading partner of the manufacturer. However, the product has entered the pharmaceutical distribution supply chain.

- A manufacturer learns that wholesale distributor B received product and transaction history going back to the manufacturer from wholesale distributor A, but the listed dosage form of the product on the transaction history is not one that has ever been used by the manufacturer. Wholesale distributor B provided a copy of the transaction history it received from wholesale distributor A to the manufacturer, and the manufacturer concluded, after reviewing the copy and receiving similar reports from other trading partners, that a fraudulent transaction had occurred. Because wholesale distributor B did not purchase the product from the manufacturer, it is not an immediate trading partner of the manufacturer. However, the product has entered the pharmaceutical distribution supply chain.

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12 FDA reserves authority to articulate additional “other high risk[s]” in subsequent guidance(s).
IV. NOTIFICATION OF ILLEGITIMATE PRODUCTS AND PRODUCTS WITH A HIGH RISK OF ILLEGITIMACY

A. Notification to FDA

As discussed above, trading partners must, as applicable, make the notifications described in section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act related to illegitimate product determinations, and, for manufacturers, the notification of a high risk of illegitimacy described in section 582(b)(4)(B)(ii)(II). This section of the guidance addresses the process by which trading partners should notify FDA and other trading partners regarding illegitimate products under section 582. After review of the circumstances surrounding the event, if FDA determines that notification is not required under section 582(b)(4)(B)(ii)(I), (c)(4)(B)(ii), (d)(4)(B)(ii), (e)(4)(B)(ii), or (b)(4)(B)(ii)(II) of the FD&C Act, FDA intends to inform the submitting entity.

1. Process to Notify FDA of Illegitimate Products

The following process should be used to notify FDA of illegitimate products:


(2) Trading partners should follow the instructions on the Web page for accessing Form FDA 3911 (Appendix 1). Using this form, trading partners should provide information about the person or entity initiating the notification, the product determined to be illegitimate that is the subject of the notification to FDA, and a description of the circumstances surrounding the event that prompted the notification.

(3) Form FDA 3911 should be submitted using the method provided in the form or on the Web page.

(4) FDA will acknowledge receipt of the notification and assign an incident number. This number should be referenced in all future correspondence about the illegitimate product, including any request for termination.

(5) In addition to notifying FDA, the trading partner that determines it has an illegitimate product in its possession or control must notify all immediate trading partners that it has reason to believe may also possess the drug. Trading partners may notify other trading partners of an illegitimate product using existing systems and processes used for similar types of communications to those partners, which might include, but are not limited to, posting of notifications on a company Web site, telephoning, sending an email, or mailing or faxing a notification.

2. Process used by manufacturers to Notify FDA of a Product With a High Risk of Illegitimacy
The following process should be used by manufacturers to notify FDA of a product with a high risk of illegitimacy: under section 582(b)(4)(B)(ii)(II):

1. Manufacturers should access FDA’s Web page at:
   http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm

2. Manufacturers should follow the instructions on the Web page for accessing Form FDA 3911 (Appendix 1). Using this form, manufacturers should provide information about the person or entity initiating the notification, the product determined to have a high risk of illegitimacy that is the subject of the notification to FDA, and a description of the circumstances surrounding the event that prompted the notification.

3. FDA will acknowledge receipt of the notification and assign an incident number. This number should be documented in all future correspondence about the product with the high risk of illegitimacy, including any request for termination.

4. In addition to notifying FDA, the manufacturer that determines that a product has a high risk of illegitimacy must notify all immediate trading partners that it believes may possess the drug. Manufacturers may notify other trading partners of a product with a high risk of illegitimacy using existing systems and processes used for similar types of communications to those partners, which might include, but are not limited to, posting of notifications on a company Web site, telephoning, sending an email, or mailing or faxing a notification.

5. If a product with a high risk of illegitimacy is found to be an illegitimate product, manufacturers should submit a follow-up notification that explains the updated classification and references the incident number of the original notification of high risk of illegitimacy.

6. If it is determined that a product that was subject to a high risk of illegitimacy notification is not an illegitimate product, manufacturers must submit a request for termination of the high risk of illegitimacy notification to the FDA according to the process in Section B below.

B. Process for Termination of Notification in Consultation With FDA

Section 582(h)(2)(A) of the FD&C Act directs FDA to issue guidance setting forth the process that trading partners shall follow for terminating notifications regarding illegitimate product, or for manufacturers, terminating notification of a high risk of illegitimacy, in consultation with FDA, under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B). Section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) require trading partners to have in place systems to enable them to terminate notifications, in consultation with FDA. This section of the guidance addresses

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13 Insofar as section IV.B. of this guidance sets forth the process by which trading partners should terminate notifications of an illegitimate product or products with a high risk of illegitimacy in consultation with FDA, it has binding effect.
the process by which trading partners must terminate such notifications in consultation with FDA. This process must be used when trading partners believe that a notification they made to FDA regarding illegitimate product, or for a manufacturer, a notification of a high risk of illegitimacy, is no longer necessary.

The process for terminating notifications in consultation with FDA is as follows:

(1) The trading partner making a notification to the FDA shall be responsible for making the request for termination.


(3) Trading partners must follow the instructions on the Web page for accessing Form FDA 3911 (Appendix 1). Using this form, trading partners must provide to FDA information about the person or entity initiating the request for termination, the illegitimate product or the product with a high risk of illegitimacy, the notification that was issued, and an explanation about what actions have taken place or what information has become available that makes the notification no longer necessary. Trading partners should include the FDA-assigned incident number associated with the notification in the request for termination.

(4) This form must be submitted by using the method provided in the form or on the Web page. The trading partner’s submission of a request for termination of a notification will be viewed as a request for consultation with FDA, as required in section 582 of the FD&C Act. FDA may request any additional information it determines necessary to complete the consultation.

(5) FDA will review the request and consult with the trading partner. The response time will depend on the number of requests for termination and the circumstances surrounding the requests for termination that are received by FDA.

FDA interprets the DSCSA’s requirement for trading partners to “mak[e] a determination, in consultation with the Secretary, that a notification is no longer necessary” to require that trading partners provide the Agency with an opportunity to provide its expert views and advice on proposed terminations of notifications. Therefore, a trading partner must wait until FDA responds to the termination request before the trading partner notifies other trading partners that a notification is terminated. FDA intends to respond to requests for termination within 10 business days of submission. In some cases, FDA may contact a trading partner to notify the partner that additional time is needed to respond to the request for termination. If a trading partner believes that exigent circumstances require expedited consideration of a termination request (e.g., a potential drug shortage), the trading partner must describe those circumstances to FDA in the termination request on the FDA Form 3911 when making the request for termination.

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Under section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) of the FD&C Act, after FDA provides its consultation response, and the trading partner determines that the notification is no longer necessary, the trading partner that made the request for termination must promptly notify immediate trading partners that the notification has been terminated. Trading partners may notify their trading partners of a termination using existing systems and processes used for similar types of communications to those partners, which might include, but are not limited to, posting of notifications on a company Web site, telephoning, sending an email, or mailing or faxing a letter or notification.

V. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average as follows.

**Notify FDA of an Illegitimate Product:**
- 1 hour for manufacturers and repackagers
- 1 hour for wholesale distributors
- 1 hour for dispensers

**Notify Trading Partners of an Illegitimate Product or a Product With a High Risk of Illegitimacy:**
- 0.20 hour (12 minutes) for manufacturers and repackagers
- 0.20 hour (12 minutes) for wholesale distributors
- 0.20 hour (12 minutes) for dispensers

**Consult With FDA and Terminate Notification:**
- 1 hour for manufacturers and repackagers
- 1 hour for wholesale distributors
- 1 hour for dispensers

**Notify Trading Partners That a Termination Has Been Terminated:**
- 0.20 hour (12 minutes) for manufacturers and repackagers
- 0.20 hour (12 minutes) for wholesale distributors
- 0.20 hour (12 minutes) for dispensers

These estimates include the time to review instructions, gather the data needed, and complete and review the information collection and transmit to FDA. It also includes the time to notify trading partners of a termination using existing systems and processes used for similar types of communications to those partners, which might include, but are not limited to, posting of notifications on a company Web site, telephoning, sending an email, or mailing or faxing a letter or notification.
partners. Send comments regarding this burden estimate or suggestions for reducing this burden to: Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0806 (expires 12/31/2018).
APPENDIX 1: FORM FDA 3911

FORM FDA 3911 and the FORM FDA 3911 Instructions Supplement are available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/HumanDrugForms/default.htm

If you are experiencing difficulties accessing the form, please contact the FDA forms manager at FormsManager@OC.FDA.GOV for assistance.
DISCUSSION REQUESTED: STLCoP is asking the Board to consider an additional license/registration class as reflected in the enclosed correspondence.
November 30, 2016

Kimberly Grinston, Executive Director
Missouri Board of Pharmacy
PO Box 625
Jefferson City, MO 65102

Dear Ms. Grinston:

I have been asked to write to you about allowing international pharmacy faculty members and students to participate in international educational exchanges in Missouri. Thank you for considering ways in which we can incorporate pharmacy practice settings into educational experiences for international pharmacists and pharmacy students. Allowing international pharmacists and pharmacy students to visit pharmacy practice sites in Missouri will provide a meaningful and educational experience that can be used to improve pharmacy practice in other countries. It will also help us reciprocate with our international partners who generously offer the same opportunities to our faculty and students when we visit their countries.

The purpose of this letter is to suggest ways of enabling international pharmacists and pharmacy students to visit practice sites such as hospital and community pharmacies.

I anticipate that we would invite approximately six to ten international visitors per year for terms ranging from two weeks to three months. With your approval, these exchanges could be designed to help the international visitors learn about the U.S. healthcare system in general and pharmacy education and practice in particular. Also with your approval, we would like to have one of the activities of these exchanges to include visits to various practice sites, such as hospitals, clinics and community pharmacies. **Note that we would anticipate that international visitors would have a limited scope and would not participate in direct patient care activities.**

There may be several options that would allow us to expose our international partners to pharmacy practice in Missouri, and I would be willing to explore any of them. To get the conversation started, though, I would like to propose that the Board consider creating a new category of registrant or licensee for international pharmacists and pharmacy students, possibly referred to as “International Pharmacy Visitor.” Perhaps this category could be similar to the Pharmacy Technician category with a few exceptions:

- Perhaps a passport number could be used on the application in lieu of a Social Security Number.
- The registration or license could have a short expiration, such as six months or a year.
- In light of the short-term nature of these exchanges and the logistical difficulties obtaining fingerprinting and criminal background checks, we would appreciate it if the Board could consider forgoing these two requirements.

Thank you for considering these suggestions. I look forward to exploring these options with you.

Sincerely,

Kenneth W. Schafermeyer, RPh, PhD
Professor of Pharmacy Administration
Director, Office of International Programs
#D7 Promoting Safe E-Prescribing

- Erika L. Abramson, “Causes and Consequences of E-Prescribing Errors in Community Pharmacies”

DISCUSSION REQUESTED: Vice-President Tadrus has asked to discuss ways to collaborate with the Board of Healing Arts to address/promote safe e-prescribing practices.
RevIew

Causes and consequences of e-prescribing errors in community pharmacies

This article was published in the following Dove Press journal:
Integrated Pharmacy Research and Practice
20 May 2015
Number of times this article has been viewed

Erika L Abramson
Departments of Pediatrics and Healthcare Policy and Research, Weill Cornell Medical College, New York, NY, USA

Abstract: Major national policy forces are promoting the adoption and use of health information technology (health IT) to improve the quality, safety, and efficiency of health care delivery. One such health IT is electronic prescribing (e-prescribing), which is the direct transmission of prescription information from a provider to a pharmacy. Given research showing that handwritten prescriptions are unsafe and associated errors can lead to tremendous inefficiency for patients and pharmacists, e-prescribing has many potential benefits. However, as with the introduction of any new technology, unintended, adverse consequences may result. The purpose of this review is to explore the causes and consequences of e-prescribing errors in community pharmacies, which are pharmacies not affiliated with a hospital or clinic. Many new types of errors – including provider order entry errors, transcription errors, and dispensing errors – appear to result from e-prescribing. These lead to important consequences for pharmacies, including safety threats to patients, reduced efficiency for pharmacists, processing delays, and increased pharmacy cost. Increased attention to system design and pharmacist training, as well as additional research in this area, will be critical to realize the full benefits of e-prescribing.

Keywords: electronic prescribing, medication errors, community pharmacies

Background

Medication errors are common, costly, and result in significant patient harm, making them a major public health concern. The 2006 Institute of Medicine (IOM) report, Preventing Medication Errors estimated that over 1.5 million preventable adverse drug events (ADEs) occur annually in the USA.1 Many of these occur in the outpatient setting. National costs for preventable ADEs are estimated to be $3.5 billion annually.1

Until recently, nearly all prescribing occurred using handwritten prescriptions. Handwritten prescriptions have several associated potential dangers, including the potential for misinterpretation errors due to illegibility. A study evaluating over 9,000 prescriptions written by 78 primary care providers in New York and Massachusetts found that illegibility errors occurred on average more than once per prescription – an alarmingly high rate.2 In addition to the dangers associated with poor legibility, the need for pharmacy clarification can result in significant extra work for pharmacists as well as delays for patients in obtaining prescriptions.

In order to improve the safety of and efficiency in health care delivery in this country, national policies are promoting the adoption and use of health information technology (health IT).3,4,5 One of the main types of health IT being targeted through these programs is electronic prescribing (e-prescribing). E-prescribing is the direct computer-to-
computer transmission of prescription or prescription-related information from the prescriber to a pharmacy, pharmacy benefit manager, or health plan. Prescription information is generated within the context of an electronic order entry system, which often provides the prescriber with clinical decision support (CDS) to aid in the correct prescribing of medications at the point of care.

As a result of these policies, use of e-prescribing has increased dramatically. As of 2013, 7 in 10 community-based physicians were utilizing e-prescribing, 95% of pharmacies were accepting e-prescriptions, and over 6 billion transactions occurred in that year. That is compared to only 7% of physicians e-prescribing as of 2008.

There are many theoretical benefits associated with the increased use of e-prescribing. From a safety perspective, these include a reduction in medication errors as a result of fewer illegible prescriptions, improved prescription ordering due to the CDS embedded in e-prescribing systems, and better ability to track prescriptions. Indeed, studies evaluating the safety effects of e-prescribing in the ambulatory setting have been promising. Multiple studies have shown that e-prescribing can reduce prescription errors. Other potential benefits include improved efficiency for pharmacists and providers, decreased need for pharmacy clarification of prescription information via phone calls, and decreased patient wait time for prescriptions.

Despite its potential, it is important to recognize that there are important unintended and adverse consequences that can result from adoption and use of e-prescribing. While most research on unintended consequences has focused on the interplay between prescribers and e-prescribing systems, pharmacists play an integral role in ensuring that patients receive medication safely and have been greatly impacted by the introduction of e-prescribing systems.

The objective of this review article is to examine the causes and consequences of e-prescribing errors in community pharmacies. Community pharmacies are pharmacies that do not directly affiliate with hospitals or clinics, and are where the majority of prescriptions are filled. A considerable challenge for community-based pharmacists in that unlike hospital-based or clinic-based pharmacists, they generally do not have access to the patient’s electronic health record (EHR) and thus have far less information at hand to recognize potential errors.

This review is organized into four sections. The first section is a description of the methodology used to identify relevant articles. The second section reviews the causes of e-prescribing errors, organized according to stage of the medication process. The third section reviews the consequences of e-prescribing errors, organized into three major categories (pharmacy rework, delays for patients, and cost). The last section discusses the implications of this review with a focus on the health policy perspective. Understanding causes and consequences of errors experienced in community pharmacies as a result of e-prescribing will be critical to developing more comprehensive safety strategies and to ultimately realizing the full potential of e-prescribing.

Methods

A comprehensive search was performed in December 2014 by a medical librarian to identify literature on e-prescribing errors among community pharmacies. Potentially relevant articles were found by searching the biomedical electronic databases Ovid MEDLINE, Ovid EMBASE, and The Cochrane Library. A combination of controlled vocabulary and text words were used and translated appropriately to the relevant databases. Results were limited to English language. The primary search was conducted in MEDLINE by use of the terms: exp Electronic Prescribing/OR Clinical Pharmacy Information Systems/OR ((electronic or online or computer$) or automat$) adj3 (prescri$ or medication$)).mp. OR e-prescri$.mp. OR prescri$ system$1.mp. OR erx.mp. AND (safe$ or err$ or adverse).ti, ab. OR exp medication errors/or exp Risk Management/or exp Quality of Health Care/or exp Medical Errors/or exp Safety/or medical audit/ AND Pharmacies/OR Community Pharmacy Services/OR ((communities or community) adj pharmac$).mp.

This search yielded a total of 268 results. The author reviewed the title and abstract for all articles and reviewed any article in its entirety if it appeared to meet inclusion criteria (focused on causes or consequences of e-prescribing errors in the community pharmacy setting). All references for full articles were also reviewed to identify any additional articles not captured in the original literature review.

Results

Causes of errors

There are many different types of errors related to e-prescribing seen in community-based pharmacies. For the purposes of this review, they have been organized into three broad categories: order entry errors from the provider side, transcription errors, and dispensing errors. Each will be discussed in turn. A summary table is also provided (Table 1).
Table 1 Summary table: causes of e-prescribing errors in community pharmacies

<table>
<thead>
<tr>
<th>Type of error</th>
<th>Association with e-prescribing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Order entry error from the provider side</strong></td>
<td>• Wrong drug, pharmacy, patient</td>
</tr>
<tr>
<td></td>
<td>• Incorrect directions, conflicting information</td>
</tr>
<tr>
<td>• Wrong quantity errors</td>
<td>• Easy to select incorrectly from drop-down menus</td>
</tr>
<tr>
<td>• Refill errors</td>
<td>• Autopopulated information may be incorrect or carried over incorrectly from prior prescriptions</td>
</tr>
<tr>
<td><strong>Transcription errors</strong></td>
<td>• Many systems require providers to enter the quantity and type of unit to be dispensed, forcing providers to “guess” if they are unaware</td>
</tr>
<tr>
<td>• Incorrect physician or a patient selected by pharmacist</td>
<td>• Obsolete or incorrect information may be propagated when old refill prescriptions are used as templates</td>
</tr>
<tr>
<td>• Incorrect information entered by pharmacist into pharmacy system</td>
<td></td>
</tr>
<tr>
<td><strong>Dispensing errors</strong></td>
<td>• Provider/patient appear differently in order entry and pharmacy databases so pharmacists may guess when multiple choices appear</td>
</tr>
<tr>
<td>• Errors associated with modified prescriptions</td>
<td>• Provider order entry and pharmacy systems do not directly interface, forcing pharmacists to print prescriptions or memorize information to enter it into pharmacy system</td>
</tr>
<tr>
<td>• Incomplete processing of all prescriptions for a single patient</td>
<td>• System may interface but not all necessary prescription information is available on a single screen</td>
</tr>
<tr>
<td>• Dispensing of discontinued medications</td>
<td>• Because providers cannot modify a sent prescription, they may send two back-to-back, which makes it unclear which is correct</td>
</tr>
<tr>
<td>• Duplicate dispensing</td>
<td>• Prescriptions for the same patient may not arrive at a single time or may be mixed with those of other prescriptions</td>
</tr>
<tr>
<td></td>
<td>• Patients may have e-prescriptions and paper prescriptions (ie, for controlled substances)</td>
</tr>
<tr>
<td></td>
<td>• Providers may incorrectly assume that simply discontinuing a prescription from the provider side will filter to the pharmacy once that prescription has already been processed</td>
</tr>
<tr>
<td></td>
<td>• Pharmacy may process a prescription twice if they receive two requests (ie, electronically and by facsimile)</td>
</tr>
</tbody>
</table>

Order entry errors from the provider side

One of the most critical roles for community pharmacists is to recognize and intercept prescription errors before they can reach a patient and cause harm. Thus, new types of ordering errors introduced by e-prescribing are a major concern for pharmacists. A study of 3,850 e-prescriptions generated by providers in three states found that 11.7% contained errors, of which 35.0% were considered potential ADEs. In this study, the most common types of errors were omitted information (particularly duration, dose, or frequency), unclear or conflicting information, and clinically incorrect information. Other studies investigating types of e-prescribing errors related to order entry have found that wrong drug quantity, wrong duration of therapy, wrong dosing directions, and wrong dosing formulations occur frequently. Wrong patient and wrong drug errors have also been reported to occur with some regularity.

It is likely that at least some of these errors are a direct consequence of e-prescribing and were generally not seen (or seen with much less frequency) with handwritten prescriptions. For example, it is easy to select the wrong patient, wrong pharmacy, or wrong drug from drop-down menus. Information that is autopopulated into certain prescription fields may help to foster errors such as incorrect directions or conflicting information errors. Many e-prescribing systems require prescribers to enter the medication quantity and type of unit to be dispensed as discrete fields. In contrast, with handwritten prescriptions, providers often wrote “quantity sufficient” in the dispense field, relying on the pharmacist to dispense the appropriate unit and package size. Incorrect guesses on these fields by providers lead to wrong quantity errors. In addition, many providers use old e-prescriptions as the basis to generate refills; failing to update information may result in incorrect or obsolete information being propagated onto the refill prescription.

Transcription errors

While one of the theoretical benefits of e-prescribing is the direct transmission of prescription information to pharmacies, difficulties in directly interfacing and connecting order entry systems with pharmacy technology has resulted in certain types of transcription errors. For example, mismatches between how patient and physician names are stored in
provider and pharmacy data systems can lead to difficulty for pharmacists in identifying the correct provider or patient. In one study, pharmacists reported guessing (sometimes incorrectly) the patient or prescriber for prescriptions when multiple options were possible, or having to spend time clarifying the information with the prescriber’s office.  

Other studies have reported that pharmacists frequently have to manually transcribe some or all information from e-prescriptions into the pharmacy system due to incompatibilities with pharmacy software, or have to print out e-prescriptions to be able to read all the fields on their computer software. A workaround used by pharmacists is memorizing information from one screen to allow inputting of information in a different screen. All of these workflow strategies greatly increase the potential of transcription errors.

Dispensing errors
Dispensing errors represent an important concern for pharmacists. A study of dispensing errors in 2003 found that 3% of new prescriptions had associated dispensing errors, which, extrapolated to the number of prescriptions written annually, would represent more than 45 million dispensing errors on an annual basis. There is data to suggest that direct transmission of e-prescriptions to pharmacies, even compared with prescriptions generated using electronic order entry but that are printed or faxed, reduces dispensing errors.

However, there remain important types of dispensing errors resulting from e-prescribing that have been identified.

One type of error results from modified prescriptions; because providers cannot alter an e-prescription once it has been sent, pharmacists at times receive back-to-back e-prescriptions for the same patient. This results in confusion on which prescription should be filled, with potential for error. Moreover, because of this, providers often have to call the pharmacy to clarify which prescription should be filled, reducing efficiency for both providers and pharmacists.

Errors around e-prescribing refills have also been described. Providers have been reported to miss electronic refill requests issued by pharmacists, resulting in patient delays in receiving prescriptions and pharmacy rework in calling providers. Pharmacists have also reported concern around incorrect refill prescriptions. This may be a result of the fact that less well-trained staff are sending refill prescriptions because of the ease of ordering these prescriptions electronically compared with handwritten prescriptions that required the provider to write the entire prescription or at least review it before signing.

Another dispensing challenge relates to timing and bundling of e-prescriptions. With traditional paper prescriptions, patients typically arrive in the pharmacy with all prescriptions in hand and there is an expected wait time as the prescription is filled. With e-prescriptions, studies have found that patients may arrive at the pharmacy thinking that the prescription is already filled, when in fact it has not yet been sent or processed. In addition, e-prescriptions for multiple patients may arrive simultaneously, making it more complex to fill all the prescriptions for a single patient at one time. Unless patients have an e-prescription receipt, they may not be completely aware of how many prescriptions are due to be filled. A particular area of difficulty arises from controlled substances, which generally require paper prescriptions. Thus, a patient may have a mixture of paper and electronic prescriptions, again potentially jeopardizing timely filling of all prescriptions for one patient.

Pharmacy dispensing of discontinued medications is another important source of errors related to e-prescribing. One study found that 1.5% of discontinued medications were dispensed, with potential harm in 12% of these cases. It is likely that many physicians incorrectly assume that simply discontinuing a prescription through order entry will result in the prescription being discontinued on the pharmacy end. A related issue surrounds dispensing duplicate medications to patients. At times, pharmacies may receive a facsimile and e-prescription for the same medication. Particularly, if processed by different pharmacists, there is greatly increased potential for duplicate dispensing.

Lastly, research suggests that pharmacists may be more vulnerable to making errors when processing e-prescriptions rather than paper prescriptions because e-prescriptions are not portable unless printed. With paper prescriptions, pharmacists have a tangible, mobile memory aid that can be carried when completing tasks not involving the computer (such as dispensing a medication) or that they can easily refer to when interrupted mid-task. In one study, pharmacists at times forgot about tasks completely when distracted while processing an e-prescription.

Consequences of e-prescribing errors
E-prescribing errors can have important consequences for community pharmacists. Three major categories of consequences include the following: 1) rework and reduced efficiency for pharmacists; 2) delays for patients; and 3) cost burden for pharmacies. Each of these will be discussed in turn (Table 2).

Reduced efficiency for pharmacists
With any prescription error, pharmacists must spend time investigating the error in order to safely dispense
medications to a patient. This can be a significant time burden for pharmacists. A study performed in Sweden found that 2.0% of new e-prescriptions required pharmacist clarification, which was actually significantly more than nonelectronic prescriptions.25 Notably, nearly 90% of the suggested pharmacist recommendations were accepted by prescribers, underscoring the importance of pharmacists in intercepting potential errors. A similar US-based study found that pharmacists had to intervene on e-prescriptions in intercepting potential errors.19 This same study also found that while one-third of issues were resolved in less than 30 minutes, nearly 25% took more than 8 hours to be resolved.15

The impact of problematic e-prescriptions on workflow for pharmacists is striking. One study evaluating the impact of pharmacist workflow on e-prescribing found that after implementation of an e-prescribing system, pharmacists spent 12.9% more time correcting prescription problems and 45.8% more time in problem-solving activities around prescriptions. In addition, there was a small decrease in time actually spent filling prescriptions and communicating with patients. A different study that looked at time to issue resolution for problematic e-prescriptions found that while one-third of issues were resolved in less than 30 minutes, nearly 25% took more than 8 hours to be resolved.15

Time away from direct communication with patients may negatively impact some of the more important roles served by pharmacists. This includes counseling patients about medication and side effects, administration of vaccines (now often an important role filled by community pharmacies), and disease management. This is an important area for further study.

### Processing delays for patients

As mentioned earlier, because filling an e-prescription does not require a patient to present that prescription to a pharmacist, at times patients arrive in pharmacies incorrectly thinking their e-prescription has been already been processed.19 This leads to frustration and delays for patients. Several studies have noted patient delays, sometimes lengthy, while pharmacists try to clarify e-prescription errors.13,14

Delays in dispensing medications to patient can also be an important source of patient harm. For example, one study of pharmacy callbacks to 22 primary care practices to clarify prescriptions found that pharmacy callbacks were common. Notably, problems for “acute” medications, defined as medications where delays in administration could lead to worsening of a medical condition or prolonged pain, were not resolved on the same day 34% of the time.28

### Increased cost

There are several types of associated costs for pharmacies that may result from e-prescribing errors. Pharmacies often are responsible for the transaction costs associated with e-prescription processing. Thus, incorrect or duplicate prescriptions may result in the accrual of significant fees for pharmacies. One study, for example, found monthly e-prescription transaction fees of thousands of dollars for a single pharmacy, a large proportion of which was a result of erroneous prescriptions.19 This same study also found higher rates of unfilled e-prescriptions compared with paper prescriptions, likely due to the fact that filling could be initiated without the first step of the patient bringing in the prescription to the pharmacy.19 Unfilled prescriptions not only cost pharmacies money for the e-prescription processing fees, but also associated restocking costs. Of course, unfilled prescriptions can also have important health consequences for patients. A study of 195,930 e-prescriptions found that only 78% were filled, with even lower fill rates for new medications.29 Many of these were medications for chronic conditions, including hypertension, diabetes, and hyperlipidemia.

In addition, the time required by pharmacists for addressing e-prescription errors has important implications for dispensing costs. A study of 68 pharmacies in five states found pharmacists had to intervene 102 times on 2,690 e-prescriptions.14 The average intervention time required by pharmacists was 6.07 minutes. The authors estimated this represented an incremental dispensing cost of $4.74.
Discuss 

This review of causes and consequences of e-prescribing errors among community pharmacies shows that there are a wide variety of errors associated with e-prescribing which can have significant effects on patient safety, efficiency, and cost. While the focus of this review article is community pharmacies, of paramount concern are the potential safety implications for patients associated with the prescribing errors and dispensing delays described earlier. It is estimated that 1.5 million patients experience a preventable ADE annually, leading to 7,000 deaths at a direct medical cost of nearly $21 billion. Pharmacists clearly play a critical role in identifying errors and mitigating these numbers, but the public health burden remains substantial and underscores the need for more work in this area.

As shown through this review, an error at any stage can also have a myriad of downstream consequences. For example, an ordering error that requires pharmacist intervention will result in pharmacist time spent clarifying the prescription. This forces the pharmacist away from other roles, such as counseling patients or dispensing medications. Delays in dispensing prescriptions leads to increased patient frustration and potential health impacts if critical medicines (such as antibiotics) are not able to be taken in a timely manner. Lastly, there are increased costs associated with dispensing due to the extra time required by pharmacists to complete all their daily tasks.

From a policy perspective, it is clear that greater research and monitoring into the causes and consequences of e-prescribing errors in community pharmacies needs to be performed. Locally, organizations can create e-prescribing incident report tools to better track errors occurring internally. This has successfully been used to elicit pharmacist perspectives on errors. National organizations, such as the American Medical Informatics Association, have been advocating for additional research investigating the unintended consequences of health IT. The Office of the National Coordinator for Health IT even recently released a guide for health care organizations entitled Guide to Reducing Unintended Consequences of Electronic Health Records. Use of these tools may help organizations prioritize system refinements, facilitating safe EHR use and potentially improving provider satisfaction with these systems. Importantly, however, this research must move beyond its traditional focus on providers and health care organizations to pharmacists as well.

There also needs to be an ongoing partnership between providers, pharmacists, and the vendor community to continue to focus on optimizing the design of EHRs and the e-prescribing functionality using a human factors approach. This includes order entry screens, CDS, and the interface between pharmacy and e-prescribing systems. Otherwise, serious order entry, transcription, and dispensing errors will continue to occur. In recognition of the potential negative effects on safety and quality that suboptimal system design can have, increasing national focus is addressing the usability of health IT.

Lastly, there needs to be greater attention paid to the training of pharmacists on use of these systems as well as on error and task interruption recovery. Studies have found that many pharmacists receive little or no formal training on use of e-prescribing systems, particularly hires after the systems go-live. Dissemination around best practices for implementation and training, as well as resources for pharmacists and patients, have been developed and may be useful in this regard. For example, the Agency for Healthcare Research and Quality developed a toolkit for pharmacies on e-prescribing. However, ongoing studies must continue and resources developed on an ongoing basis given how rapidly technology changes and advances.

Limitations

There are several limitations to this review. First, our literature search was limited to articles published in English and indexed in Ovid MEDLINE, Ovid EMBASE, and the Cochrane Library. Thus, there may be relevant articles that were not identified. Second, the methodology utilized in the included studies was variable and this review did not perform an objective evaluation of the quality of the individual articles included.

Conclusion

In sum, it is clear that health IT and e-prescribing are critical for advancing health care in this country. Compared with most major industries, health care is way behind. However, there are significant unintended consequences that have been introduced as a result of e-prescribing. Only through careful and ongoing work to understand the causes, consequences, and potential solutions to these unintended consequences, will we be able to truly maximize its potential. Specific recommendations include the following: 1) organizations must monitor unintended consequences locally and more research must be performed broadly in order to better maximize the expected safety benefits from e-prescribing; 2) vendors and pharmacists must partner to optimize the design of e-prescribing systems to better fit pharmacist workflow;
3) organizations must formally train pharmacists on how to best utilize e-prescribing systems, ideally guided by best practices developed and disseminated throughout this health care sector.

Acknowledgment
The author would like to thank Diana Delgado, M LS, for her assistance with the literature search for this review paper.

Disclosure
The author reports no conflicts of interest in this work.

References
#D8  Pharmacist Drug Utilization Review

- Chicago Tribune Article, “Pharmacies Miss Half of Dangerous Drug Combinations”

**DISCUSSION REQUESTED:** Board members asked to discuss the article and Missouri’s DUR and patient counseling requirements.
Pharmacies miss half of dangerous drug combinations

By Sam Roe, Ray Long and Karisa King
Chicago Tribune

DECEMBER 15, 2016, 8:44 AM

The Tribune reporter walked into an Evanston CVS pharmacy carrying two prescriptions: one for a common antibiotic, the other for a popular anti-cholesterol drug.

Taken alone, these two drugs, clarithromycin and simvastatin, are relatively safe. But taken together they can cause a severe breakdown in muscle tissue and lead to kidney failure and death.

When the reporter tried to fill the prescriptions, the pharmacist should have warned him of the dangers. But that's not what happened. The two medications were packaged, labeled and sold within minutes, without a word of caution.
The same thing happened when a reporter presented prescriptions for a different potentially deadly drug pair at a Walgreens on the Magnificent Mile.

And at a Wal-Mart in Evergreen Park, a Jewel-Osco in River Forest and a Kmart in Springfield.

In the largest and most comprehensive study of its kind, the Tribune tested 255 pharmacies to see how often stores would dispense dangerous drug pairs without warning patients. Fifty-two percent of the pharmacies sold the medications without mentioning the potential interaction, striking evidence of an industrywide failure that places millions of consumers at risk.

CVS, the nation's largest pharmacy retailer by store count, had the highest failure rate of any chain in the Tribune tests, dispensing the medications with no warning 63 percent of the time. Walgreens, one of CVS' main competitors, had the lowest failure rate at 30 percent — but that's still missing nearly 1 in 3 interactions.

In response to the Tribune tests, CVS, Walgreens and Wal-Mart each vowed to take significant steps to improve patient safety at its stores nationwide. Combined, the actions affect 22,000 drugstores and involve additional training for 123,000 pharmacists and technicians.

"There is a very high sense of urgency to pursue this issue and get to the root cause," said Tom Davis, CVS' vice president of pharmacy professional services.

CVS, which filled about 1 billion prescriptions last year, said the company would improve policies and its computer system to "dramatically" increase warnings to patients.

Walgreens said it would, among other changes, increase training for pharmacists. "We take this very seriously," said Rex Swords, Walgreens' vice president of pharmacy and retail operations and planning.

Dangerous drug combinations are a major public health problem, hospitalizing tens of thousands of people each year. Pharmacists are the last line of defense, and their role is growing as Americans use more prescription drugs than ever. One in 10 people take five or more drugs — twice the percentage seen in 1994.

Some pharmacists who were tested got it right, coming to the counter to issue stern warnings. "You'll be on the floor. You can't have the two together," said one pharmacist at a Walgreens on Chicago's Northwest Side. Said a Kmart pharmacist in Rockford: "I've seen people go to the hospital on this combination."
But in test after test, other pharmacists dispensed dangerous drug pairs at a fast-food pace, with little attention paid to customers. They failed to catch combinations that could trigger a stroke, result in kidney failure, deprive the body of oxygen or lead to unexpected pregnancy with a risk of birth defects.

Location didn't matter: Failures occurred in poor neighborhoods on the South Side as well as in affluent suburbs and the Gold Coast. Even the Walgreens at Northwestern Memorial Hospital in downtown Chicago failed its test.

The newspaper also tested independent pharmacies, many of which take pride in providing personalized care. As a group, they had a higher failure rate than any retail chain, missing risky drug interactions 72 percent of the time. Chains overall failed 49 percent of their tests.

The Tribune study, two years in the making, exposes fundamental flaws in the pharmacy industry. Safety laws are not being followed, computer alert systems designed to flag drug interactions either don't work or are ignored, and some pharmacies emphasize fast service over patient safety. Several chain pharmacists, in interviews, described assembly-line conditions in which staff hurried to fill hundreds of prescriptions a day.

Wal-Mart, operator of 4,500 U.S. pharmacies, failed 43 percent of its tests. The company said it would update and improve its pharmacy alert system and train pharmacists on the changes.

Kmart failed 60 percent of the tests. Phil Keough, pharmacy president for Sears Holdings, which owns Kmart, said he was disappointed with the results. "While not happy, we also take this as an opportunity to look in the mirror and see where we can get better," he said.

Costco, a membership warehouse club whose pharmacies are open to the general public, failed 60 percent of the tests; the company declined to comment.

The Tribune also tested two Chicago-area chains: Jewel-Osco, which failed 43 percent of the time, and Mariano's, 37 percent.

Jewel-Osco declined an interview request and instead emailed the Tribune a one-sentence written statement: "Osco pharmacists have a history of providing knowledgeable, exemplary care to our customers and their health, well-being and safety is our primary concern."

Mariano's also declined to answer questions. The chain said in a written statement: "None of our pharmacists are intentionally disregarding drug interactions or patient safety."
The chain wrote, "Our pharmacists look at each patient profile which includes patient history, allergy profile, pre-existing conditions and other factors such as age, all of which must be considered when assessing the potential for a drug interaction."

But in the Tribune tests, pharmacists at Mariano's stores rarely asked for all of that information.

**Last line of defense**

In the fight to protect patients from dangerous drug interactions, doctors shoulder significant responsibility. They are the ones who write the prescriptions.

But one physician may not know what another has prescribed, and research has found that doctors' knowledge about specific interactions is often poor.

In filling prescriptions, pharmacists are uniquely positioned to detect potential drug interactions, warn patients and prevent harm. Pharmacists themselves say that is one of their primary duties.

Yet little data exists about how well they perform in real-world situations.

The Tribune set out to find the answer. To select drug pairs to be used in the tests, the newspaper enlisted the help of two leading experts on drug interactions: pharmacy professors Daniel Malone of the University of Arizona and John Horn of the University of Washington. Five pairs were chosen, three of which posed life-threatening risks. Another could cause patients to pass out. A fifth included an oral contraceptive and could lead to unplanned pregnancies.

According to the two experts, all of the drugs had been on the market for years, and the pairs presented well-established interactions that pharmacists should easily catch. "No-brainers," Horn called them.

Writing the prescriptions was Dr. Steven C. Fox, a Chicago physician who treats many elderly patients on multiple medications. He knew the risks of interactions firsthand.

Fox wrote the prescriptions in the names of 18 Tribune journalists, 15 of whom conducted tests in the field. They presented the prescriptions written in their names or, in some instances, their colleagues' names. The reporters tested 30 stores at each of seven leading chains as well as numerous independent pharmacies. Most stores were in the Chicago area; some were in Indiana, Wisconsin and Michigan.
Reporters presented the prescriptions together or a couple of days apart, then waited to see if the orders would be filled.

In Illinois, pharmacists who detect a serious interaction must contact the prescribing doctor to see if the order is correct or if an alternative therapy is available, according to the Illinois Department of Financial and Professional Regulation. Pharmacists are then supposed to alert the patient.

Carmen Catizone, executive director of the National Association of Boards of Pharmacy, said the professional standard is clear. "Anytime there's a serious interaction, there's no excuse for the pharmacist not warning the patient about that interaction," he said.

In the Tribune study, a test was considered a pass if the pharmacist attempted to contact Fox about the interaction or warned the reporter.

Drug information leaflets placed inside the bag or stapled to the outside were not considered sufficient to warrant a pass. Illinois regulators said these materials typically are not adequate replacements for verbal warnings; some of the materials don't warn about specific interactions, and experts say patients frequently throw out the leaflets without reading them.

After the tests, reporters called many of the pharmacists to inform them of the results and to discuss the findings.

Why were so many pharmacies missing dangerous drug combinations?

**Speed vs. safety**

Mayuri Patel, a pharmacist at a Wal-Mart in west suburban Northlake, said she typically fills 200 prescriptions in a nine-hour shift, or one every 2.7 minutes.

At another Wal-Mart where she was trained, it was even busier, she said: "We were doing 600 a day with two pharmacists with 10-hour shifts." That works out to one prescription every two minutes.

In the Tribune tests, she caught a potentially deadly drug pair, warning the reporter at the counter: "This is a common interaction."

It is difficult to say why so many pharmacists failed the same test, but interviews and studies point to a possible explanation: the emphasis on speed.
Several stores dispensed risky drug pairs with no warning in less than 15 minutes. At a Kmart in Valparaiso, Ind., it was 12 minutes. At an independent pharmacy on the North Side, it was five.

The Tribune found that pharmacists frequently race through legally required drug safety reviews—or skip them altogether. According to Illinois law, pharmacies are required to conduct several safety checks, including whether the dose is reasonable and whether the medication might interact with other drugs the patient is taking.

But in the Tribune tests, pharmacies rarely asked what other medications testers were using.

"They're cutting corners where they think they can cut," said Bob Stout, president of the New Hampshire Board of Pharmacy, which sampled data from two retail chains in the state and found that pharmacists spent an average of 80 seconds on safety checks for each prescription filled.

"What happens, I found on the board, is people stop doing (safety) reviews," Stout said. "They're not going in looking at patient records."

Most pharmacies use computer software designed to flag drug interactions. But experts say computer alerts are so common that pharmacists can get "alert fatigue" and ignore many of the warnings.

At the same time, chain pharmacies are increasingly promoting quick service. Drive-through windows are now common, and services like CVS' walk-in MinuteClinics appeal to consumers' preference for speed.

These efforts may send a message to patients that speed is more important than quality health care. Patients have internalized that message and feel entitled to short wait times, pharmacists said.

"The patient will get mad if you call the doctor and take time," said Sadia Shuja, a pharmacist at Skypoint Pharmacy in Schaumburg who caught a dangerous drug pair in the Tribune tests. "Sometimes they think it is fast food."

To ease workload, most pharmacies employ technicians to manage tasks that require less medical expertise.

Arsen Mysllinj, a Kmart pharmacist in Rockford who passed the Tribune test, said technicians at his store and others often screen for drug interactions after entering patients' drug orders into a computer. If interactions appear, he said, the technicians are trained to print out the warning on
the screen and hand it to a pharmacist. It would be better, he said, for pharmacists to do the screening.

Kmart said that in light of the test results, it would review its relevant policies, computer systems and training programs.

Unionized pharmacists, including those in Illinois, have periodically pushed for minimum staffing rules, but those efforts have not gone far. Some pharmacists say time spent pitching company promotions could be better spent on patient safety.

In the Tribune tests, the majority of Kmart pharmacists dispensed risky drug combinations without warning testers. But several did take time to try to enroll the reporters in the company's savings program.

'Scorecard' pressures

At CVS, prompt service isn't just a vague goal. It is a carefully measured metric that the chain uses, along with other assessments, to grade its pharmacies and rank them against one another, records and interviews show.

Several current or former CVS pharmacists criticized the practice, saying it pressures them to focus more on corporate criteria than on drug interactions and other safety checks.

"You get stressed, and it takes your mind away from the actual prescriptions," said Chuck Zuraitis, head pharmacist at a CVS in south suburban Park Forest and a union steward for Teamsters Local 727, which represents 130 CVS pharmacists in the Chicago area. His pharmacy was not among those tested.

Performance and business metrics are common at big chain pharmacies and in other industries. Supporters say they make companies more efficient and responsive to customers.

In 2012, the nonprofit Institute for Safe Medication Practices conducted a national survey of 673 pharmacists and found that nearly two-thirds worked at stores that track the time it takes to fill prescriptions. About 25 percent worked at companies that guaranteed short wait times.

Of the pharmacists at stores that advertised quick service, 4 in 10 said they had made a medication error as a result of hurrying to fill a prescription within a set time.
In 2013, the National Association of Boards of Pharmacy called on states to prohibit, restrict or regulate company policies that measure the speed of pharmacists' work. But, the association says, little has changed in state law.

Internal CVS records obtained by the Tribune show that the company tracks numerous pharmacist tasks, including whether prescriptions are filled in the time promised to customers and whether voicemails are retrieved in a timely fashion.

"Every prescription is timed," said Deepak Chande, a former head pharmacist at a CVS in southwest suburban Worth, "and this is the worst of the pharmacist's nightmares."

If pharmacists fall behind, the backlog pops up in color on their computer screens, said Chande, also a former union steward. "It's an unreal pressure," he said. "Your mind is kind of frantically trying to obey it."

CVS officials declined to be interviewed about metrics but issued a statement and answered questions in writing. The company said prescriptions do not have to be filled quickly, but it expects pharmacists to have medications ready by the time promised to the customer.

Records show that head pharmacists receive a monthly "WeCARE Scorecard" that tracks the percentage of prescriptions filled by the times promised. The pharmacies are ranked by district, by region and nationwide.

CVS' computer system prioritizes prescriptions based on patients' requested pickup times, with preference given to customers with urgent needs — for instance, someone on his way home from the hospital after surgery. Pharmacists can reset a promised pickup time if they think it cannot be met, the company wrote.

The color indicators on computer screens are meant to help pharmacists with prioritizing their work, CVS said. The company also wrote that several years ago it removed a red indicator for prescriptions that had gone beyond the promised pickup time because pharmacists "felt the color red denoted something negative or alarming."

"We switched to an 'orange' indicator to inform a pharmacy team which prescriptions may not be ready before a customer's expected arrival time," CVS wrote.

Another CVS metric, documents show, tracks how many patients sign up for automatic refills. Zuraitis said posters on pharmacy walls record how many flu shots have been administered. "You feel like you're trying to sell people something," he said.
CVS said automatic refills help patients stay on schedule with the drugs they need to treat chronic conditions. The company said it measures the number of flu vaccinations offered to customers to help support the recommendation by the federal Centers for Disease Control and Prevention that people receive a flu shot annually.

At Walgreens, officials said the company collects business metrics as a way to monitor staffing levels and service. The firm said it does not use them in a manner that emphasizes productivity over patient safety.

Alethea Little, a Walgreens pharmacist in west suburban Forest Park who properly warned a tester, said metrics are no excuse for missing drug interactions.

"Our flu shot goal is 10 a day, 12 a day, 50 a day," she said. "And the phone rings off the hook. You just got to do what you got to do, essentially."

**Squeezed by chains**

Independent pharmacies face a different kind of pressure: intense competition from the big chains.

B.M. Patel, a pharmacist for 40 years who owns Riteway Pharmacy on Chicago's Northwest Side, missed the test interaction but didn't make excuses. "It was a mistake," he said. "Maybe I should be paying more attention."

But he also said small pharmacies know that if they don't fill a prescription, the customer might simply go to a nearby chain store. Business at his store, he said, "is not good. I can still survive, but not too long. We don't really know how long it's going to last."

The number of independent stores has been shrinking nationwide. In Illinois, the number dropped about 9 percent from 689 in 2013 to 624 last year, according to the National Community Pharmacists Association.

Several independents tested by the Tribune looked like classic drugstores, offering medications alongside greeting cards, stuffed animals and candy bars. Others were less inviting. One dispensed drugs behind a thick window; at another, a reporter had to knock several times to gain entry.
In Chicago's Pilsen neighborhood, independent pharmacist Audrey Galal passed her test while working at a Mexicare Pharmacy, a small storefront on a block of brick buildings. The store is in the process of closing, she said, in part because of competition from chains.

Galal said she did not think small drugstores would knowingly sell harmful medications, but they might be reluctant to turn away business.

"These pharmacists are acting like businesspeople, just trying to keep their pharmacies afloat instead of being clinicians," said Galal, who now works at a Mexicare in Little Village.

Andy Politis, a pharmacist and part owner of Oakmill Pharmacy in north suburban Niles who passed the test, said he was surprised how many independents failed. "The independent guys should be better because they don't have the same pressure as the big stores with so many prescriptions," he said.

B. Douglas Hoey, chief executive of the national community pharmacists group, said the results were alarming. "It's something that shouldn't happen — both for chains and independents," he said. "Even one is too many."

Several independents said the findings prompted them to make changes. After failing its test, Summit Medical Pharmacy in the southwest suburbs beefed up internal checks and worked with a software company to ensure that even minor drug interactions are detected.

Since then, the new system has flagged several interactions that led to consultations with doctors and patients, head pharmacist Pankaj Bhalakia said.

"We changed the whole system," he said. "I don't think there could be a problem in the future."

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**Major pharmacy chains vow safety improvements**
In response to the Tribune tests, some of the nation's largest pharmacy chains said they would take significant steps to improve patient safety.

CVS

CVS said it will change its policies and computer system to require pharmacists to call the prescribing doctor or warn the patient when a serious drug interaction is flagged. Those changes will apply to the chain's 30,000 pharmacists at its 9,600 drugstores.

Currently, CVS allows pharmacists to override computer alerts if they review the warning and accompanying medical literature and conclude the prescription is appropriate. In the future, the system will not allow pharmacies to dispense certain flagged medications unless the pharmacists document in the computer that they have called the doctor or counseled the patient.

CVS said its pharmacists will undergo a comprehensive training and certification program on the new rule, to be implemented early next year. The rule will apply to other safety issues, such as drug-allergy interactions, duplicative therapies and orders involving unusually high or low doses, later in the year.

To reduce "alert fatigue," CVS said it will work with its database providers to streamline alerts to help ensure that pharmacists are presented with the most important warnings.

In addition, CVS said it will change its approach to the "offer to counsel." Throughout the industry, pharmacists often address a legal requirement that pharmacies must offer to counsel patients by having staff ask customers at checkout, "Do you have any questions for the pharmacist today?" or sometimes simply, "Any questions?" CVS said it will require a more robust and explanatory communication.

CVS said the new wording has not been finalized but that the company's 50,000 technicians will be trained in the new policy.

Walgreens

Walgreens said it will provide additional training on drug interactions for its 27,000 pharmacists at its 8,175 U.S. drugstores, including the 222 pharmacies in the New York metropolitan area under the Duane Reade banner. A pharmacy staff meeting on drug interactions will be held chainwide.

To give pharmacists more time to help patients, Walgreens said it is accelerating efforts to move administrative tasks out of stores and to a centralized office.
Walgreens also said it has notified staffers of relevant policies and procedures, including that pharmacists should always counsel patients on new prescriptions.

**Wal-Mart**

Wal-Mart said it will update and improve its pharmacy alert system. Once that process is completed, the company's pharmacy operating manual will be amended accordingly, and Wal-Mart's 16,000 pharmacists at 4,500 stores will be required to undergo computer-based training on the changes.

The company also said it will send a notification to all of its pharmacists reminding them of best practices in terms of identifying drug interactions and warning patients. Wal-Mart said it will reinforce that pharmacists should counsel all patients filling new prescriptions.

**Kmart**

Kmart said it is reviewing its policies, computer systems and training programs relevant to its 528 pharmacies.

The company said it is also studying whether to bolster the way it approaches the "offer to counsel" and whether to require new customers to fill out medication forms to help staff detect drug interactions.

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This 'attr(data-c-typename)' is related to: Drug Research, Drugs and Medicines, Medical Research
Wednesday January 18, 2017
2:00 pm Annual Meeting with the Schools

#D9 STLCoP/UMKC Pharmacy Annual School Review and Meeting
DISCUSSION REQUESTED: In July 2016, the federal Department of Health & Human Services enacted a non-discrimination rule that would be applicable to most pharmacies. APhA summaries of the new rule requirements are included in the agenda. The office has been asked what the Board’s enforcement position is or will be. Staff is requesting additional guidance.
Nondiscrimination: New HHS regulation affects pharmacies

RACHEL BALICK

A final rule issued by the federal government may allow civil lawsuits against pharmacies that deny language assistance services to patients with limited English proficiency or refuse to treat patients in a manner consistent with their gender identity. The U.S. Department of Health & Human Services (HHS) rule is aimed at advancing health equity and reducing disparities in health care.

The rule, which implements Section 1557 of the Affordable Care Act (ACA), requires health care entities receiving federal financial assistance—such as those that accept Medicaid and Medicare—to engage in certain practices to prevent discrimination on the basis of age, race, color, nationality, or gender, including gender identity. It also applies to programs that HHS itself administers and health plans sold in the marketplace.

The rule's effective date is July 18, 2016, and includes additional deadlines in October and December.

Gender identity

Section 1557 has the distinction of being the first federal rule to prohibit discrimination on the basis of gender identity in federally funded health programs. Previous civil rights laws enforced by HHS's Office for Civil Rights (OCR) broadly barred discrimination only if based on race, color, national origin, disability, or age. Gender identity discrimination includes refusal to dispense transition-related medications.

HHS clarifies that, in addition to gender identity, discrimination based on pregnancy and sex stereotyping qualifies as sex discrimination.

Enhanced communication

At the heart of the rule are requirements that pharmacies take reasonable steps to provide meaningful access to language services to individuals with limited English proficiency or a disability, particularly people who are blind or deaf. The rule includes a requirement that pharmacies display posters informing patients that the pharmacy will offer language assistance to patients who need it. HHS will make the notices translated into several languages available online to ease costs and facilitate compliance.

“The most problematic part of the provision has to do with how we communicate with patients who speak other languages,” Theresa Tolle, BSPharm, FAPhA, Speaker of the APhA House of Delegates, told Pharmacy Today. Tolle is the owner and chief pharmacist of Bay Street Pharmacy in Sebastian, FL. “I am not yet certain how my pharmacy will comply with this part of the regulation and what the costs might be to provide a service that allows for an interpreter,” she added.

Liability exposure

Individuals who pursue civil actions based on Section 1557 can now use the rule's requirements to help prove that a health care entity discriminated against them, which could expose pharmacies to liability for actions that previously may not have been found discriminatory. The burden is on the plaintiff, however, to prove that services were denied due to discrimination—not simply that the pharmacy failed to provide them. Patients also have the option to submit reports of civil rights violations to the Office for Civil Rights at www.hhs.gov/ocr.

“I think that many pharmacy owners and small business owners will be caught off guard by this new regulation and may struggle to meet all of the requirements,” Tolle told Today. But compliance difficulties do not necessarily indicate unwillingness. “Of course, I would think that most small businesses would do many of the things required in this regulation to accommodate their customers, but prior to this regulation they were not required to do so,” she said.

“APhA strongly encourages pharmacists to develop a language access plan and discuss cost-saving strategies with their colleagues.”

Next steps for pharmacies

The rule suggests—but does not require—that pharmacies develop language access plans to improve compliance and increase access to language services. It's not a safe harbor from the rule, but having such a plan will weigh favorably in the event of a discrimination complaint or an investigation into whether the entity has taken reasonable steps to provide meaningful access.

“APhA strongly encourages pharmacists to develop a language access plan and discuss cost-saving strategies with their colleagues,” said Jenna Ventresca, JD, APhA Associate Director for Health Policy. “Doing so will help satisfy the rule’s requirements and improve health equity, which will improve patient care.”
New Federal Nondiscrimination Regulation Imposes Requirements on Pharmacies

On May 18, HHS and its Office of Civil Rights released the Nondiscrimination in Health Programs and Activities Final Rule. According to HHS, under the Rule, individuals are protected from discrimination in health coverage and care on the basis of race, color, national origin, age, disability and sex, including discrimination based on pregnancy, gender identity and sex stereotyping. In addition to implementing Section 1557 of the Affordable Care Act’s prohibition on sex discrimination, the Final Rule also enhances language assistance for people with limited English proficiency and helps to ensure effective communication for individuals with disabilities. This regulation is applicable health care entities and providers receiving federal funds from HHS, such as health insurers, hospitals, physicians and pharmacies. Most of the provisions relevant to pharmacies take effect on July 18, 2016.

Compliance and Notice Requirements. The Final Rule requires entities to file an assurance of compliance (form HHS-690) as a condition of any application for Federal financial assistance1 and to take continuous steps to notify the public regarding the following: (1) the entity does not discriminate; (2) the entity can provide free services and materials for those with limited English proficiency or a disability; (3) how to obtain aids and services; (4) contact method for the employee responsible for compliance; (5) the availability of a grievance procedure; and (6) OCR’s contact information for discrimination complaints. Posting of such information must be in conspicuous physical locations, on entities’ websites and in significant public communications. Translated resources made available by HHS for the purpose of satisfying notice requirements are available here.

Individuals with Limited English Proficiency (LEP). Covered entities must take reasonable steps to provide meaningful access for each LEP individual eligible to be served or likely encountered. The Proposed Rule listed relevant factors to consider when determining whether language obligations have been satisfied. The Final Rule only specifies one relevant factor - whether or not the entity had an effective and appropriate written language access plan. Although such a plan is not explicitly required by the Final Rule, APhA strongly encourages pharmacies to develop such plans to establish a framework to provide health care and services non-discriminatorily and the reasonable steps that will be taken to provide access to persons with LEP. HHS notes that substantial weight will be given to the nature and importance of the

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1 Nondiscrimination in Health Programs and Activities; Final Rule, 42 C.F.R. 92, §92.4 (2016) stating. “Federal financial assistance. (1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal government provides or otherwise makes available assistance in the form of: (i) Funds; (ii) Services of Federal personnel; or (iii) Real and personal property or any interest in or use of such property, including: (A) Transfers or leases of such property for less than fair market value or for reduced consideration; and (B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal government. (2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including all tax credits under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health-related insurance coverage for payment to or on behalf of an individual obtaining health related insurance coverage from that entity or extended by the Department directly to such individual for payment to any entity providing health-related insurance coverage.”

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program or activity and the particular communication in relation to whether language obligations have been satisfied.

The Final Rule reiterates that covered entities may not rely on family members, friends, and minor children to provide interpretation services. In addition, the Final Rule describes the skills needed for on-site staff able to provide interpretive services (i.e. qualified bilingual/multilingual staff standard). The Final Rule provides exceptions to these prohibitions, clarifies that the individual with LEP is not required to accept language assistance services and encourages staff to record when language assistance services were offered and denied.

The Final Rule does not set thresholds for the number of languages assistance services that must be provided but does set a threshold for taglines — short statements written in non-English languages that indicate the availability of language assistance services free of charge. Covered entities must supply taglines in at least the top 15 languages spoken by limited English proficient populations statewide.

Individuals with disabilities. Covered entities must provide effective communications with individuals with disabilities and must adhere to federal law and standards of Title II of the Americans with Disabilities Act (ADA), which are more stringent standard. Under the Final Rule, covered entities must provide auxiliary aids and services to individuals with impaired sensory, manual or speaking skills, and certain facilities will need to conform for ADA 2010 accessible design standards. The rule does not adopt specific technology standards but does require covered entities to ensure that programs and activities provided in electronic or information technology are accessible to individuals with disabilities unless doing so would pose undue financial/administrative burden and would result in a fundamental alteration in the nature of the program or activity. If such conditions occur, the entity must provide information in another format that strives to ensure that individuals with disabilities have access to the services or benefits.

Sexual Orientation. The proposed rule does not resolve whether there is a prohibition of discrimination based on sexual orientation, but OCR will evaluate sexual orientation discrimination complaints to determine whether they involve discriminatory stereotyping of sexual attraction or behavior.

Exceptions to the discrimination rule. The proposed rule does not answer whether an exception exists for discrimination rooted in religious beliefs.

Enforcement. OCR will enforce section 1557 using the procedures detailed in Title VI of the Civil Rights Act. However, the procedures of the Age Act will be used in issues regarding

Language assistance services may include, but are not limited to:
(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;
(2) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English; and
(3) Taglines.

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age discrimination. Covered entities must provide OCR with requested information in a timely manner or be at risk of being found in noncompliance. In such circumstances, OCR can apply enforcement tools, including suspension or termination of funding. Although OCR has discretion when evaluating efforts entities have taken to maintain and achieve compliance, good faith attempts are not a defense.

In addition to OCR’s authority, individuals may sue directly under section 1557 in federal court, and compensatory damages are available in such actions.

**Discrimination by insurers and in employee health benefit programs.** The proposed rule also addresses discrimination by insurers and employee health benefit programs.

**More information regarding the Final Rule is available here.**

**Summary of Key Requirements Affecting Pharmacies:**

*The compliance date of the below requirements is July 18, 2016 unless otherwise noted.*

1. **Designation of responsible employee** (only if the covered entity has 15 or more employees)
   - Must designate at least one employee to coordinate its efforts to comply with and carry out Section 1557 and this regulation’s requirements, including investigation of any grievance or allegation that action would be prohibited by Section 1557 or this regulation
   - **Tip:** Pharmacies that have a designated employee to satisfy standards under Section 504 or Title IX may use that individual to comply with Section 1557

2. **Adoption of grievance procedures** (only if the covered entity has 15 or more employees)
   - Must adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this regulation
   - **Tip:** Pharmacies that have a grievance procedure to satisfy standards under Section 504 may use that procedure to address disability claims under Section 1557 and all other Section 1557 claims, provided that the entity modifies the procedure to apply to race, color, national origin sex, and age discrimination
   - **Resource:** Example of a Section 504 grievance procedure that incorporates due process standards ([http://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/section-504-grievance-procedure/index.html](http://www.hhs.gov/civil-rights/for-providers/clearance-medicare-providers/section-504-grievance-procedure/index.html))

3. **File assurance of compliance form when applying for federal funding**
   - Will be revised to include all civil rights law which covered entities must comply

4. **Training** (encouraged, not required)
   The information in this document is for informational purposes only and should not be construed as legal advice or opinion.
- Covered entities are encouraged, but **not required**, to train employees periodically on compliance with Section 1557. In the assumptions of the proposed rule, used to determine cost, it assumes that employers are most likely to train employees who interact with the public which is estimated to be 50% of employees. Pharmacists are included in the pool of staff anticipated to need training.

- **Useful resource:** To facilitate training that covered entities choose to provide, OCR will make available a training curriculum, and will engage in outreach and technical assistance to promote understanding of and compliance with the final rule (as of 5/25 this resource has not been made available).

5. **Notices of nondiscrimination (a), taglines (b), and significant publications and communications (c & d)** [Pharmacies must comply within 90 days of the rule’s July 18 effective date]:
   
   a. **Notice of nondiscrimination:** Must be placed in conspicuous **physical locations** where the entity interacts with the public (i.e. in store) and in a conspicuous location on the covered entity’s website accessible from the home page of the covered entity’s website – the notice posting must adhere to the following:
      
      (1) the covered entity does not discriminate on the basis of race, color, national origin, sex, age or disability in its health programs and activities;
      (2) the covered entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;
      (3) the covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;
      (4) how to obtain aforementioned aids and services;
      (5) an identification of, and contact information for, the responsible employee (required if there are 15 or more employees);
      (6) the availability of a grievance procedure and how to file a grievance; and
      (7) how to file a discrimination complaint with OCR.

   b. **Taglines**: Must be in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States
      
      **Tagline example:** ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx).

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3 Taglines mean short statements written in non-English languages that indicate the availability of language assistance services free of charge.

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c. **Significant publications and significant communications** targeted to beneficiaries, enrollees, applicants, and members of the public (except those that are small-sized) posting must include:
   - Content: same as that of notices in physical locations/ website
   - Taglines: same as that of physical locations

d. **Significant publications and significant communications that are small-sized** (e.g., postcards and tri-fold brochures) posting must include in a conspicuously visible font-size:
   (1) Non-discrimination statement (the covered entity does not discriminate on the basis of race, color, national origin, sex, age or disability in its health programs and activities)
   (2) Taglines: In at least the top two languages spoken by individuals with limited English proficiency of the relevant State or States.

**Tip:** A covered entity may combine the notice’s content with the content of other notices if the combined notice clearly informs individuals of their civil rights under Section 1557 and this regulation.

**Resource:** Translated materials for covered entities ([http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html](http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html)): includes a sample notice of nondiscrimination, statement of nondiscrimination and taglines, all translated into various languages and developed for compliance with the regulation.

6. **Take reasonable steps to provide meaningful access, free of charge and in a timely manner, for individuals with limited English proficiency to each individual with limited English proficiency eligible to be served or likely encountered in its health programs and activities**
   - Must be provided free of change, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency
   - Specific requirements for interpreter and translation services (required if it is a reasonable step)
     - Offer a qualified interpreter\(^4\) to an individual with limited English proficiency
     - Use a qualified translator\(^5\) when translating written content in paper or electronic form

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\(^4\) Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:
(1) Adheres to generally accepted interpreter ethics principles, including client confidentiality;
(2) has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language; and
(3) is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

\(^5\) Qualified translator means a translator who:
(1) Adheres to generally accepted translator ethics principles, including client confidentiality;Show citation box
(2) has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language; and
(3) is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

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- Restrictions: Covered entity cannot:
  - Require a LEP individual to provide his/her own interpreter
  - Rely on an adult accompanying an individual with LEP to interpret or facilitate communication, exceptions are:
    i. Emergency involving imminent threat to safety of welfare of an individual or the public and no qualified interpreter is immediately available
    ii. Specific request from the LEP individual to have the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances
    iii. Rely on staff other than qualified bilingual/multilingual staff to communicate directly with LEP individuals
  - Additional requirements are listed for video remote interpreting services

- Language Access Plan: not required, but **APhA strongly encourages** covered entities to develop a language access plan to establish a framework to deliver health care and services non-discriminatorily and outline the reasonable steps that will be taken to provide access to persons with LEP

**Tip**: Although individuals with LEP are not required to accept language assistance services, covered entities should document when such services are offered and the patients refuses them


7. Take reasonable steps to provide meaningful access, free of charge and in a timely manner to provide effective communication for individuals with disability
   - A covered entity shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities

8. Must make accessible electronic and information technology programs or activities to individuals with disabilities unless there is undue financial and administrative burdens or a fundamental alteration in the nature of the health program or activity
   - Expectation to adapt: When undue financial and administrative burdens or a fundamental alteration exist, the covered entity must provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

9. Requirement to make reasonable modifications to policies, practices or procedures

The information in this document is for informational purposes only and should not be construed as legal advice or opinion.
A covered entity shall make reasonable modifications to policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term “reasonable modifications” shall be interpreted in a manner consistent with the term as set forth in the ADA Title II regulation at 28 CFR 35.130(b)(7).

10. Covered entities that were required to adhere to the 2010 ADA Standards for Accessible Design prior to July 18, 2016 must comply with those standards for new construction or alteration prior to July 18, 2016
   - If construction or alteration commenced on or after July 18, 2016: Must comply with 2010 ADA Standards for Accessible Design.
   - If a facility was not covered by the 2010 ADA Standards prior to July 18, 2016: Must now comply with the 2010 Standards if the construction was commenced after December 18, 2017 (18 months after the effective date of the Final Rule).
   - If a facility was constructed or altered in conformance with the 1991 Standards or the 2010 Standards: Will be deemed to comply with the requirements of this section and other relevant sections noted in the Final Rule.
   - If a facility was constructed or altered in accordance with the Uniform Federal Accessibility Standards (UFAS): Will be deemed compliance with this section only if construction or alteration was commenced before July 18, 2016 and the facility or part of the facility was not covered by standards under the ADA.
   - Note: According to the Final Rule “As nearly all covered entities under the final rule are already covered by the ADA standards, these changes impose a de minimis cost.”

11. Evaluation of compliance – the Director shall consider:
   - Nature and importance of the health program or activity and the particular communication at issue, to LEP individual
   - Other relevant factors, including whether a covered entity has developed and implemented an effective written language access plan, the is appropriate to its particular circumstances, to be prepared to meet the obligation of this section.

   Tip: A language access plan is not required, but APhA strongly encourages covered entities to develop a language access plan to establish a framework to provide health care and services non-discriminatorily and the reasonable steps that will be taken to provide access to persons with LEP

Part IV

Department of Health and Human Services

Office of the Secretary

45 CFR Part 92
Nondiscrimination in Health Programs and Activities; Final Rule


## TABLE 7—ACCOUNTING STATEMENT

<table>
<thead>
<tr>
<th>Category</th>
<th>Primary estimate</th>
<th>Low estimate</th>
<th>High estimate</th>
<th>Source</th>
</tr>
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<tbody>
<tr>
<td><strong>BENEFITS</strong></td>
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<tr>
<td>Qualitative Benefits (02)</td>
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<tr>
<td>Potential health improvements and longevity extensions as a result of reduced barriers to medical care for transgender individuals.</td>
<td></td>
<td></td>
<td></td>
<td>RIA</td>
</tr>
<tr>
<td><strong>COSTS</strong> (millions)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Annualized monetized</td>
<td>Covered entities train 40% of their employees on the new regulations</td>
<td>Covered entities train 60% of their employees on the new regulations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3%</td>
<td>192.5</td>
<td>177.0</td>
<td>208.1</td>
<td>RIA</td>
</tr>
<tr>
<td>7%</td>
<td>197.8</td>
<td>181.4</td>
<td>214.2</td>
<td>RIA</td>
</tr>
<tr>
<td>Non-quantified costs (02)</td>
<td>Costs of increased provision of health care services as a result of reduced barriers to access for transgender individuals.</td>
<td></td>
<td></td>
<td>RIA</td>
</tr>
<tr>
<td>Transfers (02)</td>
<td>Health insurance premium reductions for affected women, with offsetting increases for other premium payers in affected plans.</td>
<td></td>
<td></td>
<td>RIA</td>
</tr>
<tr>
<td>Effects on State and Local Governments (02)</td>
<td>$17.8 million costs in the first 2 years (training + enforcement)</td>
<td></td>
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<td>RIA</td>
</tr>
<tr>
<td>Effects on Small Entities (02)</td>
<td>Average of less than $1,000 per small entity per year</td>
<td></td>
<td></td>
<td>RFA</td>
</tr>
</tbody>
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### List of Subjects in 45 CFR Part 92

Administrative practice and procedure, Civil rights, Discrimination, Elderly, Health care, Health facilities, Health insurance, Health programs and activities, Individuals with disabilities, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Department of Health and Human Services adds 45 CFR part 92 as follows:

### PART 92—NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AGE, OR DISABILITY IN HEALTH PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE AND HEALTH PROGRAMS OR ACTIVITIES ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OR ENTITIES ESTABLISHED UNDER TITLE I OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

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Subpart A—General Provisions

§ 92.1 Purpose and effective date.

The purpose of this part is to implement Section 1557 of the Patient Protection and Affordable Care Act (ACA) (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. Section 1557 provides that, except as provided in Title I of the ACA, an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance or under any program or activity that is administered by an Executive Agency or any entity established under Title I of the ACA. This part applies to health programs or activities administered by recipients of Federal financial assistance from the Department, Title I entities that administer health programs or activities, and Department-administered health programs or activities. The effective date of this part shall be July 18, 2016, except to the extent that provisions of this part require changes to health insurance or group health plan benefit design (including covered benefits, benefits limitations or restrictions, and cost-sharing mechanisms, such as coinsurance, copayments, and deductibles), such provisions, as they apply to health insurance or group health plan benefit design, have an applicability date of the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2017.

§ 92.2 Application.

(a) Except as provided otherwise in this part, this part applies to every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity.

(b)(1) Exclusions to the application of the Age Discrimination Act of 1975, as set forth at 45 CFR 91.3(b)(1), apply to claims of discrimination based on age under Section 1557 or this part.

(2) Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.

(c) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 92.3 Relationship to other laws.

(a) Rule of interpretation. Neither Section 1557 nor this part shall be construed to apply a lesser standard for the protection of individuals from discrimination than the standards applied under Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, or the regulations issued pursuant to those laws.

(b) Other laws. Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals under Title VI of the Civil Rights Act of 1964, Title VII of the Civil Rights Act of 1964, the Architectural Barriers Act of 1968, Title IX of the Education Amendments of 1972, Sections 504 or 508 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, the Americans with Disabilities Act Amendments Act of 2008, or other Federal laws or to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.

§ 92.4 Definitions.

As used in this part, the term—


2010 Standards means the 2010 ADA Standards for Accessible Design, as defined at 28 CFR 35.104.


Age means how old an individual is, or the number of elapsed years from the date of an individual’s birth.


Applicant means an individual who applies to participate in a health program or activity.

Auxiliary aids and services include:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.303(b); note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; listening systems; telephones compatible with hearing aids; closed caption decoders; open captioning and closed captioning, including real-time captioning; voice, text, and video-based telecommunication products and systems, text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotelephonic displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing.

(2) Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs; large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials accessible to individuals who are blind or have low vision.

(3) Acquisition or modification of equipment and devices;

(4) Other similar services and actions.

Covered entity means:

(1) An entity that operates a health program or activity, any part of which receives Federal financial assistance;

(2) An entity established under Title I of the ACA that administers a health program or activity; and

(3) The Department.
Department means the U.S. Department of Health and Human Services.

Director means the Director of the Office for Civil Rights (OCR) of the Department.

Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the ADA, 42 U.S.C. 12102, as amended. Where this part cross-references regulatory provisions that use the term “handicap,” “handicap” means “disability” as defined in this section.

Electronic and information technology means the same as “electronic and information technology,” or any term that replaces “electronic and information technology,” as it is defined in 36 CFR 1194.4.

Employee health benefit program means:

(1) Health benefits coverage or health insurance coverage provided to employees and/or their dependents established, operated, sponsored or administered by, for, or on behalf of one or more employers, whether provided or administered by entities including but not limited to an employer, group health plan (as defined in the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1191(b)(1)), third party administrator, or health insurance issuer.

(2) An employer-provided or employer-sponsored wellness program;

(3) An employer-provided health clinic; or

(4) Long term care coverage or insurance provided or administered by an employer, group health plan, third party administrator, or health insurance issuer for the benefit of an employer’s employees.

Federal financial assistance. (1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal government provides or otherwise makes available assistance in the form of:

(i) Funds;

(ii) Services of Federal personnel; or

(iii) Real and personal property or any interest in or use of such property, including:

(A) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(B) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal government.

(2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including all tax credits under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health-related insurance coverage for payment to or on behalf of an individual obtaining health-related insurance coverage from that entity or extended by the Department directly to such individual for payment to any entity providing health-related insurance coverage.

 Federally-facilitated MarketplaceSM means the same as “Federally-facilitated Exchange” defined in 45 CFR 155.20.

Gender identity means an individual’s internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual’s sex assigned at birth. The way an individual expresses gender identity is frequently called “gender expression,” and may or may not conform to social stereotypes associated with a particular gender. A transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth. Health Insurance MarketplaceSM means the same as “Exchange” defined in 45 CFR 155.20.

Health program or activity means the provision or administration of health-related services, health-related insurance coverage, or other health-related coverage, and the provision of assistance to individuals in obtaining health-related services or health-related insurance coverage. For an entity principally engaged in providing or administering health services or health insurance coverage or other health coverage, all of its operations are considered part of the health program or activity, except as specifically set forth otherwise in this part. Such entities include a hospital, health clinic, group health plan, health insurance issuer, physician’s practice, community health center, nursing facility, residential or community-based treatment facility, or other similar entity. A health program or activity also includes all of the operations of a State Medicaid program, a Children’s Health Insurance Program, and the Basic Health Program.

HHS means the U.S. Department of Health and Human Services.

Individual with a disability means any individual who has a disability as defined for the purpose of Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 705(20)(B)–(F), as amended. Where this part cross-references regulatory provisions applicable to a “handicapped individual,” “handicapped individual” means “individual with a disability” as defined in this section.

Individual with limited English proficiency means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English.

Language assistance services may include, but are not limited to:

(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;

(2) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English; and

(3) Taglines.

National origin includes, but is not limited to, an individual’s, or his or her ancestor’s, place of origin (such as country or world region) or an individual’s manifestation of the physical, cultural, or linguistic characteristics of a national origin group.

On the basis of sex includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.

Qualified bilingual/multilingual staff means a member of a covered entity’s workforce who is designated by the covered entity to provide oral language assistance as part of the individual’s current, assigned job responsibilities and who has demonstrated to the covered entity that he or she:

(1) Is proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology, and

(2) Is able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.
Qualified individual with a disability means, with respect to a health program or activity, an individual with a disability who, with or without reasonable modifications to policies, practices, or procedures, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of aids, benefits, or services offered or provided by the health program or activity.

Qualified interpreter for an individual with a disability: (1) A qualified interpreter for an individual with a disability means an interpreter who via a remote interpreting service or an on-site appearance:

(i) Adheres to generally accepted interpreter ethics principles, including client confidentiality; and
(ii) is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, terminology and phraseology.

(2) For an individual with a disability, qualified interpreters can include, for example, sign language interpreters, oral translators (individuals who represent or spell in the characters of another alphabet), and cued language translators (individuals who represent or spell by using a small number of handshapes).

Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:

(1) Adheres to generally accepted interpreter ethics principles, including client confidentiality;

(2) has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language; and

(3) is able to interpret effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

Qualified translator means a translator who:

(1) Adheres to generally accepted translator ethics principles, including client confidentiality;

(2) has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language; and

(3) is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

Reciprocal means any State or its political subdivision, or any instrumentality of a State or its political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, to whom Federal financial assistance is extended directly or through another recipient and which operates a health program or activity, including any subunit, successor, assignee, or transferee of a recipient.


Section 1557 means Section 1557 of the ACA (42 U.S.C. 18116).

Sex stereotypes means stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics. These stereotypes can include the expectation that individuals will consistently identify with only one gender and that they will act in conformity with the gender-related expressions stereotypically associated with that gender. Sex stereotypes also include gendered expectations related to the appropriate roles of a certain sex.

State-based MarketplaceSM means a Health Insurance MarketplaceSM established by a State pursuant to 45 CFR 155.100 and approved by the Department pursuant to 45 CFR 155.105.

Taglines mean short statements written in non-English languages that indicate the availability of language assistance services free of charge.

Title I entity means any entity established under Title I of the ACA, including State-based Marketplaces and Federally-facilitated Marketplaces.


§92.5 Assurances required.

(a) Assurances. An entity applying for Federal financial assistance to which this part applies shall, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director, that if the entity’s health programs and activities will be operated in compliance with Section 1557 and this part.

(1) Individuals who are no longer participants in the recipient’s or State-based MarketplaceSM’s health program or activity but who were participants in the health program or activity that such discrimination occurred; or

(ii) Individuals who would have been participants in the health program or
activity had the discrimination not occurred.

(b) Voluntary action. A covered entity may take steps, in addition to any action that is required by Section 1557 or this part, to overcome the effects of conditions that result or resulted in limited participation in the covered entity’s health programs or activities by individuals on the basis of race, color, national origin, sex, age, or disability.

§ 92.7 Designation of responsible employee and adoption of grievance procedures.

(a) Designation of responsible employee. Each covered entity that employs 15 or more persons shall designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under Section 1557 and this part, including the investigation of any grievance communicated to it alleging noncompliance with Section 1557 or this part or alleging any action that would be prohibited by Section 1557 or this part. For the Department, including the Federally-facilitated Marketplaces, the Director will be deemed the responsible employee under this section.

(b) Adoption of grievance procedures. Each covered entity that employs 15 or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by Section 1557 or this part. For the Department, including the Federally-facilitated Marketplaces, the procedures for addressing complaints of discrimination on the grounds covered under Section 1557 or this part will be deemed grievance procedures under this section.

§ 92.8 Notice requirement.

(a) Each covered entity shall take appropriate initial and continuing steps to notify beneficiaries, enrollees, applicants, and members of the public of the following:

(1) The covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities;

(2) The covered entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;

(3) The covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;

(4) How to obtain the aids and services in paragraphs (a)(2) and (3) of this section;

(5) An identification of, and contact information for, the responsible employee designated pursuant to § 92.7(a), if applicable;

(6) The availability of the grievance procedure and how to file a grievance, pursuant to § 92.7(b), if applicable; and

(7) How to file a discrimination complaint with OCR in the Department.

(b) Within 90 days of the effective date of this part, each covered entity shall:

(1) As described in paragraph (f)(1) of this section, post a notice that conveys the information in paragraphs (a)(1) through (7) of this section; and

(2) As described in paragraph (g)(1) of this section, if applicable, post a nondiscrimination statement that conveys the information in paragraph (a)(1) of this section.

(c) For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, the content of a sample notice that conveys the information in paragraphs (a)(1) through (7) of this section, and the content of a sample nondiscrimination statement that conveys the information in paragraph (a)(1) of this section, in English and in the languages triggered by the obligation in paragraph (d)(1) of this section.

(d) Within 90 days of the effective date of this part, each covered entity shall:

(1) As described in paragraph (f)(1) of this section, post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States; and

(2) As described in paragraph (g)(2) of this section, if applicable, post taglines in at least the top two languages spoken by individuals with limited English proficiency of the relevant State or States.

(e) For use by covered entities, the Director shall make available, electronically and in any other manner that the Director determines appropriate, taglines in the languages triggered by the obligation in paragraph (d)(1) of this section.

(f)(1) Each covered entity shall post the notice required by paragraph (a) of this section and the taglines required by paragraph (d)(1) of this section in a conspicuously-visible font size:

(i) In significant publications and significant communications targeted to beneficiaries, enrollees, applicants, and members of the public, except for significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures;

(ii) In conspicuous physical locations where the entity interacts with the public; and

(iii) In a conspicuous location on the covered entity’s Web site accessible from the home page of the covered entity’s Web site.

(2) A covered entity may also post the notice and taglines in additional publications and communications.

(g) Each covered entity shall post, in a conspicuously-visible font size, in significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures:

(1) The nondiscrimination statement required by paragraph (b)(2) of this section; and

(2) The taglines required by paragraph (d)(2) of this section.

(h) A covered entity may combine the content of the notice required in paragraph (a) of this section with the content of other notices if the combined notice clearly informs individuals of their civil rights under Section 1557 and this part.

Subpart B—Nondiscrimination Provisions

§ 92.101 Discrimination prohibited.

(a) General. (1) Except as provided in Title I of the ACA, an individual shall not, on the basis of race, color, national origin, sex, age, or disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which this part applies.

(2) This part does not apply to employment, except as provided in § 92.208.

(b) Specific discriminatory actions prohibited. Under any health program or activity to which this part applies:

(1)(i) Each covered entity must comply with the regulation implementing Title VI, at § 80.3(b)(1) through (6) of this subchapter.

(ii) No covered entity shall, on the basis of race, color, or national origin, aid or perpetuate discrimination against any person by providing significant assistance to any entity or person that discriminates on the basis of race, color, or national origin in providing any aid, benefit, or service to beneficiaries of the covered entity’s health program or activity.
(2)(i) Each recipient and State-based MarketplaceSM must comply with the regulation implementing Section 504, at §§ 84.4(b), 84.21 through 84.23(b), 84.31, 84.34, 84.37, 84.38, and 84.41 through 84.52(c) and 84.53 through 84.55 of this subchapter. Where this paragraph cross-references regulatory provisions that use the term “recipient,” the term “recipient or State-based MarketplaceSM” shall apply in its place.

(ii) The Department, including the Federally-facilitated Marketplaces, must comply with the regulation implementing Section 504, at §§ 85.21(b), 85.41 through 85.42, and 85.44 through 85.51 of this subchapter.

(iii) Each covered entity may not, directly or through contractual or other arrangements, utilize criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals on the basis of sex.

(iv) In determining the site or location of a facility, a covered entity may not make selections that have the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs to which this regulation applies, on the basis of sex; or with the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals on the basis of sex.

(v) A covered entity may operate a sex-specific health program or activity (a health program or activity that is restricted to members of one sex) only if the covered entity can demonstrate an exceedingly persuasive justification, that is, that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective.

(4)(i) Each covered entity must comply with the regulation implementing the Age Act, at § 91.11(b) of this subchapter.

(ii) No covered entity shall, on the basis of age, aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person that discriminates on the basis of age in providing any aid, benefit, or service to beneficiaries of the covered entity’s health program or activity.

(5) The enumeration of specific forms of discrimination in this paragraph does not limit the generality of the prohibition in paragraph (a) of this section.

(c) The exceptions applicable to Title VI apply to discrimination on the basis of race, color, or national origin under this part. The exceptions applicable to Section 504 apply to discrimination on the basis of disability under this part. These provisions are found at §§ 80.3(d), 84.4(c), 85.21(c), 91.12, 91.15, and 91.17–18 of this subchapter.

(d) Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), and (b)(4), and paragraph (c) of this section use the term “recipient,” the term “covered entity” shall apply in its place. Where the regulatory provisions referenced in paragraphs (b)(1), (b)(3), and (b)(4) and paragraph (c) of this section use the terms “program or activity” or “program” or “education program,” the term “health program or activity” shall apply in their place.

Subpart C—Specific Applications to Health Programs and Activities

§ 92.201 Meaningful access for individuals with limited English proficiency.

(a) General requirement. A covered entity shall take reasonable steps to provide meaningful access to each individual with limited English proficiency eligible to be served or likely to be encountered in its health programs and activities.

(b) Evaluation of compliance. In evaluating whether a covered entity has met its obligation under paragraph (a) of this section, the Director shall:

(1) Evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the individual with limited English proficiency; and

(2) Take into account other relevant factors, including whether a covered entity has developed and implemented an effective written language access plan, that is appropriate to its particular circumstances, to be prepared to meet its obligations in § 92.201(a).

(c) Language assistance services requirements. Language assistance services required under paragraph (a) of this section must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency.

(d) Specific requirements for interpreter and translation services. Subject to paragraph (a) of this section:

(1) A covered entity shall offer a qualified interpreter to an individual with limited English proficiency when oral interpretation is a reasonable step to provide meaningful access for that individual with limited English proficiency; and

(2) A covered entity shall use a qualified translator when translating written content in paper or electronic form.

(e) Restricted use of certain persons to interpret or facilitate communication. A covered entity shall not:

(1) Require an individual with limited English proficiency to provide his or her own interpreter;

(2) Rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(3) Where the individual with limited English proficiency specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances;

(4) Rely on staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency.

(f) Video remote interpreting services. A covered entity that provides a qualified interpreter for an individual with limited English proficiency through video remote interpreting services in the covered entity’s health programs and activities shall provide:

(1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(2) A sharply delineated image that is large enough to display the interpreter’s
face and the participating individual’s face regardless of the individual’s body position;
(3) A clear, audible transmission of voices; and
(4) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the video remote interpreting.

(g) Acceptance of language assistance services is not required. Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services.

§ 92.202 Effective communication for individuals with disabilities.

(a) A covered entity shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in health programs and activities, in accordance with the standards found at 28 CFR 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term “public entity,” the term “covered entity” shall apply in its place.

(b) A recipient or State-based Marketplace shall provide appropriate auxiliary aids and services to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

§ 92.203 Accessibility standards for buildings and facilities.

(a) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace shall comply with the 2010 Standards as defined in § 92.4, if the construction or alteration was commenced after July 18, 2016. Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace in conformance with the 1991 Standards, as defined in § 92.4, shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction or alteration was commenced on or before July 18, 2016. Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State-based Marketplace in conformance with the Uniform Federal Accessibility Standards as defined in § 92.4, shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), cross-referenced in § 92.101(b)(2)(i) with respect to those facilities, if the construction was commenced before July 18, 2016 and such facility was not covered by the 1991 Standards or 2010 Standards.

§ 92.204 Accessibility of electronic and information technology.

(a) Covered entities shall ensure that their health programs or activities provided through electronic and information technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity shall provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through electronic and information technology.

(b) Recipients and State-based Marketplaces shall ensure that their health programs and activities provided through Web sites comply with the requirements of Title II of the ADA.

§ 92.205 Requirement to make reasonable modifications.

A covered entity shall make reasonable modifications to policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term “reasonable modifications” shall be interpreted in a manner consistent with the term as set forth in the ADA Title II regulation at 28 CFR 35.130(b)(7).

§ 92.206 Equal program access on the basis of sex.

A covered entity shall provide individuals equal access to its health programs or activities without discrimination on the basis of sex; and a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual’s sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.

§ 92.207 Nondiscrimination in health-related insurance and other health-related coverage.

(a) General. A covered entity shall not, in providing or administering health-related insurance or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, or disability.

(b) Discriminatory actions prohibited. A covered entity shall not, in providing or administering health-related insurance or other health-related coverage:
(1) Deny, cancel, limit, or refuse to issue or renew a health-related insurance plan or policy or other health-related coverage, or deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, or disability;
(2) Have or implement marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, or disability in a health-related insurance plan or policy, or other health-related coverage; or
(3) Deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other
limitations or restrictions on coverage, for any health services that are
ordinarily or exclusively available to
individuals of one sex, to a transgender
individual based on the fact that an
individual’s sex assigned at birth,
gender identity, or gender otherwise
recorded is different from the one to
which such health services are
ordinarily or exclusively available;
(4) Have or implement a categorical
coverage exclusion or limitation for all
health services related to gender
transition; or
(5) Otherwise deny or limit coverage,
deny or limit coverage of a claim, or
impose additional cost sharing or other
limitations or restrictions on coverage,
for specific health services related to
gender transition if such denial,
limitation, or restriction results in
discrimination against a transgender
individual.
(c) The enumeration of specific forms
of discrimination in paragraph (b) does
not limit the general applicability of the
prohibition in paragraph (a) of this
section.
(d) Nothing in this section is intended
to determine, or restrict a covered entity
from determining, whether a particular
health service is medically necessary or
otherwise meets applicable coverage
requirements in any individual case.
§ 92.208 Employer liability for
discrimination in employee health
benefit programs.
A covered entity that provides an
employee health benefit program to its
employees and/or their dependents
shall be liable for violations of this part
in that employee health benefit program
only when:
(a) The entity is principally engaged
in providing or administering health
services, health insurance coverage, or
other health coverage;
(b) The entity receives Federal
financial assistance a primary objective
of which is to fund the entity’s
employee health benefit program; or
(c) The entity is not principally
engaged in providing or administering
health services, health insurance
coverage, or other health coverage, but
operates a health program or activity,
which is not an employee health benefit
program, that receives Federal financial
assistance; except that the entity is
liable under this part with regard to the
provision or administration of employee
health benefits only with respect to the
employees in that health program or
activity.
§ 92.209 Nondiscrimination on the basis
of association.
A covered entity shall not exclude
from participation in, deny the benefits
of, or otherwise discriminate against an
individual or entity in its health
programs or activities on the basis of the
race, color, national origin, sex, age, or
disability of an individual with whom
the individual or entity is known or
believed to have a relationship or
association.
Subpart D—Procedures
§ 92.301 Enforcement mechanisms.
(a) The enforcement mechanisms
available for and provided under Title
VI of the Civil Rights Act of 1964, Title
IX of the Education Amendments of
1972, Section 504 of the Rehabilitation
Act of 1973, or the Age Discrimination
Act of 1975 shall apply for purposes of
Section 1557 as implemented by this part.
(b) Compensatory damages for
violations of Section 1557 are available
in appropriate administrative and
judicial actions brought under this rule.
§ 92.302 Procedures for health programs
and activities conducted by recipients
and State-based Marketplaces.
(a) The procedural provisions
applicable to Title VI apply with respect
to administrative enforcement actions
concerning discrimination on the basis
of race, color, national, origin, sex, and
disability discrimination under Section
1557 or this part. These procedures are
found at §§ 80.6 through 80.11 of this
subchapter.
(b) The procedural provisions
applicable to the Age Act apply with
respect to enforcement actions
concerning age discrimination under
Section 1557 or this part. These procedures are
found at §§ 91.41 through 91.51 of this
subchapter.
(c) When a recipient fails to provide
OCR with requested information in a
timely, complete, and accurate manner,
OCR may find noncompliance with
Section 1557 and initiate appropriate
enforcement procedures, including
beginning the process for fund
suspension or termination and taking
other action authorized by law.
(d) An individual or entity may bring
a civil action to challenge a violation of
Section 1557 or this part in a United
States District Court in which the
individual or entity is known or
believed to have a relationship or
association with us, such as:
• [Name of covered entity]:
  Provides free aids and services to people
  with disabilities to communicate effectively
  with us, such as:

Appendix A to Part 92—Sample Notice
Informing Individuals About
Nondiscrimination and Accessibility
Requirements and Sample
Nondiscrimination Statement:
Discrimination is Against the Law
[Name of covered entity] complies with
applicable Federal civil rights laws and does
not discriminate on the basis of race, color,
national origin, age, disability, or sex. [Name
of covered entity] does not exclude people or
treat them differently because of race, color,
national origin, age, disability, or sex.
[Name of covered entity]:
• Provides free aids and services to people
  with disabilities to communicate effectively
  with us, such as:
○ Qualified sign language interpreters
○ Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
○ Qualified interpreters
○ Information written in other languages
- If you need these services, contact [Name of Civil Rights Coordinator]

If you believe that [Name of covered entity] has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: [Name and Title of Civil Rights Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email]. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, [Name and Title of Civil Rights Coordinator] is available to help you.


Nondiscrimination statement for significant publications and signification communications that are small-size:

[Name of covered entity] complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.

Appendix B to Part 92—Sample Tagline Informing Individuals With Limited English Proficiency of Language Assistance Services

ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–xxx–xxxx–xxxx (TTY: 1–xxx–xxx–xxxx).

Appendix C to Part 92—Sample Section 1557 of the Affordable Care Act Grievance Procedure

It is the policy of [Name of Covered Entity] not to discriminate on the basis of race, color, national origin, sex, age or disability. [Name of Covered Entity] has adopted an internal grievance procedure providing for prompt and equitable resolution of complaints alleging any action prohibited by Section 1557 of the Affordable Care Act (42 U.S.C. 18116) and its implementing regulations at 45 CFR part 92, issued by the U.S. Department of Health and Human Services. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities. Section 1557 and its implementing regulations may be examined in the office of [Name and Title of Section 1557 Coordinator], [Mailing Address], [Telephone number], [TTY number—if covered entity has one], [Fax], [Email], who has been designated to coordinate the efforts of [Name of Covered Entity] to comply with Section 1557.

Any person who believes someone has been subjected to discrimination on the basis of race, color, national origin, sex, age or disability may file a grievance under this procedure. It is against the law for [Name of Covered Entity] to retaliate against anyone who opposes discrimination, files a grievance, or participates in the investigation of a grievance.

Procedure:

- Grievances must be submitted to the Section 1557 Coordinator within (60 days) of the date the person filing the grievance becomes aware of the alleged discriminatory action.
- A complaint must be in writing, containing the name and address of the person filing it. The complaint must state the problem or action alleged to be discriminatory and the remedy or relief sought.
- The Section 1557 Coordinator (or her/his designee) shall conduct an investigation of the complaint. This investigation may be informal, but it will be thorough, affording all interested persons an opportunity to submit evidence relevant to the complaint. The Section 1557 Coordinator will maintain the files and records of [Name of Covered Entity] relating to such grievances. To the extent possible, and in accordance with applicable law, the Section 1557 Coordinator will take appropriate steps to preserve the confidentiality of files and records relating to grievances and will share them only with those who have a need to know.
- The Section 1557 Coordinator will issue a written decision on the grievance, based on a preponderance of the evidence, no later than 30 days after its filing, including a notice to the complainant of their right to pursue further administrative or legal remedies.

The person filing the grievance may appeal the decision of the Section 1557 Coordinator by writing to the Administrator/Chief Executive Officer/Board of Directors/etc., within 60 days of receiving the Section 1557 Coordinator’s decision. The Administrator/Chief Executive Officer/Board of Directors/etc. shall issue a written decision in response to the appeal no later than 30 days after its filing.

The availability and use of this grievance procedure does not prevent a person from pursuing other legal or administrative remedies, including filing a complaint of discrimination on the basis of race, color, national origin, sex, age or disability in court or with the U.S. Department of Health and Human Services, Office for Civil Rights. A person can file a complaint of discrimination electronically through the Office for Civil Rights Complaint Portal, which is available at: https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201.

Complaint forms are available at: http://www.hhs.gov/ocr/office/file/index.html. Such complaints must be filed within 180 days of the date of the alleged discrimination. [Name of covered entity] will make appropriate arrangements to ensure that individuals with disabilities and individuals with limited English proficiency are provided auxiliary aids and services or language assistance services, respectively, if needed to participate in this grievance process. Such arrangements may include, but are not limited to, providing qualified interpreters, providing taped cassettes of material for individuals with low vision, or assuring a barrier-free location for the proceedings. The Section 1557 Coordinator will be responsible for such arrangements.


Sylvia M. Burwell,
Secretary.

[FR Doc. 2016–11458 Filed 5–13–16; 11:15 am]
BILLING CODE 4153–01–P
SECTION E – OPEN
Licensees Presently Under Discipline

- Pharmacists
- Pharmacies
- Drug Distributors
- Interns
- Pharmacy Technicians – Conditional Registration
- Pharmacy Technicians – Employment Disqualification List
## Licensees Presently Under Disciplinary Order

<table>
<thead>
<tr>
<th>Licensee</th>
<th>Action Taken</th>
<th>From/Through</th>
<th>Complaint</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goetze-Niemer Co., Inc.</td>
<td>Probation</td>
<td>08/19/2015 02/18/2017</td>
<td>2013-004431 Probation for eighteen (18) months. Repeat violations of products stored outside of the manufacturer's recommended temperature range. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
</tr>
<tr>
<td>Medisca Inc</td>
<td>Probation</td>
<td>09/10/2014 09/09/2017</td>
<td>2011-007123 Probation for three (3) years. Disciplinary action in other states; entered plea agreement in US District Court that between 2005 and 2007 it obtained human growth hormone from a source in China, relabeled it, introduced it into interstate commerce, and purported it was approved by the FDA. Section 338.055.2(5), (8), and (13), RSMo.</td>
</tr>
<tr>
<td>Medisca Inc</td>
<td>Probation</td>
<td>09/10/2014 09/09/2017</td>
<td>2011-007122 Probation for three (3) years. Disciplinary action in other states; entered plea agreement in US District Court that between 2005 and 2007 it obtained human growth hormone from a source in China, relabeled it, introduced it into interstate commerce, and purported it was approved by the FDA. Section 338.055.2(5), (8), and (13), RSMo.</td>
</tr>
<tr>
<td>Medisca Inc</td>
<td>Probation</td>
<td>09/10/2014 09/09/2017</td>
<td>2011-007093 Probation for three (3) years. Disciplinary action in other states; entered plea agreement in US District Court that between 2005 and 2007 it obtained human growth hormone from a source in China, relabeled it, introduced it into interstate commerce, and purported it was approved by the FDA. Section 338.055.2(5), (8), and (13), RSMo.</td>
</tr>
<tr>
<td>T L Corporation</td>
<td>Probation</td>
<td>01/24/2013 01/23/2017</td>
<td>2011-004178 Restricted license issued on Probation for four (4) years. Operated as a drug distributor without a license. Section 338.055.2(6), RSMo.</td>
</tr>
<tr>
<td>Lic Num/Licensee</td>
<td>DBA</td>
<td>Complaint</td>
<td>Action Taken</td>
</tr>
<tr>
<td>-----------------</td>
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</tr>
<tr>
<td>2008027645/Al-Lozi, Ala M</td>
<td></td>
<td>Suspension for 30 days followed by Probation for five (5) years. Diversion of controlled substances from employer without a valid prescription for herself. Section 338.055.2(5), (13), (15), and (17), RSMo.</td>
<td>10/24/2014 11/23/2014</td>
</tr>
<tr>
<td>2005033291/Baehr, Jennifer L</td>
<td></td>
<td>Suspension for one (1) year followed by Probation for five (5) years. While pharmacist-in-charge, misappropriated controlled substances from employer for personal use, impaired pharmacist, and pled guilty to Class C felony. Section 338.055.2(1), (2), (5), (6), (13), (15), and (17), RSMo.</td>
<td>12/02/2011 12/01/2012</td>
</tr>
<tr>
<td>1999141844/Baker, Jodie Jane</td>
<td></td>
<td>Two (2) years Suspension followed by three (3) years Probation. Violation of discipline involving failure to submit compliance reports to Board; failure to complete alcohol/drug treatment program and did not submit submit required documentation of such program; failure to call-in daily and did not submit to testing when selected by Board's urinalysis program. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>04/08/2014 04/07/2016</td>
</tr>
<tr>
<td>028642/Ballard, Bruce D</td>
<td></td>
<td>Probation for two (2) years. Violation of discipline involving dispensing errors. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>10/28/2015 10/27/2017</td>
</tr>
<tr>
<td>045170/Beckett, Abbey C</td>
<td></td>
<td>Suspended for thirty (30) days followed by Probation for five (5) years. As pharmacist-in-charge, misappropriated controlled substances from pharmacy for personal use, forged controlled substance prescriptions, failed to timely file loss reports, and entered deferred prosecution agreement regarding charges of Possession of a Controlled Substance, Stealing a Controlled Substance, and Fraudulently Attempting to Obtain a Controlled Substance. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo</td>
<td>04/27/2012 04/26/2017</td>
</tr>
<tr>
<td>043330/Berger, Randall M</td>
<td></td>
<td>Suspension for three (3) years, followed by probation for five (5) years. As pharmacist-in-charge, misappropriated controlled substances from employer and sold them to other individuals; pled guilty to one felony count of conspiring, combining, confederate and agreeing with other persons known and unknown, to distribute hydrocodone. Section 338.055.2(2), (5), (13), and (15), RSMo.</td>
<td>02/25/2011 10/31/2012</td>
</tr>
</tbody>
</table>

LICENSE EXPIRED 10/31/12, SUSPENSION TOLLED TILL RENEWS--1382 DAYS
### Licenses Presently Under Disciplinary Order

<table>
<thead>
<tr>
<th>Lic Num/Licensee</th>
<th>DBA</th>
<th>Complaint</th>
</tr>
</thead>
<tbody>
<tr>
<td>043330/Berger, Randall M</td>
<td></td>
<td>Suspension</td>
</tr>
<tr>
<td>043330/Berger, Randall M</td>
<td></td>
<td>Suspension for three (3) years, followed by probation for five (5) years. As pharmacist-in-charge, misappropriated controlled substances from employer and sold them to other individuals; pled guilty to one felony count of conspiring, combining, confederate and agreeing with other persons known and unknown, to distribute hydrocodone. Section 338.055.2(2), (5), (13), and (15), RSMo.</td>
</tr>
<tr>
<td>043330/Berger, Randall M</td>
<td></td>
<td>LICENSE EXPIRED 10/31/12, SUSPENSION TOLLED 10/31/12 to 7/28/14, SUSPENSION STARTED AGAIN 7/29/14 WHEN RENEWED. 482 SUSPENSION DAYS REMAIN.</td>
</tr>
<tr>
<td>043330/Berger, Randall M</td>
<td></td>
<td>Probation</td>
</tr>
<tr>
<td>2003026181/Broadbent, Carmen K</td>
<td></td>
<td>Probation</td>
</tr>
<tr>
<td>2003026181/Broadbent, Carmen K</td>
<td></td>
<td>03/07/2015 03/06/2018</td>
</tr>
<tr>
<td>2003026181/Broadbent, Carmen K</td>
<td></td>
<td>Probation for three (3) years. As pharmacist-in-charge, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
</tr>
<tr>
<td>027483/Buntin, William R</td>
<td></td>
<td>Suspension</td>
</tr>
<tr>
<td>027483/Buntin, William R</td>
<td></td>
<td>07/01/2012 09/30/2012</td>
</tr>
<tr>
<td>027483/Buntin, William R</td>
<td></td>
<td>Suspended for three (3) months followed by Probation for five (5) years. While pharmacist-in-charge, violation of discipline involving outdated drugs in pharmacy, controlled substance not included in controlled substance inventory, failure to timely respond to inspection compliance notice, compounding log and product label did not contain active/therapeutic ingredients for a compounded product, expired license displayed, sold pseudoephedrine products without a current Methamphetamine Epidemic Self-Certification, failed to maintain updated electronic record of controlled substance shipments. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
</tr>
<tr>
<td>027483/Buntin, William R</td>
<td></td>
<td>10/01/2012 09/30/2017</td>
</tr>
<tr>
<td>027483/Buntin, William R</td>
<td></td>
<td>Probation</td>
</tr>
<tr>
<td>027483/Buntin, William R</td>
<td></td>
<td>07/13/2012 07/12/2017</td>
</tr>
<tr>
<td>044686/Crader, Jodi L</td>
<td></td>
<td>Suspension</td>
</tr>
<tr>
<td>044686/Crader, Jodi L</td>
<td></td>
<td>10/13/2011 07/12/2012</td>
</tr>
<tr>
<td>044686/Crader, Jodi L</td>
<td></td>
<td>Suspended for nine (9) months followed by probation for five (5) years. Operated a vehicle while under the influence of drugs, practiced pharmacy while impaired, abused controlled and non-controlled drugs by taking the medications more frequently than prescribed, and had same drug filled on same day at two different pharmacies. Section 338.055.2(1), (5), (13), (15), and (17), RSMo</td>
</tr>
<tr>
<td>044686/Crader, Jodi L</td>
<td></td>
<td>07/13/2012 07/12/2017</td>
</tr>
<tr>
<td>044686/Crader, Jodi L</td>
<td></td>
<td>Probation</td>
</tr>
<tr>
<td>044686/Crader, Jodi L</td>
<td></td>
<td>01/03/2015 01/02/2020</td>
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<tr>
<td>042911/Drake, Mary V</td>
<td></td>
<td>Probation</td>
</tr>
<tr>
<td>042911/Drake, Mary V</td>
<td></td>
<td>01/03/2015 01/02/2020</td>
</tr>
<tr>
<td>042911/Drake, Mary V</td>
<td></td>
<td>Sixty (60) days suspension--credit given for suspension served under Illinois disciplinary order, followed by Probation for five (5) years. Disciplinary action in Illinois relating to diversion of controlled substances from employer for personal use. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
</tr>
<tr>
<td>Lic Num/Licensee</td>
<td>Complaint</td>
<td>Action Taken</td>
</tr>
<tr>
<td>-----------------</td>
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</tr>
<tr>
<td>201018151/5 Floyd, Joseph Lyn</td>
<td>Revoked and cannot reapply for seven (7) years. Misappropriated controlled substances from employers, incorrectly dispensed controlled and non-controlled substances, dispensed improperly labeled prescriptions, and use of controlled substances to the extent it impaired his ability to function as a pharmacist.</td>
<td>Revoked</td>
</tr>
<tr>
<td>2010026492/Gates, Allison C</td>
<td>Five (5) years probation. Admitted to being under the influence of alcohol while practicing.</td>
<td>Probation</td>
</tr>
<tr>
<td>042363/Gregory, Jeffrey M</td>
<td>Pharmacist license revoked and cannot reapply for seven (7) years. Plead guilty to one felony count of Adulteration of a Commercial Product.</td>
<td>Revoked</td>
</tr>
<tr>
<td>040707/Griggs, Douglas E</td>
<td>Suspended for six (6) months followed by Probation for five (5) years. Misappropriated controlled substances from employer for personal use, impaired.</td>
<td>Suspension</td>
</tr>
<tr>
<td>028136/Grove, Donald W, Jr</td>
<td>Probation for three (3) years. As pharmacist-in-charge, insufficient and incorrect compounding logs, misbranded by incorrectly labeling compounded drug products, dispensed adulterated drug products made with expired ingredients, failed to verify expiration dates, and failed to properly supervise personnel to assure compliance with laws/regulations.</td>
<td>Probation</td>
</tr>
<tr>
<td>045232/Harris, Craig</td>
<td>Probation for three (3) years. As pharmacist-in-charge, no annual review/missing sections of sterile products policies/procedures; failure to conduct annual process validation of aseptic technique; compounding log missing information; failure to maintain refrigerator/freezer temperature logs; unsecured storage of controlled substances; pharmacy permit did not include sterile compounding classification; improper prepackaging; unlawful sharing of CSOS certificate; inaccurate inventory; failure to electronically record receipts of CSOS orders; unsanitary conditions; improper labeling; improper dispensing of controlled substances; and failure to correct Compliance Notice deficiencies.</td>
<td>Probation</td>
</tr>
<tr>
<td>043616/Hoehn, Patricia A</td>
<td>Probation for five (5) years. Plead guilty to the Class D Felony of using &quot;False Statements Relating to Health Care Matters&quot; in the United States District Court, Eastern District of Missouri.</td>
<td>Probation</td>
</tr>
</tbody>
</table>
### Missouri Division of Professional Registration

#### Licensees Presently Under Disciplinary Order

**Pharmacist**

<table>
<thead>
<tr>
<th>Lic Num/Licensee</th>
<th>DBA</th>
<th>Complaint</th>
<th>Action Taken</th>
<th>Action From/Through</th>
</tr>
</thead>
<tbody>
<tr>
<td>040431/Hollaway, Daniel J</td>
<td></td>
<td>2008-002040</td>
<td>Suspension</td>
<td>09/12/2012 09/11/2014</td>
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<tr>
<td>040431/Hollaway, Daniel J</td>
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<td>2008-002040</td>
<td>Probation</td>
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<tr>
<td>2004034762/Horsman, Joshua P</td>
<td></td>
<td>2010-007303</td>
<td>Suspension</td>
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<tr>
<td>2004034762/Horsman, Joshua P</td>
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<td>2010-007303</td>
<td>Probation</td>
<td>08/05/2014 08/04/2019</td>
</tr>
<tr>
<td>201308703/Huning, Grant Martin</td>
<td></td>
<td>2015-001117</td>
<td>Voluntary Surrender</td>
<td>07/26/2016 07/25/2023</td>
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<tr>
<td>2012013212/Jackson, Hillary A</td>
<td></td>
<td>2014-000525</td>
<td>Suspension</td>
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<td>2012013212/Jackson, Hillary A</td>
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<td>2014-000525</td>
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<td>045077/Jones, Michael T</td>
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<td>2013-006818</td>
<td>Suspension</td>
<td>06/21/2016 06/20/2019</td>
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<tr>
<td>045077/Jones, Michael T</td>
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<td>2013-006818</td>
<td>Probation</td>
<td>06/21/2019 06/20/2024</td>
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<tr>
<td>026334/Kammer, M D</td>
<td></td>
<td>2009-004608</td>
<td>Probation</td>
<td>01/19/2012 01/18/2017</td>
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</tbody>
</table>

- **Suspension for two (2) years followed by Probation for five (5) years.** As owner and pharmacist-in-charge, misappropriated controlled substances from pharmacy; dispensed controlled substances to himself without a prescription, without proper labeling and without directions. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.
- **Voluntary surrender of license, and cannot reapply for seven (7) years.** Admitted to diversion of controlled substances from employer; adulterated drugs. Pleaded guilty to a Class C felony of tampering with consumer products. Section 338.055.2(1), (5), (6), (13), (15), and (17) RSMo.
- **Suspension for two (2) weeks followed by Probation for five (5) years.** Purchased controlled substances without a valid prescription for personal consumption. Section 338.055.2(1), (13), (15), and (17), RSMo.
- **Suspension for two (2) weeks followed by Probation for five (5) years.** Misappropriation of controlled substances from employer for personal use, created and filled controlled substance prescriptions not authorized by her healthcare providers for herself, worked while impaired. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.
<table>
<thead>
<tr>
<th>Lic Num/Licensee DBA</th>
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<th>Action Taken</th>
<th>Action From/Through</th>
</tr>
</thead>
<tbody>
<tr>
<td>040031/Kessler, Timothy E</td>
<td>Suspension for two (2) years followed by Probation for five (5) years. Misappropriated controlled substances from employer for personal consumption, falsified inventory records to cover up his misappropriation. Section 338.055.2(1), (5), (13), (15) and (17), RSMo.</td>
<td>06/22/2013 06/21/2018</td>
<td>2010-001357</td>
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<tr>
<td>043358/Kimbel, Craig M</td>
<td>Suspension for three (3) years, followed by Probation for five (5) years. Pled guilty to three felony counts of Fraudulently Attempting to Obtain A Controlled Substance. Section 338.065.1, RSMo.</td>
<td>04/25/2013</td>
<td>2008-000979</td>
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<tr>
<td>2005000313/Krieg, Shannon M</td>
<td>Two (2) additional years of probation. Violation of discipline, tested positive for marijuana, failed to call-in daily to drug testing, and submitted diluted urinalysis samples. Section 338.055.2(5), (6), (13), and (15), RSMo. Revoked, and cannot reapply for seven (7) years. Violation of discipline, failed to meet with the Board at requested meetings, failed to submit to a urine sample for drug testing, hair sample test indicated he was in an area where illicit drugs, including cocaine were being used.</td>
<td>12/14/2023</td>
<td>2016-001469</td>
</tr>
<tr>
<td>2009025376/Law, Amanda L</td>
<td>Probation for five (5) years effective 5/1/2016. Ingested a controlled substance obtained from employer without a valid prescription; pled guilty to felony possession of a controlled, then withdrew guilty plea following completion of drug court. Section 338.055.2(2), (5), (13), (15), and (17), RSMo.</td>
<td>04/30/2021</td>
<td>2013-000992</td>
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<tr>
<td>2004031557/Lindsey, Mika Lynn</td>
<td>Probation for five (5) years. Found guilty, or entered a plea of guilty or nolo contendere to selling pseudoephedrine without proper certification. Section 338.055.2 (5), (6), (13), and (15) RSMo.</td>
<td>05/22/2021</td>
<td>2014-005282</td>
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<tr>
<td>2001018155/Lowe, Teresa Ann</td>
<td>Probation for two (2) years. Dispensing errors, Section 338.055.2 (5) and (13) RSMo.</td>
<td>05/16/2018</td>
<td>2014-004084</td>
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<tr>
<td>027646/Magee, Patrick E</td>
<td>Probation for five (5) years. Tested positive for controlled substances, did not have valid prescription(s), alcohol addiction. Section 338.055.2(5), (13), (15), and (17), RSMo.</td>
<td>08/01/2017</td>
<td>2007-005181</td>
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<tr>
<td>2007019763/Mawuenyega, Rebecca</td>
<td>Probation for three (3) years. Dispensing errors, failed to identify controlled substances and amounts returned to the hospital pharmacy and failed to destroy them in a manner that they were beyond reclamation, entered hospital IV room/sterile products area without appropriate garbing, misbranding due to medications dispensed in containers bearing incorrect information,. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>05/07/2017</td>
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## Licensees Presently Under Disciplinary Order

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<th>Action Taken</th>
<th>Action From/Through</th>
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<tbody>
<tr>
<td>2005007845/Maxwell, Rhonda L</td>
<td>2014-007574 Probation for three (3) years. As Pharmacist-in-Charge, failure to maintain adequate security to deter theft of drugs and diversion of controlled substances. Verified and dispensed prescriptions for pseudoephedrine under the name of a doctor, not lawfully authorized by the doctor; 2 of which were written and filled for Maxwell. Failure to report pseudoephedrine sales to the Missouri electronic pseudoephedrine tracking system. misbranding; and record keeping violations, improperly labeled prescriptions. Section 338.055.2(5), (6), (13), (15), and (17), RSMo.</td>
<td>08/11/2016 08/10/2019</td>
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<tr>
<td>028380/Middleton, Darryl K</td>
<td>2014-002317 Probation for three (3) years. As pharmacist-in-charge, created and filled a prescription without prescriber authorization for himself to be used for his pet, misbranding and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>01/06/2016 01/05/2019</td>
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<tr>
<td>042307/Mitchell, Brian</td>
<td>2012-007516 Revoked, cannot reapply for five (5) years. Pled guilty to felony knowingly and willfully executing a scheme to defraud a health care benefit program. Section 338.065, RSMo.</td>
<td>11/11/2015 11/10/2020</td>
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<tr>
<td>028332/Morris, Lynn A</td>
<td>2014-007286 Probation for three (3) years. Allowed employees to obtain non-controlled medications by creating prescriptions under the name of a doctor without the doctor's authorization or without being physically examined by the doctor; dispensed prescriptions without doctor authorization; misbranding; and recordkeeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>04/17/2015 04/16/2018</td>
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<tr>
<td>029418/Nippes, Jeffrey K</td>
<td>2012-000064 Revoked, cannot reapply for seven (7) years. Impaired pharmacist; misappropriated controlled substances from employer for personal consumption; pled guilty to one count of theft/stealing. Section 338.055.2(1), (2), (5), (13), (15), and (17), RSMo.</td>
<td>05/31/2013 05/31/2020</td>
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<td>028845/Nyberg, Dwight K, Jr</td>
<td>2012-003950 Probation for five (5) years. As pharmacist-in-charge, diversion of controlled substances for personal use without a valid, patient specific prescription. Section 338.055.2(5), (13), (15), and (17), RSMo.</td>
<td>01/22/2016 01/21/2021</td>
<td>VOLUNTARY SURRENDER OF LICENSE EFFECTIVE 1/21/16</td>
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<tr>
<td>2000148445/Ori, Lee Eric</td>
<td>2013-006282 Three (3) years probation. As pharmacist-in-charge, verified and dispensed unauthorized prescriptions, misbranding by unauthorized distribution of a legend drug, and record keeping violations. Section 338.055.2(4), (5), (6), (13), and (15), RSMo.</td>
<td>07/26/2016 07/25/2019</td>
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<tr>
<td>2010027151/Ostropolitskly, Artem</td>
<td>2011-005290 Probation for three (3) years. Dispensed unauthorized refills. Section 338.055.2(5), (13), and (15), RSMo.</td>
<td>06/14/2014 06/13/2017</td>
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<td>2000148345/Owens, Anthony</td>
<td>2011-002793 Suspension for thirty (30) days followed by Probation for five (5) years. Possessed and consumed cocaine. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.</td>
<td>07/10/2012 08/09/2012</td>
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<tr>
<td>2011-002793 Suspension for thirty (30) days followed by Probation for five (5) years. Possessed and consumed cocaine. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.</td>
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<tr>
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<td>Palans, Andrew G</td>
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<td>Pironis, Uldis V</td>
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<td>Schreiner, Ashley Irene</td>
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<td>Richardson, Mary R</td>
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<td>Radtke, Amanda A</td>
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<td>Ross, Clintin Z</td>
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<td>Pomaville, Kerri L</td>
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<td>06/02/2012 06/01/2017</td>
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<td>Schreiner, Ashley Irene</td>
<td>Probation</td>
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<td>Radtke, Amanda A</td>
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<td>02/26/2016 02/25/2023</td>
<td>2012-005409</td>
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<td>Pomaville, Kerri L</td>
<td>Probation</td>
<td>06/02/2012 06/01/2017</td>
<td>2008-003342</td>
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<td>Schreiner, Ashley Irene</td>
<td>Probation</td>
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<td>2011-006494</td>
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<td>Pomaville, Kerri L</td>
<td>Probation</td>
<td>06/02/2012 06/01/2017</td>
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<td>Richardson, Mary R</td>
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<tr>
<td>2002022650/Stark, Kristina L</td>
<td>2011-004395</td>
<td>Revoked</td>
<td>03/02/2012 03/02/2019</td>
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<tr>
<td>2013026251/Steele, Cody Ross</td>
<td>2014-007462</td>
<td>Probation</td>
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<tr>
<td>2011019651/Taylor, William E</td>
<td>2014-007297</td>
<td>Probation</td>
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<td>2005011039/Thomas, Erin E</td>
<td>2013-006921</td>
<td>Probation</td>
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<td>2011032868/Thompson, Timothy Eugene</td>
<td>2014-005340</td>
<td>Revoked</td>
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<tr>
<td>042316/Wagenknecht, Mark A</td>
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<tr>
<td>028605/Walker, Michael L</td>
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<td>034753/Welch, Shannon T</td>
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<tr>
<td>029907/Williams, James H, Jr</td>
<td>2014-003538</td>
<td>Probation</td>
<td>09/15/2016 09/14/2021</td>
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<tr>
<td>Probation for five (5) years. Disciplinary action in Kansas relating to diversion of controlled substances for personal use. Section 338.055.2 (1), (5), (13), (15) and (17), RSMo.</td>
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<tr>
<td>2005007715/Young-Guffey, Wendy S</td>
<td>2010-007974</td>
<td>Revoked</td>
<td>10/13/2011 10/12/2018</td>
</tr>
<tr>
<td>Revoked and cannot reapply for seven (7) years. Violation of discipline involving expired license, failed to submit compliance reports, failed to comply with urinalysis testing program requirements, failed to take/pass jurisprudence exam, and failed to participate in alcohol/drug and mental health treatment programs. Section 338.055.2(1), (5), (6), (13), and (15), RSMo.</td>
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<tr>
<td>Licensee</td>
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<tr>
<td>Care Pharmacy LLC</td>
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<td>County Market Pharmacy 375</td>
<td>Probation</td>
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<tr>
<td>CVS/pharmacy #16845</td>
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<td>10/24/2014 10/23/2017</td>
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<tr>
<td>Entirelypets Pharmacy LLC</td>
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<td>01/28/2014 10/21/2017</td>
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<tr>
<td>Family Pharmacy Inc.</td>
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<tr>
<td>Lynn A. Morris, RPh.</td>
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<tr>
<td>Family Pharmacy of Missouri LLC</td>
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<tr>
<td>Grove Professional Pharmacy Inc</td>
<td>Probation</td>
<td>08/13/2016 08/12/2018</td>
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</table>
**Licensees Presently Under Disciplinary Order**

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<th>Action Taken</th>
<th>Action From/Through</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013042651/Creative Compounds Inc</td>
<td>Harbor Compounding &amp; Home Health Pharmacy</td>
<td>Probation until 07/15/2020. Entered into a Stipulated Settlement and Disciplinary Order with the California Board of Pharmacy for sterile and non-sterile compounding violations-failure to maintain records, failure to properly test sterile compounds, and failure to disclose required ownership information. Section 338.055.2 (5), (8), and (13), RSMo.</td>
<td>11/18/2016</td>
<td>07/15/2020</td>
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<tr>
<td>2014002930/National Prescription Services Inc</td>
<td>HRI Pharmacy</td>
<td>Probation</td>
<td>01/29/2014</td>
<td>01/28/2017</td>
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<tr>
<td>003756/J &amp; D Pharmacy Inc</td>
<td>J &amp; D Pharmacy Inc</td>
<td>Probation for three (3) years. Insufficient and incorrect compounding logs, misbranding by incorrectly labeling compounded drug products, dispensed adulterated drug products made with expired ingredients, and failed to verify expiration dates. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>05/07/2014</td>
<td>05/06/2017</td>
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<tr>
<td>2003010139/Jefferson City Apothecary, LLC</td>
<td>Jefferson City Apothecary</td>
<td>Probation for one (1) year. Pharmacist-in-charge instructed technician to compound and dispense without a pharmacist present and without supervision. Section 338.055.2(6), (10), and (15), RSMo.</td>
<td>10/15/2016</td>
<td>10/14/2017</td>
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<td>John Hollis Pharmacy</td>
<td>Probation</td>
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<td>01/13/2018</td>
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<td>2015001480/Lexi's Medicine, Inc.</td>
<td>Lexi's Medicine, Inc.</td>
<td>Probation</td>
<td>01/20/2015</td>
<td>01/19/2020</td>
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<tr>
<td>2008019033/Grand Medical Group, LLC</td>
<td>Medicine Shoppe Pharmacy</td>
<td>Probation for three (3) years. Inspection violations including CII safe unlocked and CIII-Vs not dispersed through inventory, overfilled stock bottles, failure to timely complete controlled substance inventory, failure to provide patient counseling, labeling errors, failure to maintain distribution records, adulteration of drug products, failure to use gloves when handling tablets, and return to stock violations. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>07/11/2015</td>
<td>07/10/2018</td>
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<tr>
<td>2005035753/Arcadia Ego, Inc.</td>
<td>Mitchell Pharmacy</td>
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<td>10/27/2015</td>
<td>10/26/2022</td>
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<tr>
<td>2009033432/Precision Pharmacies LLC</td>
<td>Precision Pharmacy</td>
<td>Probation</td>
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<tr>
<td>2014-007285</td>
<td>Probation for five (5) years. President/pharmacist-in-charge of prior permit pled guilty to knowingly selling pseudoephedrine at retail without possessing a valid self-certification from the Attorney General of the United States. Section 338.055.2(2) and (15), RSMo.</td>
<td>01/20/2015</td>
<td>01/19/2020</td>
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<tr>
<td>2013-006051</td>
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<td>Probation</td>
<td>05/07/2014</td>
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<td>2013-005303</td>
<td>Probation</td>
<td>10/15/2016</td>
<td>10/14/2017</td>
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</table>

Probation until 2/10/17. Disciplinary action in other states regarding multiple sterile compounding violations, acting as a manufacturer/wholesaler without a license, and various labeling and recordkeeping violations. Section 338.055.2(5), (8), and (13), RSMo.
<table>
<thead>
<tr>
<th>Lic Num/Licensee</th>
<th>DBA</th>
<th>Complaint</th>
<th>Action Taken</th>
</tr>
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<tbody>
<tr>
<td>004254/Rider Drug Inc.</td>
<td>Rider Drug Inc.</td>
<td>2014-004022 Probation for three (3) years. No annual review/missing sections of sterile products policies/procedures; failure to conduct annual process validation of aseptic technique; compounding log missing information; failure to maintain refrigerator/freezer temperature logs; unsecured storage of controlled substances; permit did not include sterile compounding classification; improper prepackaging; unlawful sharing of CSOS certificate; inaccurate inventory; failure to electronically record receipts of CSOS orders; unsanitary conditions; improper labeling; improper dispensing of controlled substances; and failure to correct Compliance Notice deficiencies. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>01/22/2016 01/21/2019</td>
</tr>
<tr>
<td>006018/Semo Drugs Of Kennett</td>
<td>Semo Drugs Of Kennett</td>
<td>2012-006772 Probation for three (3) years. Technician theft of controlled substances, failure to maintain adequate security to deter theft of controlled substances. Section 338.055.2(6), RSMo.</td>
<td>01/06/2016 01/05/2019</td>
</tr>
<tr>
<td>2001019642/Rostie Enterprises, LLC</td>
<td>The Medicine Shoppe</td>
<td>2005-006704 Revoked and cannot reapply for seven (7) years. Pharmacist-in-charge/owner participated in scheme whereby excessive, suspicious, unsigned controlled substance prescriptions faxed from an agent of out-of-state physicians were dispensed for cash. Section 338.055.2(5), (6), (13), and (15), as well as 4 CSR 220-2.010(1)(N).</td>
<td>01/07/2013 01/06/2020</td>
</tr>
<tr>
<td>2002009522/Sung (Sam) Y. Bae</td>
<td>The Medicine Shoppe Pharmacy</td>
<td>2012-001101 Probation for three (3) years. Dispensed controlled and non-controlled prescriptions for office stock, did not obtain patient-specific prescriptions for the dispensings, prescriptions received were not valid due to insufficient information, improper labeling, failure to properly document controlled substance transfers and controlled substance destruction, transferred controlled substances to facility not DEA registered, shared CSOS password with employees, controlled substance losses, failure to implement effective security controls. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>03/18/2014 03/17/2017</td>
</tr>
<tr>
<td>2000148820/Sung Y. Bae</td>
<td>The Medicine Shoppe Pharmacy</td>
<td>2012-004219 Probation for three (3) years. Failure to properly document controlled substance transfers and controlled substance destruction, improper transfer of Schedule II controlled substances, unauthorized sharing of CSOS key with employees, reuse of medications from cassettes, opus cassette violations, electronic data processing system errors. Section 338.055.2(5), (6), (13), and (15), RSMo.</td>
<td>03/18/2014 03/17/2017</td>
</tr>
<tr>
<td>2015039678/Village Fertility Pharmacy Inc.</td>
<td>Village Fertility Pharmacy Inc.</td>
<td>2013-001836 Restricted permit issued on Probation for three (3) years. Shipped into Missouri prior to licensure and disciplinary action in other states. Section 338.055.2(4), (5), 6), and (8), RSMo.</td>
<td>11/05/2015 11/04/2018</td>
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<tr>
<td>2000157695/Walgreen Co</td>
<td>Walgreens #05278</td>
<td>2014-000543 Probation for three (3) years. Loss of controlled substances due to technician diversion and failure to maintain security for controlled substances sufficient to guard against theft and diversion. Section 338.055.2(6) and (15), RSMo.</td>
<td>03/17/2016 03/16/2019</td>
</tr>
<tr>
<td>2005014836/WALGREEN CO.</td>
<td>Walgreens #09301</td>
<td>2014-004530 Probation for three (3) years. Loss of controlled substances due to technician diversion and failure to maintain security for controlled substances sufficient to guard against theft and diversion. Section 338.055.2(6) and (15), RSMo.</td>
<td>05/17/2016 05/16/2019</td>
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### Licensees Presently Under Disciplinary Order

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<th>Action From/Through</th>
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<td>003121/L &amp; P Corp</td>
<td>Wharf Pharmacy</td>
<td>Probation</td>
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<td>2014-006377</td>
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<tr>
<td></td>
<td>Probation for three (3) years. Dispensed controlled substances without valid prescription or proper authorization from prescriber, dispensed controlled substances without a valid patient-practitioner relationship, failed to maintain accurate controlled substance/prescription records; pharmacists immunizing without complete protocol. Failure to comply with REMS requirements (prescriber not properly certified). Misbranding of a controlled substance due to failure to comply with REMS requirements. Inaccurate records, failure to keep records in a uniform fashion for at least 5 years.</td>
<td></td>
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<tr>
<td>2010015142/Wickliffe Pharmaceutical Inc</td>
<td>Wickliffe Veterinary Pharmacy</td>
<td>Probation</td>
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<td>10/23/2018</td>
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<td></td>
<td>2016-000040</td>
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<tr>
<td></td>
<td>Probation until 10/23/2018. Entered into an Agreed Order with the Kentucky Board of Pharmacy for sterile and non-sterile compounding violations-failed potency tests, allowing technicians to work unsupervised and improper storage of compounded preparations. Controlled Substance prescriptions were dispensed utilizing a prescriber whose license and/or DEA registration was not current, allowing employees to work without proper licensure. Entered into an Executed Consent Order with the Oregon, Alabama, Colorado, and Texas Boards of Pharmacy based on the discipline imposed by the Kentucky Board of Pharmacy Section 338.055.2 (5), (8), and (13), RSMo.</td>
<td></td>
<td></td>
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<tr>
<td>Lic Num/Licensee</td>
<td>DBA</td>
<td>Complaint</td>
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<td>2015028229/Goff, Ryan T</td>
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<td>2015-006355</td>
<td>Probation</td>
<td>07/12/2016 07/11/2018</td>
</tr>
</tbody>
</table>

Probation for two (2) years. Theft (non-drug). Section 338.055.2 (5) and (13), RSMo.
**MISSOURI BOARD OF PHARMACY**

**Pharmacy Technician Conditional Registration List**

These individuals are eligible for employment as pharmacy technicians under conditions printed on his/her registration

Revised 12/2/2016

*****Licensees should also check the Pharmacy Technician Employment Disqualification List and the HB 600 (tax suspension) list to verify authorization to work.******

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<thead>
<tr>
<th>LAST NAME</th>
<th>FIRST NAME</th>
<th>MIDDLE NAME</th>
<th>REGISTRATION NUMBER</th>
<th>CITY</th>
<th>STATE</th>
<th>ZIP CODE</th>
<th>ACTION TAKEN</th>
<th>EFFECTIVE DATE</th>
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Missouri Board of Pharmacy Technician Conditional Registration List
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## MISSOURI BOARD OF PHARMACY

**Pharmacy Technician Employment Disqualification List**

*These individuals are not eligible for employment as pharmacy technicians*

**Revised 12/2/2016**

***Licensees should also check the Pharmacy Conditional Registration List and the HB 600 (tax suspension) list to verify authorization to work.***

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## Board Licensing Statistics

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