MEETING NOTICE
Missouri Board of Pharmacy
Hospital Advisory Committee

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

April 29, 2019
10:00 a.m.

Notice is hereby given that the Missouri Hospital Advisory Committee will be meeting at 10:00 a.m. on April 29, 2019. A tentative agenda is attached. If any member of the public wishes to attend the meeting, s/he should be present at the Missouri Division of Professional Registration, 3605 Missouri Boulevard, Jefferson City, Missouri at 10:00 a.m. on April 29, 2019.

Except to the extent disclosure is otherwise required by law, the Missouri Board of Pharmacy is authorized to close meetings, records and votes pursuant to Section 610.021(1), (11), (12), (14), and (15), RSMo. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

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

1. Call to Order/Roll Call: Chairman Teale

2. Welcome & Introductions

3. Committee Vacancies/MPA appointee

4. Approval of Minutes
   a. March 1, 2019

5. Board of Pharmacy Update
   a. 2019 Legislation
   b. Chapter 338 Review
   c. Bd. meeting updates

6. Missouri DHSS Update
   a. Pending DHSS Rules
   b. Rulemaking Charts
   c. USP 797/800 implementation timeframe/updates

7. Missouri Hospital Association Update
   a. Pharmacy Technician Proposed Legislation
   b. Pharmacist Scope of Practice
   c. SB 357 & Hospital Inclusion/Applicability

8. Missouri Society of Health System Pharmacists Update

9. Missouri Pharmacy Association Update

    a. SB 357 (RPh Scope of Practice)
    b. SB 127 (Importation Study)
    c. SB 274 (Pharmacy Pilot Projects)
    d. SB 309 (Tobacco Cessation)
e. SB 155 (PDMP)
f. HB 257 (Bd. Disc. Agreements)
g. HB 293 (E-Prescribing)
h. HB 487 (Contraceptives)
i. HB 667 (Foreign Distributors)
j. HB 727 (Dispensing on Hospital Discharge)

11. Old Business
   a. Disposal of Patient Home Medications by a Hospital
   b. Non-Sterile Packaging in Clinics
   c. Pharmacist Administration in Hospitals/Acute Care Settings
   d. Medication Distribution to and from a Class-B Pharmacy

12. Hospital Premises Definition/Changes

13. Verification of Pharmacy Technician Activities by Nursing Staff

14. Sterile Compounding and Distribution in Health Systems
   a. April 2016 FDA Guidance
   b. Class-H requirement for distribution between owned hospitals
   c. Class-J requirements

15. 2019 Discussion Items
   a. Non-Class B Hospital Guidance
   b. Medical Marijuana

16. Future Meeting Dates/Topics

17. Adjournment
The Missouri Hospital Advisory Committee met 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:

**Committee Members Present**
Greg Teale, R.Ph., Chairman
Daniel Good, R.Ph., Member (*via conference call*)
Nathan Hanson, R.Ph., Member
Tom Hall, R.Ph., Member
John Rawson, R.Ph., Member
David Wolfrath, R.Ph., Member

**Board Members/Staff Present**
Christian Tadrus, R.Ph., President
James Gray, R.Ph., Board Member
Kimberly Grinston, Executive Director
Tom Glenski, Chief Inspector
Katie DeBold, Inspector

**Others Present**
Richard Grindstaff, Missouri Dept. of Health and Senior Services
Sarah Willson, Missouri Hospital Association

Chairman Teale opened the meeting at approximately 10:07 a.m. and roll-call was taken.

**Agenda Item # 2 (Welcome & Introductions):**

**DISCUSSION:** Chairman Teale welcomed new Committee members Tom Hall (Missouri
Baptist Medical Center) and John Rawson (Mosaic Life Care). Mr. Teale asked if the
Missouri Pharmacy Association (MPA) has identified a new Committee representative to
replace Colby Grove who was appointed to the Board; Kimberly Grinston reported a new
representative has not been named but office staff will contact MPA for updates.

**Agenda Item # 4 (Approval of Minutes):**
- October 18, 2018
January 19, 2019

DISCUSSION: Greg Teale asked to amend the minutes to reflect costs related to complying with both USP Chapter 797 and USP Chapter 800 were estimated to exceed $1,000,000 per hospital; Mr. Teale and James Gray clarified the estimated costs were not solely related to USP Chapter 800. A motion was made by Nathan Hanson, seconded by David Wolfrath, to approve the October 18, 2018, minutes as amended. Motion passed 6:0:0:0 with roll call vote as follows:

James Gray – Yes    Daniel Good – Yes    Nathan Hanson – Yes
Tom Hall- Yes      John Rawson- Yes    David Wolfrath- Yes

Chairman Teale asked to correct the minutes to indicate the Committee previously had two (2) DHSS vacancies and one (1) MPA vacancy. A motion was made by David Wolfrath, seconded by Nathan Hanson, to approve the January 19, 2019, minutes as amended. Motion passed 6:0:0:0 with roll call vote as follows:

James Gray – Yes    Daniel Good – Yes    Nathan Hanson – Yes
Tom Hall- Yes      John Rawson- Yes    David Wolfrath- Yes

Agenda Item # 5 (Board Updates): Kimberly Grinston reported the Board will be reviewing Chapter 338 throughout 2019 to incorporate standards of practice. Ms. Grinston stated the Board expressed support for MPA’s pending legislative proposal that would grant pharmacists prescribing authority and voted to hold discussion on expanding pharmacist scope of practice until after the legislative session.

Greg Teale asked if the Board has discussed or taken a position on some of the insurance fraud/billing issues that have been in the media; Kimberly Grinston indicated the Board does not have primary jurisdiction over insurance billing but may take action if a pharmacy is involved. Tom Glenski noted the Board traditionally looks for patterns of fraud but does not give advice or take a position on billing issues.

Agenda Item # 8 (MSHP Update): David Wolfrath provided the following updates:

• MSHP’s spring meeting will be held in Collinsville, IL during the last week in March.
• MSHP has changed procedures; Elected board members will now be appointed for the entire school year
• A medical marijuana survey has been circulated to gather feedback/identify a consensus among stakeholders.

Agenda Item # 9 (MHA Update): Sarah Willson provided the following updates:

• MHA is monitoring the legislative session; MHA collaborated on MPA’s recently filed pharmacist prescribing bill and is monitoring developments. MPA’s current proposal does not address hospitals, however, amended hospital language has been drafted that will likely be added soon.
• MHA is still working with MPA on a possible technician legislative proposal; Updates will be provided as known.
• MHA is still pushing DHSS to file the remaining hospital rules, including, the hospital pharmacy rules.
• Several meetings have been held regarding a possible statewide PDMP; The current status is unknown but legislative barriers may still exist.
• MHA has received multiple calls on implementation of USP Chapter 797 and Chapter 800. Based on conversations with Board staff, it appears the Board will be reviewing the chapters after they become effective and would need to adopt the chapters in rule to make them mandatory in Missouri. CMS and the hospital accrediting bodies may take a heavier enforcement position. Specifically, the Joint Commission indicated it may fully incorporate the chapters once they are effective. MHA has concerns with potential compliance costs and compounding capabilities; A letter expressing MHA’s concerns was sent to the Board and the Joint Commission.

Agenda Item # 6 (Missouri DHSS Update): Richard Grindstaff provided the following updates:
• The DHSS revised hospital rules are still under legal review; Memorandums have been drafted for the Governor’s Office once the legal review is complete.
• DHSS filed an emergency rule on February 24th that incorporated CMS’ Conditions of Participation into state regulatory standards. DHSS surveyors stopped citing state issues several months prior to the meeting; Communication will be sent to Missouri hospitals announcing incorporation of the COPs.
• DHSS has received questions on USP Chapter 797 and USP Chapter 800; DHSS usually takes 6-12 months to educate licensees before full enforcement of new standards although egregious issues may be addressed immediately.

Agenda Item # 3 (New Member Orientation): Division Counsel Sarah Ledgerwood provided introductory training on Missouri’s Sunshine Law requirements; Committee members were advised to contact Kimberly Grinston if there are future questions on Sunshine Law compliance.

Agenda Item # 10 (Proposed 2019 Legislation): Kimberly Grinston reported the legislative session is in its early stages and several bills have been heard and/or referred to Committee. Greg Teale and James Gray indicated SB 357 needs to be modified to reference hospitals in the MTS/prescribing language; Sarah Willson stated MHA is working with legislators to amend the language. Committee consensus to table further discussion until later in the meeting due to time constraints.

Agenda Item # 11 (Disposal of Patient Home Medications by a Hospital): Greg Teale noted BNDD previously indicated they would draft guidance to clarify what is allowed; Board staff agreed to check with BNDD for updates.

Agenda Item # 12 (Non-Sterile Packaging in Clinics): Greg Teale asked if the FDA has provided further clarification; Tom Glenski noted the FDA sent guidance to a Missouri hospital but stated he was unsure if/how the guidance would apply to hospitals generally.
Missouri Board of Pharmacy
Hospital Advisory Committee
Open Minutes
March 1, 2019
Page 4 of 5

Sarah Willson agreed to reach out to FDA for clarification. James Gray asked how non-sterile packaging should be labeled; Tom Glenski indicated he’s drafted preliminary guidance. Discussion tabled pending circulation of Mr. Glenski’s draft guidance document.

**Agenda Item # 13 (Pharmacist Administration in Hospital/Acute Care Settings):** Greg Tealer reported the Board referred him to DHSS for guidelines on pharmacists administering in hospital/acute care settings; Richard Grindstaff stated DHSS reviewed its rules and believes a pharmacist can administer in hospitals and acute care settings if the hospital has appropriate policies and procedures in place and administration authority has been approved by medical staff. Tom Glenski noted the hospital's determination would apply to medication administered within the DHSS licensed hospital premises; The Board of Pharmacy would have jurisdiction outside of the licensed premises. Tom Glenski further noted Chapter 338’s requirements would apply to pharmacists administering vaccines; Greg Teale and Nathan Hanson suggested additional clarification may be needed on when Chapter 338 applies.

**Agenda Item # 12 (Non-Sterile Packaging in Clinics- Cont’d):** Tom Glenski circulated the guidance draft included in Attachment A; Committee discussion held. Committee members requested a uniform guidance document from the Board that could be circulated publicly. Mr. Glenski indicated further revisions may be needed and cautioned the DEA may have different rules on who qualifies as a distributor.

**Agenda Item # 10 (Proposed 2019 Legislation- Cont’d):** The following additional discussion was held:

- Christian Tadrus suggested the Committee may want to monitor the federal Alert Act which proposes a nationwide PDMP; Mr. Tadrus indicated the proposal includes confidentiality provisions that may be problematic.
- Tom Hall inquired about the origins of the multi-dose labeling provisions in HB 727; Kimberly Grinston reported the sponsoring representative used preliminary language that was discussed in a DHSS rule review meeting. Ms. Grinston noted the sponsor has been advised the DHSS committee ultimately recommended modified language that should be included in the bill. Nathan Hanson suggested HB 727 would be an ideal place to incorporate a standards based approach and recommended the bill include language that would allow a pharmacist to use his/her discretion to select the appropriate form of labeling. Mr. Hanson noted a patient handout or electronic notice may be better in some instances than placing a label on a container or cardboard box that may eventually be discarded. James Gray and David Wolfrath noted the current law results in medication being wasted and noted allowing medication to be dispensed on discharge with a modified label or other patient information would result in an overall cost savings.

**Agenda Item # 14 (Future Meeting Dates/Topics)-** The following future meeting topics were suggested:

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Missouri Board of Pharmacy
Hospital Advisory Committee
Open Minutes
March 1, 2019
Page 4 of 5
• Disposal of Patient Home Medication by a Hospital: Kimberly Grinston advised BNDD e-mailed during the meeting and indicated a draft is being developed
• Non-Sterile Packaging by Clinics- Tom Glenski will update draft chart
• Pharmacist Administration in Hospitals/Acute Care Settings
• Distribution of Medication to/from a Class-B Hospital

Committee Consensus that a joint guidance document on the above topics would be helpful; Richard Grindstaff indicated DHSS may have legal restrictions on what can be released as guidance. Greg Teale suggested the Committee review sterile compounding distribution issues after the above topics are addressed.

Committee consensus to meet on April 29th, in Jefferson City, Missouri.

A motion was made by Tom Hall, seconded by David Wolfrath, to adjourn the meeting. Motion passed 6:0:0:0 with roll call vote as follows:

James Gray – Yes      Daniel Good – Yes      Nathan Hanson – Yes
Tom Hall - Yes      John Rawson- Yes      David Wolfrath- Yes

THE MEETING WAS ADJOURNED BY CONSENSUS AT 2:34 P.M.

______________________________
KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

Date Approved:
Hospital systems repackaging non-sterile drugs for own-system use.

<table>
<thead>
<tr>
<th>Hospital system entity type</th>
<th>Location</th>
<th>Jurisdiction</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class B pharmacy</td>
<td>Within DHSS licensed premises</td>
<td>BOP DHSS</td>
<td><strong>BOP</strong>: Comply with 20 CSR 2220-2.130 Drug Repackaging and 338.059.2 labeling. No drug distributor license required. <strong>DHSS</strong>: ??</td>
</tr>
<tr>
<td>Class B pharmacy</td>
<td>Outside of DHSS licensed premises</td>
<td>BOP</td>
<td><strong>BOP</strong>: Comply with 20 CSR 2220-2.130 Drug Repackaging and 338.059.2 labeling. No drug distributor license required. <strong>DHSS</strong>: ??</td>
</tr>
<tr>
<td>Hospital (non-BOP-licensed)</td>
<td>Within DHSS licensed premises</td>
<td>DHSS</td>
<td><strong>BOP</strong>: Does not require a drug distributor license. <strong>DHSS</strong>: ??</td>
</tr>
</tbody>
</table>
| Non-pharmacy                | Outside of DHSS licensed premises | BOP | **BOP**: Requires drug distributor license and compliance with 20 CSR 2220-5, including 5.030:  

(4) In addition to standards listed in this rule for drug distributors, drug repackagers must observe federal standards for—  
   (A) Packaging;  
   (B) Record keeping;  
   (C) Expiration dating;  
   (D) Plant facilities;  
   (E) Equipment;  
   (F) Personnel;  
   (G) Production and control procedures;  
   (H) Containers;  
   (I) Testing; and  
   (J) Federal registration requirements. |

Contact BNDD and DEA for controlled substance requirements.
338.059. Prescriptions, how labeled. — 1. It shall be the duty of a licensed pharmacist or a physician to affix or have affixed by someone under the pharmacist’s or physician’s supervision a label to each and every container provided to a consumer in which is placed any prescription drug or biological product upon which is typed or written the following information:

(1) The date the prescription is filled;
(2) The sequential number or other unique identifier;
(3) The patient’s name;
(4) The prescriber’s directions for usage;
(5) The prescriber’s name;
(6) The name and address of the pharmacy;
(7) The exact name and dosage of the drug dispensed;
(8) There may be one line under the information provided in subdivisions (1) to (7) of this subsection stating “Refill” with a blank line or squares following or the words “No Refill”;
(9) When a generic or interchangeable biological substitution is dispensed, the name of the manufacturer or an abbreviation thereof shall appear on the label or in the pharmacist’s records as required in section 338.100.

2. The label of any drug or biological product which is sold at wholesale in this state and which requires a prescription to be dispensed at retail shall contain the name of the manufacturer, expiration date, if applicable, batch or lot number and national drug code.

20 CSR 2220-2.130 Drug Repackaging

(1) A pharmacist or pharmacy may prepackage drugs for other than immediate dispensing purposes provided that the following conditions are met:
   (A) Only products which will be directly provided to the patient may be prepackaged;
   (B) Containers utilized for prepackaging shall meet, as a minimum requirement, that of Class B container standards as referenced by the United States Pharmacopoeia (USP), which has been incorporated herein by reference. Where applicable, light sensitive containers shall be used;
   (C) The maximum expiration date allowed for prepacked drugs shall be the manufacturer’s expiration date or twelve (12) months, whichever is less; and
   (D) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.

(2) The term prepacked as used in this rule is defined as any drug which has been removed from the original manufacturer’s container and is placed in a dispensing container for other than immediate dispensing to a patient.
MISSOURI RULEMAKING MAP

* Includes preparing rulemaking justification memo for Governor’s Office, fiscal notes, small business impact statement, state/federal research

* Legal review during Division, Dept. & GO approval.

* Legal review during Division, Dept. & GO approval.

* Rule will be held until next Register publication date.

* Rule will be held until next Register publication date.

* Unless requested, Bd. will not review final rule if no comments are received.
MISSOURI EMERGENCY RULE MAP

Board Approval

Staff Prepares Rule Packet

Division Review/ED Meeting

Division Prepares Official Draft

ED approval of official draft

Approval Process

* Includes preparing rulemaking justification memo for Governor’s Office, fiscal notes, small business statement, state/federal research

Division Prepares Official Draft

Approval Process

ED approval of official draft

* Legal review during Division, Dept. & GO approval.

Governor Approval

Dept. Approval

Division Approval

ED Approves Final Draft

Filing w/SOS

Published in MO Register

Final Rule Effective

* Rule will be held until next Register publication date.

Final Rule Effective 10-Days

Published in MO Register

Filing w/SOS

ED Approves Final Draft

Governor Approval

Dept. Approval

Division Approval

ED approval of official draft

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Division Prepares Official Draft

Division Review/ED Meeting

Staff Prepares Rule Packet

Board Approval

* Includes preparing rulemaking justification memo for Governor’s Office, fiscal notes, small business statement, state/federal research
Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act
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 90 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 Sara Rothman, 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

April 2016
Compounding and Related Documents
Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov

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

April 2016
Compounding and Related Documents
# TABLE OF CONTENTS

I. INTRODUCTION AND SCOPE ................................................................. 1

II. BACKGROUND .................................................................................. 1
   A. Overview ....................................................................................... 1
   B. The Prescription Requirement in Hospitals and Health Systems .......... 4

III. POLICY ......................................................................................... 5
   A. Hospital or Health System Compounding Under Section 503A of the FD&C Act .......... 5
   B. Hospital or Health System Compounding Under Section 503B of the FD&C Act .......... 6
Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

This draft guidance, when finalized, will represent 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

Pharmacies located within a hospital or standalone pharmacies that are part of a health system frequently provide compounded drug products for administration within the hospital or health system. Some of these compounders have registered with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) and others are state-licensed pharmacies subject to section 503A of the FD&C Act. This guidance describes how FDA intends to apply section 503A of the FD&C Act to drugs compounded by licensed pharmacists or physicians in state-licensed hospital or health system pharmacies for use within the hospital or health system.

In general, FDA’s guidance documents do not establish legally enforceable responsibilities. Instead, guidelines 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 guidelines means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Overview

1. Compounding Under the FD&C Act

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

\[1\] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) and in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.
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 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 or abbreviated new drug applications).

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.*

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 track and trace requirements).

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.

Because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B) of the FD&C Act, outsourcing facilities are subject to CGMP requirements, among other requirements under the FD&C Act (section 503B(a)). In addition, outsourcing facilities will be inspected by FDA on a risk-based schedule (section 503B(b)(4)). An outsourcing facility is not required to be a licensed pharmacy and may or may not obtain prescriptions for identified individual patients.

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2 All FDA guidances are available on the FDA guidance Webpage at [http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm). FDA updates guidances regularly. To ensure that you have the most recent version, please check this web page.

3 FDA has issued a draft guidance for industry *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*. Once finalized, that guidance will represent the Agency’s thinking on this topic.

4 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
2. Compounding in Hospitals and Health Systems

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 pill and needs a medicine in a liquid form that is not otherwise available.

Hospital and health system\(^5\) drug compounding and distribution practices vary. For example, some hospital pharmacies compound drugs only for use in the hospital in which the pharmacy is located (e.g., for the treatment of patients admitted to the hospital, or for use in the hospital’s emergency room), while other hospital and health system pharmacies compound and distribute their compounded drug products to other facilities within their health system (e.g., to other hospitals, clinics, infusion centers, or long-term care facilities within the health system for administration or dispensing).

In some cases, a hospital or health system pharmacy compounds drugs only after receipt of a prescription or order for an identified individual patient. Hospital and health system pharmacies may also compound drugs and distribute them within the hospital or health system before the receipt of a patient-specific prescription. The hospital or health system then holds the drug products until a patient presents with a need for the drug, for example in an operating room, where emergency procedures cannot be scheduled in advance, or in emergency departments.

Many hospitals and health systems purchase compounded drug products from compounders that have registered with FDA as outsourcing facilities under section 503B of the FD&C Act. Outsourcing facilities are subject to increased federal oversight through FDA inspection on a risk-based schedule, and quality standards (CGMP requirements) that help to assure the quality of their compounded drug products. Some hospital and health system compounders have registered with FDA as outsourcing facilities to serve as centralized compounding facilities where drug products are compounded with or without first receiving patient-specific prescriptions, and they then distribute the drugs within their health system or to affiliated health care facilities.

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

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\(^5\) FDA regards a health system as collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients. There is no definition of “health system” that applies to all sections of the FD&C Act. However, this is the definition of a “health system” used in section 506F of the Act concerning hospital repackaging of drugs in shortage.
addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with 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 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 healthcare practitioners across the country caused a fungal meningitis outbreak that resulted in over 60 deaths and over 750 cases of infection. 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.

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 the compounded drug products made under these conditions to patients and health care providers in large volumes across the country. The longer a compounded sterile drug product that is contaminated is held by a pharmacist or physician before distribution, or the longer it is held in inventory in a healthcare facility before administration, the greater the likelihood of microbial proliferation and increased patient harm.

As noted previously, compounders that elect to become outsourcing facilities must register with FDA, must comply with CGMP requirements, and are inspected by FDA according to a risk-based schedule. This mitigates the risk that their drug products will be contaminated or otherwise made under substandard conditions.

Because compounded drugs have not undergone premarket review for safety, effectiveness, and quality, they should only be used when an FDA-approved product is not available to meet the medical needs of an individual patient. As described further below, the exemptions under sections 503A and 503B of the FD&C Act are only available to compounded drugs that meet certain conditions.

B. The Prescription Requirement in Hospitals and Health Systems

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7 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](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm)
As described above, compounded drug products are not approved and, therefore, do not undergo premarket review for safety, effectiveness, and quality. In addition, drug products compounded by licensed pharmacists and licensed physicians under section 503A of the FD&C Act are exempt from CGMP requirements. As reflected in the policies set forth below, FDA believes that the conditions in sections 503A and 503B provide important protections to patients, including those treated in a hospital or other facility within a health system, from the risks associated with compounded drugs and help ensure that compounders do not operate like conventional manufacturers. Therefore, FDA generally intends to apply these conditions to compounding in health system and hospital pharmacies, and sets forth an enforcement policy below regarding the prescription requirement in section 503A.

The prescription requirement in section 503A ensures that drug products are only exempt from three key provisions of the FD&C Act designed to assure safety, efficacy, and quality if they are compounded for identified individual patients. However, as stated above, FDA recognizes that a hospital may need to maintain a supply of certain compounded drug products within the hospital but outside of the pharmacy (e.g., in an emergency department or operating room) in anticipation of a patient presenting with a critical need for the drug when there is no time for the hospital pharmacy to compound and provide the drug upon receipt of a prescription or order for that patient.

FDA also recognizes that certain characteristics of hospital pharmacies differentiate them from pharmacies that are not owned and controlled by hospitals, and from conventional manufacturers. For example, generally, the scope of distribution of drug products compounded by hospital pharmacies is limited. Hospital pharmacies usually compound drug products based on orders from practitioners who work in the hospital, distribute the drug products only within the hospital or to related healthcare facilities under common ownership and control and located within close proximity to the hospital, and administer them only to patients within the hospital or healthcare facility. Because the hospital or healthcare facility and the pharmacy are under common ownership and control, the hospital or healthcare facility is responsible for both the compounding of the drug and treatment of the patient, and the cause of any compounding-related adverse events can be more readily identified. FDA believes that the policies set forth in this guidance, based on the way a hospital pharmacy normally functions with regard to compounding for its patients, will prevent hospital pharmacies from operating like conventional manufacturers.

III. POLICY

A. Hospital or Health System Compounding Under Section 503A of the FD&C Act

To qualify for the exemptions under section 503A of the FD&C Act from sections 501(a)(2)(B), 502(f)(1), and 505(a), a drug product compounded by a licensed pharmacist in a state-licensed pharmacy or Federal facility, or by a licensed physician, must be compounded in accordance with all of the provisions of section 503A. Section 503A does not distinguish between stand-alone pharmacies and pharmacies within hospitals and health systems. Therefore, the provisions of section 503A apply to pharmacists, pharmacies, and physicians that compound drugs within a hospital or a health system that is not registered as an outsourcing facility under section 503B.
Drug products compounded by a licensed pharmacist or licensed physician that are not compounded in accordance with all of the provisions of section 503A may be subject to regulatory action for violations of the new drug approval, adequate directions for use, and CGMP requirements of the FD&C Act.

For example, under section 503A, a licensed pharmacist or a licensed physician within a hospital or health system must compound drug products for an identified individual patient. The compounding must either be (a) after the receipt of a valid prescription or order for an identified individual patient or (b) in limited quantities in advance of receipt of a valid prescription or order for an identified individual patient, and the drug must be distributed after receipt of the prescription or order.

However, FDA does not intend to take action if a hospital pharmacy distributes compounded drug products without first receiving a patient-specific prescription or order provided that:

1. The drug products are distributed only to healthcare facilities that are owned and controlled by the same entity that owns and controls the hospital pharmacy and that are located within a 1 mile radius of the compounding pharmacy;
2. The drug products are only administered within the healthcare facilities to patients within the healthcare facilities, pursuant to a patient specific prescription or order; and
3. The drug products are compounded in accordance with all other provisions of section 503A, and any other applicable requirements of the FD&C Act and FDA regulations (e.g., the drug products are not made under insanitary conditions (section 501(a)(2)(A)) or misbranded (e.g., section 502(g)).

The 1-mile radius in our policy is intended to distinguish a hospital campus from a larger health system. As explained in section II.B of this guidance, certain characteristics of hospital pharmacies distinguish them from conventional manufacturers. However, a health system pharmacy that compounds drug products without patient-specific prescriptions for facilities within its health system across a broader geographic area could function as a large manufacturing operation, but without the necessary standards to assure drug quality. If such a pharmacy contaminates or otherwise adulterates or misbrands a compounded drug, the drug has the potential to harm many patients. Outsourcing facilities, which are subject to CGMP requirements and other conditions that help to assure drug quality, can compound and distribute drug products to healthcare facilities nationwide without first receiving prescriptions for identified individual patients.

B. Hospital or Health System Compounding Under Section 503B of the FD&C Act

A compounding facility can register as an outsourcing facility if it intends to provide compounded drugs to facilities such as other hospitals or clinics outside the 1 mile radius of the pharmacy in which the drug is compounded without first obtaining a prescription for an identified individual patient.

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8 This does not include dispensing a drug product to a patient for use outside the hospital.
To qualify for the exemptions under section 503B from sections 502(f)(1), 505, and 582 of the FD&C Act, hospitals and health system compounders that elect to register with FDA as outsourcing facilities must comply with all of the provisions of section 503B. Outsourcing facilities must also comply with CGMP requirements in section 501(a)(2)(B) of the FD&C Act.