COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Tentative Agenda of Public Hearing and Full Board Meeting
November 28, 2018
11:00AM

TOPIC	PAGES

Call to Order of Public Hearing for Scheduling Certain Substances: Rafael Saenz, Chairman
- Welcome & Introductions
- Reading of Emergency Evacuation Script

Public Hearing on Scheduling:
- Possible Scheduling to Conform to DEA Scheduling of Epidiolex — 1

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Rafael Saenz, Chairman
- Approval of Agenda

Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.

Legislative/Regulatory/Guidance: Elaine Yeatts/Caroline D. Juran
- Regulatory Update
- Final Report of the Workgroup on E-Prescribing — 2-3
- Adoption of Exempt Regulation to Conform to DEA Scheduling of Epidiolex — 4-12
- Consider Draft Proposed Regulation for White Bagging and Brown Bagging — 13-15
- Consider Submission of Public Comment regarding FDA Draft Guidance Document - MOU Addressing Certain Distributions of Compounded Drug Products — 16-34, 35-55

New Business:
- Consider Criminal Background Check Results for Pharmaceutical Processor Conditional Approvals and Any Related Matters
- Motion to Convene Closed Session pursuant to §2.2-3711(8) for consultation with legal counsel regarding specific legal matters requiring the provision of legal advice
- Motion to Reconvene into Open Session

Consideration of consent orders & summary suspension or summary restrictions, if any

Adjourn

Notice of Public Hearing
Scheduling to Conform to Federal Actions

Pursuant to subsection E of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider scheduling the drug Epidiolex in Schedule V in the Virginia Drug Control Act. The drug was scheduled by the Drug Enforcement Administration on September 27, 2018. The public hearing will be conducted at **1 p.m. on November 28, 2018** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233.

Subsection E of § 54.1-3443 of the Code of Virginia:

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of 30 days from publication in the Federal Register of a final or interim final order or rule designating a substance as a controlled substance or rescheduling or descheduling a substance by amending its regulations in accordance with the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. The Board shall include a list of all substances it intends to schedule by regulation in such notice.

April 24, 2018

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**
As of November 8, 2018

Board	Board of Pharmacy	
Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] NOIRA - *Register Date: 8/6/18* *Comment closed: 9/5/18*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Delivery of dispensed prescriptions; labeling [Action 5093] NOIRA - *Register Date: 10/29/18* *Comment closes: 11/28/18* *Board to adopt proposed: 12/13/18*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25 [Action 4538] Proposed - *At Governor's Office for 169 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for applicants and licensees to have an e-profile ID number [Action 4909] Proposed - *Register Date: 9/17/18* *Comment closed: 11/16/18* *Board to adopt final: 12/13/18*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Proposed - *At Secretary's Office for 146 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Rescission of pharmacy permit [Action 5080] Fast-Track - *At Agency* [Stage 8328]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 169 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Response to petitions for rulemaking [Action 4694] Final - *Register Date: 10/1/18* *Effective: 10/31/18*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Controlled substances registration for naloxone and teleprescribing [Action 4789] Final - *At Governor's Office for 15 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Placement of chemical in Schedule I [Action 5153] Final - *Register Date: 10/29/18* *Effective: 11/28/18*

[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Emergency/NOIRA - *At Secretary's Office for 59 days* *Regulation must be effective by 12/14/18*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Registration of nonresident warehousers and nonresident third party logistics providers [Action 5083] Fast-Track - *DPB Review in progress* [Stage 8378]
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Emergency/NOIRA - *Register date: 10/29/18* *Comment on NOIRA closes 11/28/18*

Final Report of the Workgroup on E-Prescribing of Controlled Substances Containing an Opioid

November 1, 2018

Executive Summary

Final Report

Report on E-Prescribing of Controlled Substances Containing an Opiate

Pursuant to Chapter 429 of the 2017 General Assembly Session, an interim report was published in 2017 (RD431) on e-prescribing. Subsequently, a workgroup was convened on August 29, 2018 to finalize its review of actions necessary for implementation of the mandatory issuance of electronic prescriptions for controlled substances containing an opiate, effective July 1, 2020. The workgroup considered whether to monitor the progression of the federal legislation prior to recommending a legislative proposal to authorize the exemptions that were recommended in the 2017 Interim Report and then further clarified at the August meeting. There was consensus that legislation should be introduced during the 2019 General Assembly Session and that any necessary amendments in response to federal legislation could be addressed during the 2020 General Assembly Session. There was further consensus that the Secretary of Health and Human Resources should convene a workgroup within two years of the effective date of the 2019 legislation of interested stakeholders to evaluate the implementation and report to the Chairmen of the House Committee on Health, Welfare, and Institutions and the Senate Committee on Education and Health by November 1, 2022. The workgroup's evaluation should identify successes and challenges with the mandate, and offer possible recommendations for increasing the electronic prescribing of controlled substances.

COMMONWEALTH of VIRGINIA

Office of the Governor

Daniel Carey, MD
Secretary of Health and Human Resources

October 26, 2018

The Honorable Robert D. Orrock, Sr.
Chairman
House Committee on Health, Welfare, and Institutions

The Honorable Stephen D. Newman
Chairman
Senate Committee on Education and Health

Re: Final Report, E-Prescribing Workgroup, Chapter 429 Enactment Clause 3 (Regular Session, 2017)

Dear Chairmen:

Pursuant to Chapter 429 of the 2017 General Assembly Session, an interim report was published in 2017 (RD431) on e-prescribing. Subsequently, a workgroup was convened on August 29, 2018, to finalize its review of actions necessary for implementation, by July 1, 2020, of the mandatory issuance of electronic prescriptions for controlled substances containing an opiate. The workgroup previously met on August 2, 2017 and August 29, 2017, and its actions were summarized in an interim report submitted to you by Secretary Hazel on October 12, 2017. The workgroup was comprised of representatives from the Board of Pharmacy, Virginia Pharmacists Association, Virginia Council of Nurse Practitioners, National Association of Chain Drug Stores, Medical Society of Virginia, Virginia Hospital and Health Care Association, Surescripts, Virginia Dental Association, Virginia Veterinary Medical Association, Drug Enforcement Administration, and the Virginia Association of Health Plans. A complete listing of the workgroup members is enclosed. After opening remarks, David Brown, DC, Director of the Department of Health Professions (DHP), chaired the workgroup meeting.

Current data was provided by Surescripts to the members. Surescripts self-reports that it operates the nation's largest clinical health information network, serving providers in all 50 states and D.C. The company's network connects to over 98 percent of all retail pharmacies, most mail order pharmacies, and over one million U.S. providers. The Surescripts data represented two types of prescribers: Active E-prescribers (prescribers who have sent e-prescriptions to pharmacies using Surescripts network in the last 30 days using the electronic health records (EHR) software applications) and Active E-Prescribers Electronic Prescriptions for Controlled Substances (EPCS) enabled (prescribers who use an EHR software that is EPCS certified and audit approved).

During the last year, the percentage of Virginia prescribers who are active E-prescribers increased from 56.8% to 60.8%, and the percentage of prescribers who are EPCS enabled

doubled from 6.3% to 12.8%. Nationally, the percentage of prescribers who are EPCS enabled increased from 17.1% to 27.6%. Additionally, the percentage of Virginia pharmacies that are active eRx pharmacies (pharmacies that are ready and processing e-prescriptions from prescribers' applications) increased slightly from 97.5% to 98.5%, and the percentage of EPCS enabled pharmacies (pharmacies with certified and audit approved software ready to receive EPCS transactions from prescribers) increased from 90.3% to 95.9%. Nationally, the percentage of EPCS enabled pharmacies increased from 90.5% to 94.5%. During previous discussions, it was noted that there are hundreds of EPCS enabled physicians practicing within healthcare systems who do not utilize Surescripts (e.g. Kaiser Permanente) and are not included in the Surescripts data. Additionally, the Surescripts data regarding EPCS enabled prescribers does not include most dentists.

It was acknowledged that similar federal legislation is currently being considered by the United States Congress. HR 6 requires the e-prescribing of a prescription for a covered part D drug under a prescription drug plan (or under a Medicare Advantage Prescription Drug plan) for a schedule II, III, IV, or V controlled substance for drugs prescribed on or after January 1, 2021. In contrast, Virginia Code Section §54.1-3408.02 requires any prescription for a controlled substance that contains an opiate to be issued as an electronic prescription as of July 1, 2020. HR 6 was passed by the House of Representatives in June 2018 and later by the Senate in October 2018. HR 6 contains exemptions similar to the workgroup's recommendations.

The workgroup considered whether to monitor the progression of the federal legislation prior to recommending a legislative proposal to authorize the exemptions that were recommended in the 2017 Interim Report and then further clarified at the August 29, 2018, meeting. There was consensus that legislation should be introduced during the 2019 General Assembly Session (enclosed) and that any necessary amendments in response to federal legislation could be addressed during the 2020 General Assembly Session. There was further consensus that the Secretary of Health and Human Resources should convene a workgroup within two years of the effective date of the 2019 legislation of interested stakeholders to evaluate the implementation and report to the Chairmen of the House Committee on Health, Welfare, and Institutions and the Senate Committee on Education and Health by November 1, 2022. The workgroup's evaluation should identify successes and challenges with the mandate, and offer possible recommendations for increasing the electronic prescribing of controlled substances.

Please feel free to contact Caroline Juran, Executive Director of the Virginia Board of Pharmacy, at (804) 367-4456, should you have any questions.

Respectfully,

Daniel Carey, MD

Enclosures

HHR/DHP E-Prescribing Workgroup
Member List – August 29, 2018

In Attendance:

Workgroup Conveners

Daniel Carey, MD
Secretary of Health and Human Resources

David Brown, DC
Department of Health Professions, Director

Caroline Juran
Board of Pharmacy, Executive Director

Workgroup Members

Omar Abubaker, DMD, Ph.D.
Virginia Dental Association

Christina Barrille
Virginia Pharmacists Association

Ellen Byrne, DDS, PhD
Virginia Dental Association, Alternate Member

Lannie W. Cropper
Virginia Association of Chain Drug Stores

Carol Forster, MD
Kaiser Permanente

Kelly Gottschalk, DVM
Virginia Veterinary Medical Association

Doug Gray
Virginia Association of Health Plans

Richard Grossman
Virginia Council of Nurse Practitioners

Scott Johnson
HCA Hospitals

Ralston King
Medical Society of Virginia

Jodi Manz, MSW
Assistant Secretary of Health and Human Resources

R. Brent Rawlings
Virginia Hospital & Healthcare Association

Ken Whittemore, Jr., R.Ph., MBA
Surescripts, LLC

Staff

Laura Z. Rothrock
Virginia Department of Health Professions, Executive Assistant to Director David E. Brown, DC

Sheralee Copeland
Board of Pharmacy, Executive Assistant

Absent:

Ruth A. Carter
Drug Enforcement Administration

DRAFT Legislation

2019 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending §§ 54.1-3408.02 and 54.1-3410 of the Code of Virginia relating to electronic prescribing of a controlled substance containing an opiate.

Be it enacted by the General Assembly of Virginia:

1. **That § 54.1-3408.02 and 54.1-3410 of the *Code of Virginia* are amended and reenacted as follows:**

§ 54.1-3408.02. (Effective July 1, 2020) Transmission of prescriptions.

A. Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy as an electronic prescription or by facsimile machine and shall be treated as valid original prescriptions.

B. Any prescription for a controlled substance that contains an opiate shall be issued as an electronic prescription with the following exceptions:

1. A prescriber who dispenses the opiate directly to the patient or patient's agent;

2. A prescription for a controlled substance containing an opiate for a person residing in a hospital, assisted living facility, nursing home, or residential healthcare facility or receiving services from a hospice provider or outpatient dialysis facility, or;

3. A prescriber who experiences temporary technological or electrical failure or other temporary extenuating circumstance that prevents the prescription from being transmitted electronically, provided the prescriber documents the reason for this exception in the patient's medical record;

4. A prescriber who writes a prescription to be dispensed by a pharmacy located on federal property, provided the prescriber documents the reason for this exception in the patient's medical record;

5. A prescriber who writes a low volume of prescriptions, defined as less than 25 prescriptions during the most recent twelve-month period with a maximum of a seven-day supply for each prescription;

6. A prescription issued by a veterinarian;

7. A prescription for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing,

such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;

8. A prescription issued for an opiate under a research protocol;

9. A prescription issued in accordance with an Executive Order of the Governor for a declared emergency; and

10. A prescription that cannot be issued electronically in a timely manner and the patient's condition is at risk, provided the prescriber documents the reason for this exception in the patient's medical record.

C. In accordance with regulations adopted by the licensing board for a prescriber, a waiver may be granted for a period not to exceed one year of the requirement that any prescription for a controlled substance that contains an opiate be issued as an electronic prescription due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstance demonstrated by the prescriber.

§ 54.1-3410. When pharmacist may sell and dispense drugs.

A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person pursuant to a prescription of a prescriber as follows:

1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;

2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the Board's regulations;

3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order; and such directions as may be stated on the prescription.

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:

1. If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom,

or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed.

2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and devices, except for the signature of the prescriber.

A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section.

C. A drug controlled by Schedule VI may be refilled without authorization from the prescriber if, after reasonable effort has been made to contact him, the pharmacist ascertains that he is not available and the patient's health would be in imminent danger without the benefits of the drug. The refill shall be made in compliance with the provisions of § 54.1-3411.
If the written or oral prescription is for a Schedule VI drug or device and does not contain the address or registry number of the prescriber, or the address of the patient, the pharmacist need not reduce such information to writing if such information is readily retrievable within the pharmacy.

D. Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written record of the prescription required by this subsection specifies the full name of the agent of the prescriber transmitting the prescription.

E. (Effective July 1, 2020) ~~No pharmacist shall dispense a controlled substance that contains an opiate unless the prescription for such controlled substance is issued as an electronic prescription.~~ A dispenser is not required to verify that a prescriber properly falls under one of the exceptions specified in § 54.1-3408.02 for electronic prescribing prior to dispensing a controlled substance containing an opiate. A dispenser may continue to dispense a controlled substance containing an opiate from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws.

2. That the Boards of Medicine, Nursing, Dentistry, and Optometry shall promulgate regulations for issuing or renewing a temporary waiver for a prescriber within 280 days of enactment of this Act.

3. That the Secretary of Health and Human Resources shall convene a work group within two years of the effective date of this Act of interested stakeholders, including the Medical Society of Virginia, the Virginia Hospital and Healthcare Association, the Virginia Dental Association, the Virginia Association of Health Plans, and the Virginia Pharmacists Association to evaluate the implementation of this Act and shall make a report to the Chairmen of the House Committee on Health, Welfare, and Institutions and the Senate Committee on Education and Health by November 1, 2022. The workgroup's evaluation shall identify successes and challenges with the mandate, and offer possible recommendations for increasing the electronic prescribing of controlled substances.

Agenda Item: **Regulatory Action – Adoption of Final Regulations**

Scheduling Drug in Schedule V - Exempt action

Included in agenda package:

Copy of Notice of Public Hearing noting intent to schedule Epidiolex in Schedule V

Amendment to regulation: 18VAC110-20-323

Staff Note:

A public hearing was conducted before the meeting this morning.

Action is exempt from the provisions of the Administrative Process Act in accordance with § 2.2-4006.

Board action:

Adoption of final regulation in sections 322

Notice of Public Hearing
Scheduling to Conform to Federal Actions

Pursuant to subsection E of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider scheduling the drug Epidiolex in Schedule V in the Virginia Drug Control Act. The drug was scheduled by the Drug Enforcement Administration on September 27, 2018. The public hearing will be conducted at **1 p.m. on November 28, 2018** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233.

Subsection E of § 54.1-3443 of the Code of Virginia:

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of 30 days from publication in the Federal Register of a final or interim final order or rule designating a substance as a controlled substance or rescheduling or descheduling a substance by amending its regulations in accordance with the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. The Board shall include a list of all substances it intends to schedule by regulation in such notice.

April 24, 2018

Project 5748 - none

BOARD OF PHARMACY

Scheduling of Epidiolex in Schedule V

18VAC110-20-323. Scheduling for conformity with federal law or rule.

Pursuant to subsection E of § 54.1-3443 of the Code of Virginia and in order to conform the Drug Control Act to recent scheduling changes enacted in federal law or rule, the board:

1. Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;

2. Adds Dronabinol ((-)-delta-9-trans tetrahydrocannabinol) in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II; ~~and~~

3. Deletes naldemedine from Schedule II; and

4. Adds Epidiolex to Schedule V.

Consider Draft Proposed Regulation for White Bagging and Brown Bagging

Included in agenda packet:

- NOIRA
- NABP Publication regarding White and Brown Bagging
- Relevant Statute
- Draft Regulatory Amendments prepared by staff

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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	White bagging/brown bagging
Date this document prepared	12/11/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The Board intends to consider adopting a regulation to regulate brown bagging of drugs requiring reconstitution or compounding prior to administration and to set specific requirements for specialty pharmacies participating in white bagging. The intent of the regulatory action is public protection to ensure drugs are appropriately dispensed and administered.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.).

The specific authority for the Board to regulate the dispensing of prescription drugs is found in:

§ 54.1-3307. Specific powers and duties of Board.
A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.
The Board's regulations shall include criteria for:
1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.
2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.
3. Controls and safeguards against diversion of drugs or devices.
4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.
5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.
6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.
7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

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8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.
9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.
B. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

Purpose

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

The purpose of the proposed regulatory action is to address patient safety concerns relating to brown bagging and white bagging. information available to the Board will enhance its ability to protect the public health and safety.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

In the amended regulation, the Board will need to define "brown-bagging and white-bagging." At the 2016 annual meeting of the National Association of Boards of Pharmacy, a study resolution included these definitions: "*white bagging" generally refers to a patient-specific medication that is distributed by a pharmacy to a hospital, clinic, physician's office, or pharmacy for later preparation and administration to a patient where allowed by law and "brown bagging" generally refers to a patient-specific medication that is dispensed by a pharmacy to the patient and then brought by the patient to the hospital, clinic, or physician's office for administration.*"

In the addition to new definitions in the proposed regulations, the Board will consider regulations for:

- Brown bagging of drugs requiring special storage, reconstitution or compounding prior to administration;
- Requiring the specialty pharmacy participating in white bagging to notify the receiving pharmacy of the shipment to ensure appropriate coordination of patient care;
- Requiring the pharmacy to provide to the receiving pharmacy an estimated arrival date, to provide the name of the patient to whom the drug has been dispensed, and to provide the exact address where the product has been shipped.

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Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

On March 4, 2016, a Pharmacy Benefit Manager Workgroup issued its report to the Secretary of Health and Human Resources on a number of issues relating to the practice of PBMs. It included a discussion of some issues relating to "brown bagging and white bagging." The consensus among Workgroup members was that the Board of Pharmacy should review the practices to address issues of concern for patient safety. There are no viable alternatives to achieve the essential purpose of safety and efficacy of prescription drugs.

The Board will review regulations adopted in other states, such as provisions from Oregon which allow for "white bagging" with certain safeguards in place for reconstitution, labeling and accountability.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**) or by mail to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; by email to elaine.yeatts@dhp.virginia.gov; by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website

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(**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

A Regulatory Advisory Panel will not be used for development of regulatory changes; the amendments will be drafted by the Regulation Committee.

16-E

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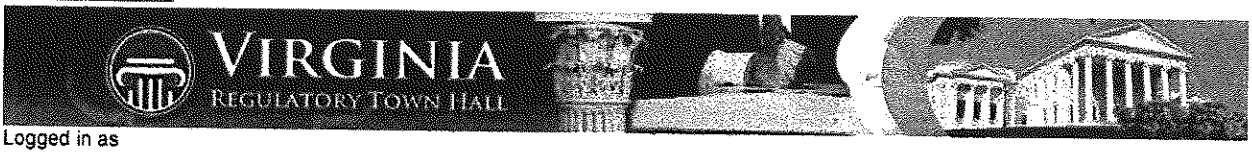

Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]**

Action	**Brown bagging and white bagging**
Stage	**NOIRA**
Comment Period	Ends 9/5/2018

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Commenter: Cynthia Williams, Riverside Health System 8/23/18 7:12 am

Comment on NOIRA for brown bagging/white bagging

I am in overall support of the NOIRA related to brown bagging and white bagging of medications. I support the use of the NABP definitions as presented. I am in overall support of the proposed regulations, but would like to submit some additional comments for considerations:

1. The brown bagging of drugs requiring special storage, reconstituion or compounding prior to administration should not be allowed from a patient safety and administering organization liability perspective. There is no method to ensure that the medication has been maintained at appropriate temperature and conditions prior to administration. Even if kept in a refrigerator at the patient home, the is no confirmation that the medication was maintained between 36-46 as required by standard. For RT medications, there is no confirmation that the medication was maintained at controlled room temperature. This not only puts the patient at risk, but puts the organization administering the medication at risk. For the most part, this practice is being driven soley for the financial benefit of insurance vendors, not for the benefit lor safety) of the patient or healthcare provider.

2. There are similar concerns related to storage for white bag medications. There is not the same assurance of integrity as if the organization had provided the medication and stored the medication as required by board of pharmacy regulation and requirements of other accrediting organizations (The Joint Commission, DNV, etc). Even with special packaging, there is not assurance of maintenance of temperature, putting the patient and administering organization at risk. Again, this practice is being driven soley for the financial benefit of insurance vendors.

3. Coordination of care with medications provided through a "white bag" process is challenging for both the healthcare provider and the patient, resulting in delays in care in many cases. The burden is put back on the patient and administering organization, while the financial benefit resides with the insurance vendor and out-of-state dispensing pharmacy. At a minimum, the burden should be placed back on the dispensing pharmacy to take ownership of coordination of shipping and receiving of medication. Ideally, regulations that pertain to any willing provider and other limitations of provision of services by payers (e.g. site of service limitations) could be strengthened to allow health systems to provide medications through normal procurement and distribution systmes.

Thank you in advance for your intent to draft regulation to control a process that lacks control and oversight today, and to improve the care and safety for our patients.

Commenter: Jamin Engel 8/31/18 11:29 am

Comments to Proposed "White" and "Brown" Bagging Regulations

Thank you for the Board's consideration in adopting regulations to regulate "brown" and "white" bagging within the State of Virginia. I am in support of these efforts, and appreciate the opportunity to submit further comments for consideration by the Board.

Overall, "brown" and "white" bagging through the utilization of specialty pharmacies has placed a significant burden on sites of care and patients. There is confusion on the differences between these two practices and the proper method of conducting business and treatment of patients. In addition, patients are becoming frustrated at a process that seems convoluted, impersonal, and a burden to receiving safe and effective care within established patient-provider locations. These established locations, if they choose to continue treatment for a patient forced to utilize a specialty pharmacy, are accepting the burden of risk for treatment with a medication procured outside traditional channels, and are spending significant resources in coordination of care.

Thank you for your consideration of the following comments:

1. Brown bagging should not be allowed. These medications require special storage and handling considerations and there is no validated method to ensure it is a safe to administer. This places an organization at high risk of liability, and the patient at high risk for adverse outcomes. Many organizations have already restricted use of brown bagging within their sites of care due to the safety risks.

2. I am in support of proposals to improve communication and chain of custody of white bagging. Often product is sent without any notification, and there are significant resources that are spent on determining who the medication is for, and when the administration is due. This results in patients showing up for administrations prior to the medication being procured, or the medication is sent to the wrong site of care.

3. Please consider modification or inclusion of 18VAC110-20-275, which requires a written contract or agreement for delivery of a filled prescription to another pharmacy for patient pickup. Specialty pharmacies has refused to sign these agreements in the past. In addition, please consider the implications of this practice on DSCSA Federal Regulations.

4. Consider the impact of white bagging on patients. In rural settings, we have patients that are driving past infusion centers for which they receive other medications. They are driving over an hour in some cases to an infusion center located in a "strip" mall, because that location has a contract with their specific insurance company. Patients do not understand why they cannot receive their medications in established, and in their opinion, safe sites of care. They are often apprehensive about the locations of these infusion centers. This practice is degrading trust in safe medication management, and reducing sites and access of care for patients.

5. Access to care may also continue to decrease as some infusion sites are receiving no reimbursement for resources and supplies used to administer these medications to patients. As specialty pharmacy continues to grow, the economic burden will continue to increase, and thus decisions will be made to discontinue treatment of these patients at previous sites of care. Organizations may also deem it too high of liability to continue.

6. Please consider language to remove restrictions to the pharmacies that patients may obtain these specialty medications. The pharmacies that serve current infusion centers, procure the same products through safe and validated supply channels. It also allows pharmacies that already take care of patients to continue to make safe decisions on care as they have access to the full

patient medical record.

Thank you again for your time and consideration!

Commenter: Elizabeth Early 9/4/18 12:28 pm

White/Brown bagging

I believe that brown bagging should not be allowed for the simple reason of that the pharmacy has to control of the medication to ensure the appropriate storage and integrity of the medication. We cannot delegate this responsibility, not even to the patient.

As for white bagging, I also do not support the use of white bagging for a facility that is capable of providing the medication for their patients. The reasons for not supporting this practice based on a variety of quality and patient safety issues. My concerns are:

- Patients receive a call from a pharmacy that is unknown to them and may be asked to provide credit card information to a company not associated with facility providing the care (difficult to differentiate from a phone scam). This may cause a delay in treatment.
- Before a shipment is sent out, the mail order pharmacy requires the approval and full copay remittance from the patient: no monthly payments or bills after the treatment as you would find at a healthcare facility. Due to the high cost and co-pays for these medications, this may cause a significant financial burden and/or result in a delay in treatment.
- The patient's next treatment becomes dependent on a delivery, not an established schedule. Coordinating ordering, receipt and administration drains a facility's resources and may test the staff's (and the patient's) patience.
- The mail order pharmacy will not have the entire medical record for the patient which may lead to issues with continuity of care between the ordering provider, the pharmacy and the facility infusing the medication.
- The patient's condition may change before the shipment is received. The patient may have to pay for another medication (in addition to the one that was sent originally). Because the drug arrives at the facility, but is the property of the patient, the pharmacy cannot use the drug on another patient and is now responsible for disposal of a hazardous product.
- Most mail order pharmacies are not willing to sign alternate site delivery contracts as required by Virginia law.
- The origin of drugs cannot be traced further back than the mail-order company. Where, when and from whom were the drugs purchased?
- Mail order pharmacies may take longer to fill backorders causing delays and cancelling treatments that may be perceived by the patient as a facility issue.
- A delivery may sit for hours in extreme heat or cold conditions. So, a box full of sensitive drugs sitting outside for hours may result in compromised contents....how does the facility ensure that it was handled appropriately and safely at all times if they are not controlling the supply chain?
- Is the facility legally responsible for any product injected into the patient even when they have lost control of the process? Will malpractice insurance cover such claims? Whose fault is it in the case of a negative outcome?
- The pharmacy preparing the drug receives no reimbursement for their time and supplies used to get the drug ready for administration. In addition, the facility may not be able to get reimbursement/denied reimbursement for the administration if there is no drug charge on the

bill.

Commenter: Marci Cali, Virginia Association of Hematology and Oncology 9/5/18 2:51 pm

Re: NOIRA on White Bagging/Brown Bagging

Dear Ms. Yeatts:

The Virginia Association of Hematology and Oncology (VAHO) appreciates this opportunity to comment on the Virginia Board of Pharmacy's (the "Board") Notice of Intended Regulatory Action to amend 18VAC110-20, Regulations Governing the Practice of Pharmacy, regarding the "white bagging" and "brown bagging" of drugs. VAHO represents over 150 oncology physicians and other oncology healthcare professionals practicing in Virginia. VAHO seeks to improve the quality of oncology care available to the people of Virginia. VAHO members are committed to ensuring that safe, evidenced-based practices for the prevention, diagnosis and treatment of cancer are available to all Virginians.

Under the definition of the National Associations of Boards of Pharmacies (NABP), VAHO recognizes "white bagging" and "brown bagging" as the following:

- "Brown Bagging" – Under this practice, a pharmacy dispenses a medication directly to a patient, who then transports the medication themselves for administration at their physician's office. Often, this practice occurs at specialty pharmacies.
- "White Bagging" – Under this practice, the pharmacy dispenses a patient's medication to the physician's office for administration. This practice is often used for oncology patients to obtain medications that are not available at all non-specialty pharmacies.

Administration of drugs for cancer patients requires a great deal of care and sensitivity to ensure safety for the patient and provider. Due to the imperative needs of oncology drugs to be treated with certain handling, storage, and transportation requirements, VAHO is deeply concerned and opposes brown bagging to deliver injectable oncolytics to cancer patients in the state of Virginia. Both white bagging and brown bagging have the potential to put the patient and their provider at risk, as well as significantly impact a patient's treatment outcomes, and for that reason, VAHO stands in opposition of the NAIRO notice. Oncology drugs are delivered to patients specifically with adequate safety measures in mind, especially during administration.

VAHO would like to voice concern over a waste issue that can arise with "white bagging" if a physician needs to make a timely decision to update a patient's dosage or adjustment of a patient's treatment. Administration of oncolytics for a patient can change rapidly, and "white bagging" has been proven to increase waster of expensive oncolytics for cancer patients and their providers across the country.

Thank you for this opportunity to share the oncology provider perspective on your proposals in the Virginia Board of Pharmacy's Notice of Intended Regulatory Action to amend 18VAC110-20, Regulations Governing the Practice of Pharmacy, regarding the "white bagging" and "brown bagging" of drugs. VAHO supports continued consideration of these regulations but is in strong opposition to "white bagging" and "brown bagging." Please feel free to contact Dr. Richard Ingram, VAHO President, if you have any questions or need any additional information. We look forward to working with you on this critical issue for oncology patients and their providers in the state of Virginia. Thank you again for your attention to this very important matter.

Respectfully Submitted,

Richard Ingram, MD

VAHO President

Commenter: Tracie Chambers, Community Health Systems 9/5/18 3:28 pm

White-bagging

My company owns 3 sites in Virginia. We are committed to helping each of sites provide the best care to all patients' while meeting all rules and regulations. Recently, during a Board visit, one site who had received a refrigerated med from a specialty pharmacy for a patient scheduled in the next day was asked if they had a written contract with this pharmacy to do business. Of course the answer was No, as this is viewed as a patient's own med and having it sent directly from the other pharmacy to the hospital pharmacy helps assure the integrity of the product prior to use versus having the med sent to the patient at home where proper storage requirements cannot be verified. The time of notification that the patient was coming in for a refrigerated, injectable med and time of receipt was approximately one week which would not allow the hospital enough time to set up a contract or written agreement with the specialty pharmacy. I would hate to have to turn this patient population away but given the quick turnaround times, there is no way to be compliant with the current guideline for contracting. I want each of our sites to be able to care for Virginia residents so would appreciate your consideration to grant exceptions for these patients' that require a refrigerated medication that insurance dictates must be purchased through a specialty pharmay and allow them to be viewed as patients' own meds just temporarily stored in the hospital pharmacy until day of administration similar to inpatients' that must use their own med if it is not available on the hospital formulary.

Commenter: Natalie Nguyen, Virginia Society of Health System Pharmacists 9/5/18 6:14 pm

Comments on Behalf of the Virginia Society of Health-System Pharmacists

VSHP is in overall support of regulation to regulate brown bagging of drugs requiring reconstitution or compounding prior to administration and the establishment of specific requirements for specialty pharmacies participating in white bagging, with the overall intent of public protection.

VSHP supports the use of definitions of brown bagging and white bagging as established by NABP.

In addition to the regulations under consideration as defined in the NOIRA, VSHP suggests expansion of regulations under consideration to include:

1. Not allowing brown bagging of medications that require special storage, reconstitution or compounding prior to administration due to the risk to the patient and the organization providing administration of the medication.

2. Leverage current "Any Willing Provider" legislation to allow health systems that have specialty pharmacy/retail pharmacy capability to provide the needed medications for patients receiving care at health system owned locations. Alternatively, include provisions that would allow health systems to provide medications through normal procurement process versus through external specialty pharmacy providers. This would allow more robust coordination, reduce the risk of medication errors and patient harm, limit risk of improper storage of medications, and minimize delays in patient care.

3. Inclusion of requirement for coordination of shipment and arrival date to include physician-based practices and other locations of care since often the transfer is not pharmacy to pharmacy.

In addition, VSHP members have inquired about whether proposed regulations will impact the following scenarios, and we look forward to providing further comment:

- Patient Assistance Programs and Manufacturer Consignment Programs
- Patient request of provider administration of non-reconstituted, non-compounded medications (such as ready to inject syringes) brown bag medications due to concerns with self-administration at home
- Exclusions for emergent situations. Example: Patients with hemophilia admitted to emergency departments requiring emergent blood factor treatment that requires reconstitution that is not carried by pharmacy. These patients usually bring their own blood factor products to the Emergency Department as a result.

White and Brown Bagging Emerging Practices, Emerging Regulation

Prepared By

The National Association of Boards of Pharmacy

White and Brown Bagging Emerging Practices, Emerging Regulation

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NABP Mission Statement

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions for the purpose of protecting the public health.

NABP Vision Statement

Innovating and collaborating today for a safer public health tomorrow.

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Overview

At the NABP 112th Annual Meeting in May 2016, the membership passed Resolution 112-1-16 requesting that NABP conduct a study to review and define the practices of "white bagging" and "brown bagging," and recommend regulatory language, if necessary, to *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act*). The "study" design and methodology were framed in the discussions of the Resolutions Committee at the Annual Meeting, as they had not been defined in the actual resolution. The Resolutions Committee determined that a task force to examine these practices was not warranted because of the finite body of knowledge surrounding them and the limited consideration of the practices by boards of pharmacy. In lieu of a task force, the Resolutions Committee proposed that NABP staff research the issue and present the findings to the Executive Committee, and the Executive Committee decide what, if any, revisions would be made to the *Model Act*.

The Executive Committee, in approving the implementation of the resolution, directed that NABP staff perform a review of the professional literature, utilize **NABP***LAW* and other sources to determine how state boards of pharmacy have defined and regulated the practices, and develop model language, if appropriate, for the Executive Committee's consideration.

Results

NABP staff executed the study as directed by the Executive Committee with the following results:

1. Within the professional literature, "White Bagging" and "Brown Bagging" are defined as follows:
    a. "White bagging" refers to the distribution of patient-specific medication from a pharmacy, typically a specialty pharmacy, to the physician's office, hospital, or clinic for administration. It is often used in oncology practices to obtain costly injectable or infusible medications that are distributed by specialty pharmacies and may not be available in all non-specialty pharmacies.
    b. "Brown bagging" refers to the dispensing of a medication from a pharmacy (typically a specialty pharmacy) directly to a patient, who then transports the medication(s) to the physician's office for administration.
2. Prevalence of "Bagging" Practices
    a. Magellan Rx Management's 2015 Medical Pharmacy Trend Report, which includes data from 59 health plans, representing 129.7 million covered individuals, found that 28% of medical benefit drug volume was distributed to physician offices by specialty pharmacies or by patients through brown bagging.

b. The 2016 Genentech Oncology Trend Report also provides data from managed care organizations, which reported that 28% of oncology drugs were distributed to practices by retail, mail, and specialty pharmacies.
c. A Zitter Health Insight's survey of managed care executives reported that 31% of provider-administered infusible oncology therapies were fulfilled by either specialty pharmacies or patient brown bagging. See a 2013 write-up in Payers Want Specialty Drug Distribution to Change.

3. Regulatory Roles – A review of state practice acts and regulations determined that few states define the concepts of white bagging or brown bagging. The delivery methods, although a component of some medical practices, such as oncology, may be a more significant issue in the reimbursement arenas.

Results Background

Pharmacists, patients, prescribers, and payers all have distinct incentives for adopting the white bagging or brown bagging model. Of significant benefit, these models give pharmacists a greater opportunity to utilize their expertise to improve patient outcomes. For example, pharmacists work closely with prescribers and other health care providers to determine the best possible treatment for specific diseases and ensure their patients understand how to optimize drug therapy and manage potential medication side effects. Pharmacists can also use their patient medication therapy management skills by checking for duplicate drug therapy, assessing drug-drug interactions, providing drug utilization reviews, and suggesting appropriate changes. Finally, pharmacists can ensure patient adherence by engaging with patients through educational, empowerment, and self-management programs.

From the prescriber perspective, there are clear benefits that come from these drug distribution models. Brown bagging and white bagging models reduce physicians' costs associated with purchasing and stocking expensive medications and limit the lengthy administrative process of billing payers for reimbursements, as the provider neither purchases the drug nor seeks drug reimbursement from a third-party payer. However, the provider is still paid for professional services associated with the drug's administration. From the payer perspective, benefits include cost savings through negotiated dispensing rates and increased transparency.

Despite offering some benefits for all parties involved, there are still issues within the brown bagging and white bagging models that must be considered. One concern stems from the nature of the medications provided through these models. These medications are often patient-specific and require special handling and can thus pose safety, operational, and unexpected financial burdens. Additionally, medication delivered directly to the patient through

the brown bagging model may have been incorrectly stored or handled, which can affect the drug's efficacy.

Another obvious challenge for specialty pharmacies comes from the potential lack of access to the patient's electronic medical record, which then requires additional coordination between the patients and their physicians.

Furthermore, under the white bagging model, physicians and dispensing pharmacies face the unpaid expense of safeguarding and storing patients' medication until drug administration.

In some instances, patients participating in white bagging or brown bagging programs often require therapy modification. Change of dosage or strength or transition to a different class of medications is common. When therapy modification occurs, it often leads to excessive waste because the previously dispensed medication cannot be reused for a different patient.

On occasion, these drugs are highly toxic and require special handling to discard. The disposal process can be very costly and requires compliance with additional state and federal requirements overseen by environmental protection agencies.

For patients, there may be some obstacles to obtaining the medication from a specialty pharmacy. Patients may have trouble acquiring the medication from the pharmacy before proceeding to their clinic, hospital, or physician's appointment because of delays in processing requests for insurance coverage. Medication delivered through the mail may arrive late or damaged. Additionally, patients may be inconvenienced by dosage changes made after receipt of their medication but prior to administration. It is also important to note the financial burdens that exist for patients who need specialty drugs, as many have costly out-of-pocket copayments.

As the specialty pharmacy model becomes more prevalent and is often mandated by third-party payers, it appears that the practices of white bagging and brown bagging will be utilized more often and incorporated into the care of a greater number of patients. The terms and conditions for this business model are most often set by the third-party payers, who are frequently not under the regulatory authority of the state boards of pharmacy. As previously mentioned, white bagging and brown bagging are not without shortcomings. The boards must determine who is accountable for verifying the authenticity and integrity of the drug before administration. Furthermore, regulators must decide who is responsible when a delay in therapy, due to a lack of coordination between patient, prescriber, and pharmacy, leads to adverse outcomes for patients. These issues are left to the state boards of pharmacy to grapple with in an effort to protect the public.

The control and responsibility for the integrity and timely delivery of the medications under each bagging practice are two of the issues most relevant to the role and responsibility of the boards of pharmacy. The specific questions to be considered are: Where, when, and from whom were the medications purchased? Were the medications manufactured abroad and not Food and Drug Administration-approved? A shipment of sensitive drugs sitting outside a pharmacy or patient's residence for hours may result in compromised contents and raises concerns about whether the medication was handled appropriately and safely at all times.

Recommendations

1. The practice of dispensing a specialty drug directly to the patient, who then transports the specialty drug to the physician's office or clinic, colloquially referred to as "brown bagging," is determined to be included in the definition of the practice of pharmacy. As such, there is no need to define this concept separately in the *Model Act*. Similarly, all the conditions and requirements applicable to the practice of pharmacy, including, but not limited to, the performance of a drug utilization review, responsibility for the integrity of the medication, patient counseling and education, and the provision of disposal instructions, are applicable to specialty drugs dispensed directly to the patient for subsequent administration by the physician.
2. The study determined that there is a legitimate patient protection issue when a specialty drug is distributed to an entity other than the patient. The pharmacy distributing the specialty drug is responsible for appropriate notification to the dispensing pharmacy or to patient's agent if the specialty drug is to be administered by the agent.

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From *The Pharmacy Act and Drug Control Act with Related Statutes,* July 1, 2018

§ 54.1-3420.2. Delivery of prescription drug order.

A. Whenever any pharmacy permitted to operate in this Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the following conditions shall be required:

1. Written notice shall be placed in each shipment alerting the consumer that under certain circumstances chemical degradation of drugs may occur; and

2. Written notice shall be placed in each shipment providing a toll-free or local consumer access telephone number which is designed to respond to consumer questions pertaining to chemical degradation of drugs.

B. If a prescription drug order for a Schedule VI controlled substance is not personally hand delivered directly to the patient or the patient's agent, or if the prescription drug order is not delivered to the residence of the patient, the delivery location shall hold a current permit, license, or registration with the Board that authorizes the possession of controlled substances at that location. The Board shall promulgate regulations related to the security, access, required records, accountability, storage, and accuracy of delivery of such drug delivery systems. Schedule II through Schedule V controlled substances shall be delivered to an alternate delivery location only if such delivery is authorized by federal law and regulations of the Board.

C. Prescription drug orders dispensed to a patient and delivered to a community services board or behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the facility on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by a community services board or behavioral health authority facility for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

D. Prescription drug orders dispensed to a patient and delivered to a Virginia Department of Health or local health department clinic upon the signed written request of a patient, a patient's legally authorized representative, or a Virginia Department of Health district director or his designee may be stored and retained at the clinic on behalf of the patient for subsequent delivery or administration.

E. Prescription drug orders dispensed to a patient and delivered to a program of all-inclusive care for the elderly (PACE) site licensed by the Department of Social Services pursuant to § 63.2-1701 and overseen by the Department of Medical Assistance Services in accordance with § 32.1-330.3 upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the site on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by the PACE site for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. The procedure for assuring confidentiality of patient information; and

e. The procedure for informing the patient and obtaining consent for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

F. The pharmacy and alternate delivery site is exempt from compliance with subsections A-E when the alternate delivery site is a hospital, medical clinic, prescriber's office, or pharmacy that does not routinely receive deliveries from the pharmacy and compliance with subsections A-E would create a delay in delivery that may result in potential patient harm.

1.To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to where the drug was shipped, the name of the patient for whom the drug was dispensed, and any special storage requirements.

2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling.

3. Prescriptions delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed prescriber, pharmacist, or either person's designee.

4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient.

G. A pharmacy shall not deliver dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage, reconstitution or compounding prior to administration.

Consider Submission of Public Comment regarding FDA Draft Guidance Document - MOU Addressing Certain Distributions of Compounded Drug Products

Included in agenda packet:

- Excerpt from Federal Register regarding public comment opportunity
- Draft of MOU with suggested changes from NABP

information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert A. Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3065]

Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the States and the Food and Drug Administration; Revised Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability for public comment of a revised draft standard memorandum of understanding (MOU) entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration" (revised draft standard MOU). The revised draft standard MOU describes the responsibilities of a State that chooses to sign the MOU in investigating and responding to complaints related to compounded drug products compounded in the State and distributed outside the State and in addressing the interstate distribution of inordinate amounts of compounded drug products.

FDA is also announcing the withdrawal of an earlier draft standard MOU entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration," which was issued in February 2015 (2015 draft standard MOU). The 2015 draft standard MOU is superseded by the revised draft standard MOU.

DATES: FDA is withdrawing its draft standard MOU that published on February 19, 2015 (80 FR 8874), as of September 10, 2018. Submit either electronic or written comments on the revised draft standard MOU by December 10, 2018, to ensure that the Agency considers your comment on this draft MOU before it begins work on the final version of the MOU. Submit either electronic or written comments on information collection issues under the Paperwork Reduction Act of 1995 by December 10, 2018 (see the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments on the MOU at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2018–N–3065 for "Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the States and the Food and Drug Administration; Revised Draft; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft MOU to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993–0002, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that: (1) The drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products distributed outside such State or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (5 percent limit) (see section 503A(b)(3)(B)(i) and (ii) of the FD&C Act).

Section 503A(b)(3)(B) of the FD&C Act directs FDA to develop, in consultation with the National Association of Boards of Pharmacy (NABP), a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i).

II. Previous Efforts To Develop a Standard MOU

In the **Federal Register** of January 21, 1999 (64 FR 3301), FDA announced the availability for public comment of a draft standard MOU, developed in consultation with NABP (1999 draft standard MOU). Over 6,000 commenters submitted comments on the 1999 draft standard MOU. Because of litigation over the constitutionality of the advertising, promotion, and solicitation provision in section 503A of the FD&C Act,[1] the draft standard MOU was not completed. In 2013, section 503A of the FD&C Act was amended by the Drug Quality and Security Act (DQSA) (Pub. L. 113–54) to remove the advertising, promotion, and solicitation provisions that were held unconstitutional, and FDA took steps to implement section 503A, including the provisions on the MOU. In the **Federal Register** of February 19, 2015 (80 FR 8874), FDA withdrew the 1999 draft standard MOU and issued the 2015 draft standard MOU for public comment. FDA received more than 3,000 comments on the 2015 draft standard MOU. By this notice, FDA is withdrawing the 2015 draft standard MOU, and the revised draft standard MOU made available today supersedes the 2015 draft standard MOU.

III. 503A Guidance

Immediately after the enactment of the DQSA, in December 2013, the Agency published a draft guidance on section 503A of the FD&C Act entitled "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act" (2013 draft 503A guidance) (see 78 FR 72901, December 4, 2013) announcing the availability of the draft guidance). The 2013 draft 503A guidance described FDA's proposed policy with regard to specific provisions of section 503A of the FD&C Act that require rulemaking or other action by FDA, such as the MOU provisions. Several commenters on the 2013 draft 503A guidance offered FDA their views on the MOU provisions of section 503A of the FD&C Act. FDA considered these comments in developing the 2015 draft standard MOU and the revised draft standard MOU it is issuing today. The final 503A guidance (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm469119.pdf*), published July 2, 2014 (see 79 FR 37742 announcing the availability of the final 503A guidance), states that FDA does not intend to enforce the 5 percent limit on distribution of compounded drug products out of the State in which they are compounded until after FDA has finalized an MOU and made it available to the States for their consideration and signature. After considering any comments on the revised draft standard MOU submitted to this docket, FDA intends to finalize the MOU and make it available for signature by individual States. FDA will determine at the time of publication of the final MOU how long it will allow States to consider whether to sign the MOU before FDA begins to enforce the 5 percent limit in those States that have not signed an MOU. As discussed below, FDA is proposing a 180-day period.

[1] The conditions of section 503A of the FD&C Act originally included restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug and the solicitation of prescriptions for compounded drugs. These provisions were challenged in court and held unconstitutional by the U.S. Supreme Court in 2002. See *Thompson* v. *Western States Med. Ctr.*, 535 U.S. 357 (2002).

IV. Revised Draft Standard MOU

FDA has now developed a revised draft standard MOU on which it is soliciting public comment. FDA has consulted with NABP in developing this revised draft standard MOU. FDA also considered the comments submitted on the 2015 draft standard MOU, as well as comments on the MOU provisions it received in connection with the 2013 draft 503A guidance. Below, FDA has summarized and discussed key provisions of the revised draft standard MOU and, where appropriate, summarized changes that the Agency made in the revised draft standard MOU. Drug products intended for veterinary use, repackaged drug products, biological products subject to licensure through a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262), and drug products compounded by outsourcing facilities are not the subject of the revised draft standard MOU.

A. Investigation of Complaints

The revised draft standard MOU provides that States that enter into the MOU will agree to:

- Investigate complaints relating to drug products compounded by a pharmacist in the State and distributed outside the State by a pharmacy, including complaints about adverse drug experiences or product quality issues to, among other things, take steps to assess whether there is a public health risk and whether such risk is adequately contained;
- Take action, in accordance with and as permitted by State law, to ensure that the relevant compounding pharmacy investigates the root cause of the problem and addresses any public health risk identified in relation to the complaint;
- Notify FDA as soon as possible, but no later than 3 business days, after receiving any complaints relating to a drug product compounded by a pharmacist in the State and distributed outside the State involving a serious adverse drug experience or serious

product quality issue, and provide FDA with certain information about the complaint, including the following:

- Name and contact information of the complainant;
- Name and address of the pharmacy/physician that is the subject of the complaint;
- Description of the complaint, including a description of any compounded drug product that is the subject of the complaint; and
- State's initial assessment of the validity of the complaint relating to a compounded drug product distributed outside the State, if available;

• Subsequent to this notification, provide FDA with the results (description and date of any State actions) of its investigation;

• Notify the appropriate regulator of physician compounding within the State of any complaints about adverse drug experiences or product quality issues related to drug products compounded by a physician in the State and distributed outside the State; and

• Maintain records of the complaints it receives, the investigation of each complaint, and any response to or action taken as a result of a complaint, beginning when the State receives notice of the complaint. The revised draft standard MOU says that the State agrees to maintain these records for at least 3 years, beginning on the date of final action or the date of a decision that the complaint requires no action.

The types of complaints of compounded drug products that should be investigated include *any* adverse drug experience and product quality issues. Even non-serious adverse drug experiences and product quality issues can be indicative of problems at a compounding facility that could result in product quality defects leading to serious adverse drug experiences if not corrected. For example, inflammation around the site of an injection can indicate drug product contamination from inadequate sterile practices at the compounding pharmacy. If the pharmacy has inadequate sterile practices, other more serious contamination could result in serious adverse events.

The revised draft standard MOU does not include specific directions to the States relating to how to conduct their investigation of complaints. Rather, as recommended by comments submitted to FDA previously, the details of such investigations are left to the States' discretion. For example, a State may review an incoming complaint describing an adverse drug experience and determine that such a complaint does not warrant further investigation. In other cases, a State may determine that an incoming complaint contains insufficient information and investigate further to determine appropriate action.

States signing the revised draft standard MOU would agree to notify FDA about certain complaints and provide FDA with certain information about the complaints so FDA could investigate the complaints itself, or take other appropriate action.[2] FDA received comments that it was not feasible for States to notify FDA of certain complaints within a 72-hour timeframe, as described in the 2015 draft standard MOU. Comments noted that gathering the information requested for submissions within just 72 hours might be difficult for States, particularly given that this period might overlap with a weekend or holiday. Some comments requested up to 7 days to provide the notification, but several others suggested that FDA revise the notification period to 3 *business* days. FDA has now revised the MOU to reflect the latter approach. The revise draft standard MOU provides that notification will occur as soon as possible, but no later than 3 business days after the State receives the complaint. This period will continue to facilitate early Federal/State collaboration on serious adverse drug experiences and serious product quality issues that have the potential to affect patients in multiple States, while providing for notification in a time frame that is more feasible for the States. We note that FDA has staff on call 24 hours a day to receive information in emergency situations.

Comments also expressed concern that certain provisions regarding complaint investigation that States entering into the MOU would agree to may require States to take action not permitted by State law and may imply that, after taking action, the State has made a legal determination that the complaint has been resolved. The revised draft standard MOU clarifies that the State should investigate and take action that the State considers to be appropriate with respect to the complaint in accordance with and as permitted by State law. FDA has also clarified that, by signing the MOU, the State agrees to assess the existence of a public health risk associated with the complaint and whether such risk is adequately contained rather than make definitive determinations of risk or confirm containment.

[2] FDA is currently considering whether to propose regulations or issue guidance documents to further its implementation of section 503A(b)(3)(B) of the FD&C Act. Notice of any such action will be provided in the **Federal Register**.

B. Inordinate Amounts

The revised draft standard MOU provides that States that enter into the MOU will agree to:

• On an annual basis (at minimum), identify, using surveys, reviews of compounding records during inspections of compounding pharmacies, or other mechanisms available to the State, compounding pharmacies that distribute inordinate amounts of compounded drug products interstate by collecting information regarding the following:

- Total number of prescription orders for compounded drug products distributed or dispensed intrastate, and
- Total number of prescription orders for compounded drug products distributed interstate;

• If the State becomes aware of a physician who is distributing compounded drug products interstate, coordinate with the appropriate regulator of physician compounding within the State to determine, using surveys, reviews of records during inspections, or other mechanisms available to the State, whether the physician distributes inordinate amounts of compounded drug products interstate by collecting information regarding the following:

- Total number of prescription orders for compounded drug products distributed or dispensed intrastate, and
- Total number of prescription orders for compounded drug products distributed interstate;

• For pharmacies or physicians that have been identified as distributing inordinate amounts of compounded drug products interstate, collect information regarding the following:

- Total number of prescription orders for sterile compounded drugs distributed interstate;
- Number of States in which the compounding pharmacy or physician is licensed or into which the compounding pharmacy or physician distributes compounded drug products; and
- Whether the State inspected for and found during its most recent inspection that the compounding pharmacy or physician distributed compounded drug products without valid prescriptions for individually identified patients;

• Notify FDA if the State identifies any pharmacy or physician within its jurisdiction that has distributed inordinate amounts of compounded drug products interstate; and

• Provide FDA with the following information regarding pharmacies or physicians that distributed inordinate amounts of compounded drug products interstate:

- Name and address of the pharmacy/physician;
- Total number of prescription orders for compounded drug products distributed or dispensed intrastate;
- Total number of prescription orders for compounded drug products distributed interstate;
- Total number of prescription orders for sterile compounded drugs distributed interstate,
- Number of States in which the compounding pharmacy or physician is licensed or into which it distributes compounded drug products, and
- Whether the State inspected for and found during its most recent inspection that the compounding pharmacy or physician distributed compounded drug products without valid prescriptions for individually identified patients.

In the revised draft standard MOU, a pharmacy or physician is considered to have distributed an inordinate amount of compounded drug products interstate if the number of prescription orders for compounded drug products distributed interstate during any calendar month is greater than 50 percent of the number of prescription orders for compounded drug products dispensed or distributed both intrastate and interstate by such pharmacy or physician during that calendar month. This concept would be called the 50 percent threshold.

Section 503A of the FD&C Act reflects Congress' recognition that compounding may be appropriate when it is based on receiving a valid prescription or notation from a prescribing practitioner for an identified individual patient. However, drug products compounded under section 503A are not required to demonstrate that they are safe or effective, bear adequate directions for use, or conform to CGMP. Congress, therefore, imposed strict limits on the distribution of drug products compounded under section 503A to protect the public health and the integrity of the drug approval process.

In particular, Congress did not intend for compounders operating under these statutory provisions to grow into conventional manufacturing operations making unapproved drugs, operating a substantial proportion of their business interstate, without adequate oversight. Although other provisions of the FD&C Act apply to State-licensed pharmacies and physicians that may qualify for the exemptions under section 503A of the FD&C Act (*e.g.*, the adulteration provisions for making drugs under insanitary conditions), and although FDA may take action in appropriate cases against compounders that violate these provisions or that operate outside of the conditions in section 503A, Congress recognized that these compounders are primarily overseen by the States. If a substantial proportion of a compounder's drugs are distributed outside a State's borders, adequate regulation of those drugs poses significant challenges to State regulators. States face logistical, regulatory, and financial challenges inspecting compounders located outside of their jurisdiction. In addition, if a compounder distributes drugs to multiple States, it can be very difficult to gather the scattered information about possible adverse events associated with those drugs, connect them to the compounder, and undertake coordinated action to address a potentially serious public health problem.

Therefore, as a baseline measure, section 503A(b)(3)(B) of the FD&C Act limits the distribution of compounded drug products outside of the State in which they are compounded to 5 percent of the total prescription orders dispensed or distributed by a licensed pharmacist, pharmacy or physician. It then directs FDA, in consultation with NABP, to develop a standard MOU that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products compounded in and distributed outside such State. Implementation of this provision involves FDA describing what inordinate amounts means and providing a mechanism for addressing interstate distribution of inordinate amounts of compounded drug products, as long as the States agree to appropriately investigate complaints relating to drug products compounded in and distributed out of the State.

In the 2015 draft standard MOU, FDA proposed that distribution interstate up to a 30 percent limit would not be inordinate, and that States entering into the MOU would agree to take action regarding pharmacists, pharmacies, or physicians that distribute inordinate amounts of compounded drugs interstate. FDA received a number of comments indicating that certain pharmacies, such as pharmacies located near state borders and home infusion pharmacies, distribute more than 30 percent of their compounded drugs to patients interstate because, for example, the patients are located in another nearby State, or because few pharmacies compound a particular drug to treat an uncommon condition for patients dispersed throughout the country. The comments noted that the proposed definition of inordinate amounts and the proposed provision in which States agree to take action could prevent such pharmacies from fulfilling patients' medical needs for the drugs that they supply. Other comments expressed concern about instances in which pharmacies are located near a State border and distribute compounded drugs to the other side of that border. FDA also received general comments questioning the Agency's basis for the 30 percent limit and indicating that it was too low. Some comments suggested that FDA increase the limit, including a suggestion to increase it to 50 percent.

The revised draft standard MOU addresses these comments in two respects. First, it would remove the provision in the 2015 draft standard MOU that States agree to take action with respect to the distribution of inordinate amounts of compounded drug products interstate. Second, it would change what is considered "inordinate amounts" from a 30 percent limit to a 50 percent threshold.

With respect to State action, the revised draft standard MOU instead provides that States entering into the MOU would agree to inform FDA of compounders that have distributed an inordinate amount of compounded drug products interstate. The Agency does not intend to take action against a compounder located in a State that has entered into the MOU solely because the compounder has exceeded the threshold for inordinate amounts. Rather, FDA proposes that States collect further information on compounders that have distributed inordinate amounts interstate and provide this information to FDA to help inform inspectional priorities.

States generally have day-to-day oversight responsibilities over State-licensed pharmacies, pharmacists, and physicians. In general, FDA considers a pharmacy or physician that distributes the majority of its compounded drugs intrastate to be primarily overseen by the State, which is responsible both for regulation of the compounder and protection of its citizens who receive the compounded drugs. However, as discussed above, if a substantial proportion of a compounder's drugs is distributed outside a State's borders, adequate regulation of those drugs poses significant challenges to State regulators. In such cases, although State oversight continues to be critical, additional oversight by FDA may afford an important public health benefit.

As stated above, in the revised draft standard MOU, FDA proposes eliminating the 30 percent limit and instead establishing 50 percent as the threshold beyond which the amount of compounded drugs distributed

interstate would be considered inordinate. Under this proposal, the threshold triggers an information collection and reporting obligation once it is reached. The Agency believes that more than 50 percent is an appropriate measure of "inordinate amounts" because it marks the point at which pharmacies and physicians are distributing the majority of their compounded drug products interstate, and the regulatory challenges associated with interstate distributors discussed above become more pronounced. At this tipping point, the risk posed by the distribution practices of the compounder may weigh in favor of additional Federal oversight in addition to State oversight.

FDA recognizes that in some cases, compounders may distribute more than 50 percent of a small quantity of compounded drug products to contiguous States. Although such compounders have exceeded the inordinate amounts threshold proposed in the revised draft standard MOU, FDA would consider other information, such as the number of patients that will receive the compounded drugs, if available, when assessing the compounders' priority for risk-based inspection. Accordingly, when a State identifies a pharmacy or physician that distributes an inordinate amount of compounded drug products interstate, the draft standard MOU provides that the State would supply the Agency with: (1) Information about the total number of prescription orders for compounded drug products that it distributed or dispensed intrastate; (2) the total number of prescription orders for compounded drug products that it distributed interstate; (3) the total number of prescription orders for sterile compounded drug products that it distributed interstate; (4) the number of States in which the compounder is licensed; and (5) whether the State inspected for and found during its most recent inspection that the compounding pharmacy or physician distributed compounded drug products without valid prescriptions for individually identified patients. FDA intends to use this information to prioritize its inspections of compounders based on risk, focusing on those that appear likely to distribute large volumes of compounded drug products, particularly when the distribution is to multiple States, the drug products are intended to be sterile, and there is information about a lack of valid prescriptions for individually identified patients.

FDA has further revised the calculation of inordinate amounts as follows. The 2015 draft standard MOU provided that a compounder is considered to have distributed an inordinate amount of compounded drug products interstate if the number of units of compounded drug products distributed interstate during any calendar month is equal to or greater than 30 percent of the number of units of compounded and non-compounded drug products distributed or dispensed both intrastate and interstate by such compounder during that calendar month. FDA received comments noting that because the calculation includes both compounded and non-compounded drug products, in many cases, a substantial factor in whether a compounder has distributed an inordinate amount of compounded drug products interstate is whether the compounder offers non-compounded drug products. For example, under that policy, many specialty compounding pharmacies that engage in interstate distribution and only distribute compounded drug products would be able to distribute fewer compounded drug products interstate before reaching an inordinate amount than a pharmacy that also fills prescriptions for non-compounded drug products, even if both pharmacies produced the same amount of compounded drug products. After considering the public comments, FDA does not believe that including non-compounded drug products within the calculation of inordinate amounts would help address the public health concerns associated with sending compounded drug products out of State that Congress sought to address in section 503A(b)(3)(B) of the FD&C Act. Accordingly, for purposes of the revised draft standard MOU, FDA is proposing to exclude consideration of non-compounded drug products from the calculation of inordinate amounts so that the denominator is determined by solely referencing compounded drug products.[3]

C. Definitions

Appendix A in the revised draft standard MOU defines key terms used in the MOU. FDA is retaining the definitions of "adverse drug experience," "serious adverse drug experience," "product quality issue," and "serious product quality issue" from the 2015 draft standard MOU.

The revised draft standard MOU also defines "distribution." With respect to that definition, for purposes of the revised draft standard MOU, FDA proposes that distribution means that a compounder has sent a compounded drug product out of the facility in which the drug was compounded. Such distribution may include, but is not limited to, delivery or shipment to a physician's office, hospital, or other health care setting for administration, and dispensing the drug product by sending it to a patient for the patient's own use. This definition is revised from the 2015 draft standard MOU and is intended to address stakeholder comments and to better effectuate the purposes of section 503A of the FD&C Act.

In the 2015 draft standard MOU, FDA proposed to define the term "distribution" to include, among other things, dispensing of a compounded drug product to a patient for the patient's own use. We received a number of comments on the 2015 draft standard MOU stating that distributing and dispensing are mutually exclusive activities, such that if a drug product is distributed, it is not also dispensed, and vice versa. Some comments asserted, in particular, that a compounded drug product should not be considered to be "distributed" when it is provided pursuant to a prescription. Other stakeholders, however, agreed with the inclusion of drug products provided pursuant to a prescription within the definition of "distribution" and maintained that this interpretation was important to protect the public health.

After considering these comments and the public health objectives of section 503A(b)(3)(B) of the FD&C Act, we have proposed to revise the definition of distribution to exclude dispensing that occurs at the facility in which the drug was compounded. We intend to consider that when a drug is picked up in this way, dispensing, but not distribution, occurs for purposes of calculating "inordinate amounts" under the MOU or applying the 5 percent limit in section 503A(b)(3)(B)(ii) of the FD&C Act.

FDA proposes that in-person dispensing, where the transaction between the compounder and the patient is completed without the compounded drug leaving the facility in which it was compounded, is appropriately overseen, primarily, by the State outside the context of the MOU, regardless of whether the compounded drug product subsequently leaves the State. Such an intrastate, local transaction generally indicates a close connection among the patient, compounder, and prescriber. By contrast, transactions by mail often have a less direct nexus among the patient, compounder, and prescriber than in-

[3] FDA also intends to exclude non-compounded drugs from the calculation of the 5 percent limit in section 503A(b)(3)(B)(ii).

person pickups and would be considered "distributions."

Under this revised proposed definition, drugs dispensed in-person that are later taken out of State would not contribute to reaching the threshold for inordinate amounts that would need to be reported to FDA under the MOU. Nor would complaints associated with compounded drug products dispensed this way and subsequently taken out of State be subject to the complaint investigation provisions of the MOU. FDA expects that, in practice, the State in which the initial transaction occurred would handle such complaints. The State may, in its discretion, notify FDA of the complaint. We recognize that including in-person dispensing in the definition of "distribution" would result in complex tracking issues in instances when a patient subsequently crosses State lines. Under the proposed revised definition, the compounder would not need to track where the patient takes the compounded drug product after it is in the patient's possession.

FDA is not persuaded by comments on the 2015 draft standard MOU urging the Agency to interpret "distribution" and "dispensing" to be entirely separate activities for purposes of section 503A(b)(3)(B) of the FD&C Act. These comments recommend using definitions for these terms used elsewhere in the FD&C Act and FDA regulations, and generally conclude that distribution does not include the transfer of a drug pursuant to a prescription.

The conditions in section 503A, including section 503A(b)(3)(B), must be interpreted consistent with the prescription requirement in section 503A(a) of the FD&C Act. If we were to interpret the word "distribution" to apply only if a drug is provided without a prescription, it would mean that drug products compounded under section 503A of the FD&C Act are excluded from regulation under the MOU and the 5 percent limit, because to qualify for the exemptions under section 503A, a compounder must obtain a valid prescription order for an individually identified patient. For the reasons stated previously in section IV.B, we believe this would achieve the opposite of what Congress intended. 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."

Nor is there anything to suggest that Congress understood distributed and dispensed to be mutually exclusive categories rather than overlapping categories for purposes of section 503A of the FD&C Act. Section 503A(b)(3)(B) of the FD&C Act does not define "distribution" to exclude dispensing, which Congress has done elsewhere when that was its intention.[4] The definition proposed by comments would write an exclusion for dispensing, in its entirety, into the statute where Congress did not. Indeed, with respect to comments suggesting that drugs dispensed pursuant to prescriptions could not also be "distributed," we note that, in section 503A(b)(3)(B) of the FD&C Act, Congress specifically contemplated that prescription orders could be "distributed" when it directed the Agency to count the number of prescription orders that pharmacists and prescribers distributed.

V. Other Issues

A. Development of a Standard MOU

A number of comments on the 1999 draft standard MOU, the 2013 draft 503A guidance, and the 2015 draft standard MOU suggested that FDA negotiate MOUs with individual States, rather than develop a standard MOU. Section 503A of the FD&C Act requires the Agency to develop a standard MOU for use by the States. Furthermore, it would be impractical to develop an individualized MOU with every State, and creating individualized MOUs would create a patchwork of regulation of interstate distribution by compounders seeking to qualify for the exemptions under section 503A of the FD&C Act. This would be confusing to the health care community, as well as regulators.

[4] In other (non-compounding) contexts, where it would further a regulatory purpose, Congress and the Agency have specifically defined "distribute" to exclude dispensing. See, for example, section 581(5) of the FD&C Act (21 U.S.C. 360eee(5)), which applies to Title II of the DQSA, and 21 CFR 208.3. Section 503A of the FD&C Act does not contain a similar definition or a similar specific direction to exclude dispensing from the meaning of distribution. We also note that these definitions were adopted for provisions that focus on conventionally manufactured drug products, which assign different obligations to dispensers than to wholesalers, packagers, or other intermediaries in light of the different role that dispensers play with respect to product labeling and the drug distribution chain. In contrast, section 503A of the FD&C Act focuses on compounded drugs, and the reasons for defining "distribution" to exclude dispensing in Title II of the DQSA or part 208 do not apply.

B. Exemptions From the Interstate Distribution Provisions

Some comments on the 2013 draft 503A guidance and the 2015 draft standard MOU requested that we consider exempting certain drug products or types of compounding entities from the threshold in the MOU and the 5 percent limit. For example, some comments recommended that we exempt nonsterile products.

American consumers rely on the FDA drug approval process to ensure that medications have been evaluated for safety and effectiveness before they are marketed in the United States. Drugs made by compounders, including those made at outsourcing facilities, are not FDA-approved. This means that they have not undergone premarket review of safety, effectiveness, or manufacturing quality. Therefore, when an FDA-approved drug is commercially available, FDA recommends that practitioners prescribe the FDA-approved drug rather than a compounded drug unless the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference for the patient as compared to the FDA-approved commercially available drug product.

In section 503A of the FD&C Act, Congress enacted several conditions to differentiate compounders from conventional manufacturers and provided that only if the compounders meet those conditions can they qualify for the exemptions from the drug approval requirements in section 505 of the FD&C Act. One of those conditions relates to limitations on the interstate distribution of compounded drug products, and FDA intends to enforce those provisions to differentiate compounding that qualifies for the exemptions from conventional manufacturing in the guise of compounding that does not, and will apply the conditions to all types of drugs and all categories of compounding.

C. Information Sharing Between States and FDA

The revised draft standard MOU provides that States will agree to notify FDA of any complaint relating to a compounded drug product distributed outside the State involving a serious adverse drug experience or serious product quality issue, and provide information about those events and issues. The revised draft standard MOU also provides that States will notify FDA if they identify a pharmacy or physician

within their jurisdiction that has distributed inordinate amounts of compounded drug products interstate.

FDA regularly posts on its compounding website information about enforcement and other actions related to compounders that violate the FD&C Act, and it is obligated to share certain information with States under section 105 of the DQSA. In addition to these measures, FDA is taking steps to proactively share information with States about complaints that it receives, consistent with Federal laws governing information disclosure.

D. Enforcement of the 5 Percent Limit on Distribution of Compounded Drug Products Out of the State in Which They Are Compounded

In the 503A guidance, FDA stated that it does not intend to enforce the 5 percent limit on distribution of compounded drug products outside of the State in which they are compounded until 90 days after FDA has finalized a standard MOU and made it available to the States for their consideration and signature. Most comments on the 2013 draft 503A guidance said this period was too short, but did not recommend a specific alternative. A few comments recommended a different timeframe, one recommending 120 days and another recommending 365 days. The 1997 Senate Committee Report for the Food and Drug Administration Modernization Act suggests that a 180-day period for States to decide whether to sign might be appropriate.[5] Consistent with the 2015 draft standard MOU, the Agency proposes a 180-day period after the final standard MOU is made available for signature before FDA will enforce the 5 percent limit in States that have not signed the MOU, and invites public comment on whether this is an appropriate timeframe. FDA will announce at the time it publishes the final standard MOU and makes it available for signature when it intends to begin enforcing the 5 percent limit in States that do not sign.

E. Physician Compounding

Several comments advised that State boards of pharmacy do not oversee physician compounding and would not be able to agree to perform the obligations under the 2015 draft standard MOU with respect to oversight of physician compounding.

FDA recognizes that physicians often do not indicate, as part of their State licensure, that they compound drug products, and that there may not be routine mechanisms, such as inspections, to determine the extent to which such physicians distribute compounded drugs interstate. It is also FDA's understanding that physicians who compound drugs generally do so for their own patients, within their own professional practice, and they distribute or dispense them intrastate. However, there is still the potential for widespread harm if physicians ship large percentages of compounded drugs interstate without State investigation of complaints associated with those compounded drugs. Accordingly, under the revised draft standard MOU, States would agree to: (1) Notify FDA and the appropriate State agency if they receive information about serious adverse drug experiences or serious product quality issues associated with drugs compounded by physicians and (2) if they become aware of a physician distributing compounded drugs interstate, coordinate with the regulator of physician compounding within the State to determine whether the physician distributes inordinate amounts of compounded drug products interstate and notify FDA of physicians that do so.

F. Prescription Orders

Commenters expressed that the meaning of the term "units," which is used in the 2015 draft standard MOU to calculate the 30 percent limit, was unclear to them.

In the revised draft standard MOU, FDA has replaced the term "unit" with "prescription order" (*i.e.*, the inordinate amounts calculation uses numbers of prescription orders for compounded drug products). "Prescription orders" includes chart orders for patients made in a healthcare setting. For purposes of this MOU, each refill is considered to be a new prescription order.

VI. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)), requires Federal Agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Section 503A of the FD&C Act describes, among other things, the circumstances under which certain drug products compounded by a licensed pharmacist or licensed physician are exempt from certain sections of the FD&C Act. One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that: (1) The drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such a State or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, pharmacy, or physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded, more than 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (see section 503A(b)(3)(B)(i) and (ii).

Section 503A(b)(3) directs FDA, in consultation with the NABP, to develop a standard MOU for use by States in complying with the provisions concerning the interstate distribution of inordinate amounts of compounded drug products interstate and appropriate investigation by a State agency of complaints relating to drug products compounded in the State and distributed outside such State.

[5] "[U]ntil the State . . . enters into a memorandum of understanding (MOU) with the Secretary or 180 days after the development of the standard MOU, whichever comes first, the [section 503A] exemption shall not apply if inordinate quantities of compounded products are distributed outside of the State in which the compounding pharmacy or physician is located." (U.S. Senate Committee Report)

The revised draft standard MOU contains the information collections that must be approved by OMB under the PRA. These information collections are described in this section of the document. For purposes of this analysis, FDA assumes that 45 States will sign the standard MOU with FDA.

Under section III.a. of the revised draft standard MOU, the State will notify FDA by email at *StateMOU@fda.hhs.gov* as soon as possible, but no later than 3 business days, after receiving any complaint relating to a compounded drug product distributed outside the State involving a serious adverse drug experience or serious product quality issue. The notification will include the following information: (1) The name and contact information of the complainant; (2) the name and address of the pharmacy or physician that is the subject of the complaint; (3) a description of the complaint, including a description of any compounded drug product that is the subject of the complaint; and (4) the State's initial assessment of the validity of the complaint relating to a compounded drug product distributed outside the State, if available. In addition, the States will maintain records of the complaints they receive, the investigation of each complaint, and any response to or action taken as a result of a complaint, beginning when the State receives notice of the complaint. The States will maintain these records for at least 3 years, beginning on the date of final action or the date of a decision that the complaint requires no action.

Based on our knowledge of State regulation of compounding practices and related complaints, we estimate that annually a total of approximately 45 States ("no. of respondents" in table 1, row 2) will notify FDA within 3 business days of receiving any complaint relating to a compounded drug product distributed outside the State involving a serious adverse drug experience or serious product quality issue. We estimate that each State will notify FDA annually of approximately 3 complaints it receives ("no. of responses per respondent" in table 1, row 2), for a total of 135 notifications of complaints sent to FDA ("total annual responses" in table 1, row 2). We estimate that preparing and submitting this information to us as described in the MOU will take approximately 0.5 hours per response ("average burden per response" in table 1, row 1), for a total of 67.5 hours ("total hours" in table 1, row 2).

We also estimate that a total of approximately 45 States ("no. of recordkeepers" in table 2) will prepare and maintain records for 3 years of the complaints they receive, investigations of complaints, and any State action taken or response to complaints. We estimate that each State will receive approximately 3 complaints annually and will prepare and maintain approximately 5 records per each complaint the State receives, for a total of 15 records per State ("no. of records per recordkeeper" in table 2), and a total of 675 records annually across all States ("total annual records" in table 2). We further estimate that preparing and maintaining these records will take approximately 1 hour per record ("average burden per recordkeeping (in hours)" in table 2), for a total of 675 hours ("total hours" in table 2).

Under section III.b of the revised draft standard MOU, on an annual basis (at minimum), the State will identify, using surveys, reviews of records during inspections, or other mechanisms available to the State, compounding pharmacies that distribute inordinate amounts of compounded drug products interstate by collecting information regarding the total number of prescription orders for compounded drug products distributed or dispensed intrastate and the total number of prescription orders for compounded drug products distributed interstate. Similarly, the State will engage in the same efforts to collect this information if it becomes aware of a physician who is distributing compounded drug products interstate. If a pharmacy or physician has been identified as distributing inordinate amounts of compounded drug products interstate, the State will also collect information regarding: (1) The total number of prescription orders for sterile compounded drug products distributed out of State; (2) the number of States in which the compounding pharmacy or physician is licensed or number of States into which the compounding pharmacy or physician distributes compounded drug products; and (3) whether the State inspected for and found during its most recent inspection that the compounding pharmacy or physician distributed compounded drug products without valid prescriptions for individually identified patients.

The States will notify FDA by email at *StateMOU@fda.hhs.gov* within 30 days of identifying a pharmacy/physician within their jurisdiction that has distributed inordinate amounts of compounded drug products interstate, as described in the revised draft standard MOU. The notification should include the name and address of the pharmacy/physician and the information that the States collected, described in the previous paragraph.

We estimate that annually a total of approximately 45 States ("no. of respondents" in table 1, row 3) will identify compounding pharmacies or physicians that distribute inordinate amounts of compounded drug products interstate. We estimate that each State will perform surveys or inspections of 150 pharmacies or physicians to identify this information ("no. of responses per respondent" in table 1, row 3). We estimate that this will take approximately 1 hour per response ("average burden per response" in table 1, row 3), for a total of 6,750 hours ("total hours" in table 1, row 3). We estimate that annually a total of 40 States ("no. of respondents" in table 1, row 4) will notify FDA of their finding that a pharmacy or physician has distributed inordinate amounts of compounded drug products interstate. We estimate that each State will notify FDA annually of approximately 50 findings it makes ("no. of responses per respondent" in table 1, row 4), for a total of 200 notifications ("total annual responses" in table 1, row 4). We estimate that preparing and submitting this information to FDA as described in the MOU will take approximately 0.5 hours per response ("average burden per response" in table 1, row 4), for a total of 100 hours ("total hours" in table 1, row 4).

Under section V of the revised draft standard MOU, a State may designate a new liaison to the MOU by notifying FDA's administrative liaison in writing. If a State's liaison becomes unavailable to fulfill its functions under the MOU, the State will name a new liaison within 2 weeks and notify FDA.

We estimate that annually a total of approximately 13 States ("no. of respondents" in table 1, row 5) will notify FDA of a new liaison to the MOU. We estimate that each State will submit to FDA annually approximately 1 notification of a new liaison ("no. of responses per respondent" in table 1, row 5), for a total of 13 notifications of a new liaison ("total annual responses" in table 1, row 5). We estimate that preparing and submitting each notification as described in the MOU will take approximately 0.2 hours per response ("average burden per response" in table 1, row 5), for a total of 2.6 hours ("total hours" in table 1, row 5).

Under section VI of the revised draft standard MOU, a State may terminate its participation in the MOU by submitting to FDA a 30-day notice of termination.

We estimate that annually a total of approximately 1 State ("no. of

respondents" in table 1, row 6) will notify FDA that it intends to terminate its participation in the MOU. We estimate that this State will submit to FDA annually approximately 1 notification of termination ("no. of responses per respondent" in table 1, row 6), for a total of 1 notification ("total annual responses" in table 1, row 6). We estimate that preparing and submitting the notification as described in the MOU will take approximately 0.2 hours per notification ("average burden per response" in table 1, row 6), for a total of 0.2 hours ("total hours" in table 1, row 6).

Under section VI of the revised draft standard MOU, if a State does not adhere to the provisions of the MOU, FDA may post a 30-day notice of termination on its website. As a result of this action by FDA, the State will notify all licensed pharmacists, pharmacies and physicians within the State of the termination and advise them that compounded drug products may be distributed (or caused to be distributed) out of the State only in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

We estimate that annually a total of approximately 1 State ("no. of respondents" in table 3) will submit to the pharmacists, pharmacies, and physicians in its State 1 notification of termination as described in the MOU ("no. of disclosures per respondent" in table 3), for a total of 1 notification of termination ("total annual disclosures" in table 3). We estimate that preparing and submitting each notification will take approximately 1 hour per notification ("average burden per disclosure (in hours)" in table 3), for a total of 1 hour ("total hours" in table 3).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Compounding MOU between FDA and States	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State notifies FDA of compounding complaints it receives.	45	3	135	0.5 (30 minutes)	67.5
State identifies pharmacies or physicians that distribute inordinate amounts of compounded drugs interstate using surveys or inspections.	45	150	6,750	1	6,750
State notifies FDA of the distribution of inordinate amounts of compounded drug products.	40	50	200	0.5 (30 minutes)	100
State notifies FDA of a new liaison to the MOU.	13	1	13	0.2 (12 minutes)	2.6
State notifies FDA of its intent to terminate participation in the MOU.	1	1	1	0.2 (12 minutes)	0.2
Total					6,920.3

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Compounding MOU between FDA and States	Number of recordkeepers	Number of Records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
State recordkeeping for 3 years of compounding complaints	45	15	675	1	675
Total					675

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Compounding MOU between FDA and States	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure (in hours)	Total hours
State notification to pharmacists, pharmacies, and physicians that its participation in the MOU has been terminated by FDA	1	1	1	1	1
Total					1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the internet may obtain the draft MOU at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: August 31, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19461 Filed 9–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3272]

Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions." The purpose of the meeting is to give stakeholders, including health care providers, patients, manufacturers, wholesalers, pharmacists, pharmacy benefit managers, veterinarians, public and private insurers, academic researchers, and the public, the opportunity to provide input on the underlying systemic causes of drug shortages, and make recommendations for actions to prevent or mitigate drug shortages. Members of Congress have asked the Agency to examine the root causes and drivers of these shortages, and to recommend measures that will provide more enduring solutions. To this end, the Commissioner has convened an inter-Agency task force of senior Federal officials of FDA, the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, and the Department of Defense. After receiving input from stakeholders, the task force intends to provide a report to Congress regarding the root causes of drug shortages. The report will also include recommendations regarding new authorities FDA or other Federal agencies could use to help provide enduring solutions to shortages.

DATES: The public meeting will be held on November 27, 2018, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public meeting by January 11, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Washington Marriott at Metro Center, 775 12th St. NW, Washington, DC 20005. The hotel's phone number is 202–737–2200.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 11, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 11, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2018–N–3272 for "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michie Hunt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire

DRAFT MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED DRUG PRODUCTS BETWEEN THE ~~STATE OF~~ [insert STATE] BOARD OF PHARMACY AND THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the ~~State of~~ [insert State] Board of Pharmacy ("Board") and the U.S. Food and Drug Administration (FDA) regarding the interstate distribution[1] of inordinate amounts[2] of compounded human drug products ~~interstate~~ and the appropriate investigation by the Board~~State of [insert State] Board of Pharmacy~~ of complaints relating to human drug products compounded in such State and distributed outside such State. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities.

II. BACKGROUND

a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:

1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and

3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).

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[1]The definition of *distribution* in this MOU is separate and distinct from and should not be used in relation to the term *distribution* as it is used in Section 503A(b)(3)(B)(i) of the FD&C Act (21 USC 353(a)). Distribution or distribute in the context of this MOU refers to the interpretation, evaluation, and implementation of a prescription drug order, including the preparation, final verification, and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient.

[2]The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy of a commercially available drug product). The interpretation of this term in each instance necessarily is based on the particular context of the distinct provisions within 503A in which the term appears.

b. To qualify for these exemptions, among other things, a compounded human drug product must meet the conditions in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:

1. Has entered into an MOU with FDA that addresses the distribution~~[,]~~ of inordinate amounts~~[,]~~ of compounded human drug products interstate and provides for appropriate investigation by ~~a State agency~~the Board of complaints relating to compounded human drug products distributed by a licensed pharmacist or licensed pharmacy outside such State (section 503A(b)(3)(B)(i)); or

2. Has not entered into an MOU with FDA and the licensed pharmacist or licensed pharmacy ~~or licensed physician~~ distributes (or causes to be distributed) compounded human drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).

c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i). The content of this MOU conforms to the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

a Investigation of Complaints Relating to Compounded Drug Products Distributed Outside the State

1. ~~Appropriate agencies of t~~The ~~State of [insert State] Board of Pharmacy~~ will investigate complaints ~~received~~ of serious adverse drug experiences or serious product quality issues relating to human drug products compounded by a pharmacist and distributed outside the State by a pharmacy. ~~Primary responsibility for investigating complaints involving drug products compounded by a pharmacist will generally lie with the [insert State Board of Pharmacy or other appropriate State agency]. The [insert State] Board of Pharmacy will maintain records of the complaint, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the State receives notice of the complaint. The [insert State] Board of Pharmacy will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.~~ See Appendix A for definitions of *serious adverse drug experiences* and *serious product quality issues*.

~~1. Complaints relating to compounded drug products distributed outside the State that will be investigated include reports received by the [insert State] Board of Pharmacy concerning adverse drug experiences or product quality issues associated with drugs compounded by a~~

~~pharmacist. See Appendix A for definitions of *adverse drug experiences* and *product quality issues.*~~

2. Any investigations performed by the ~~State of [insert State] Board of Pharmacy~~ under this MOU will include, but are not limited to, taking steps to assess (1) whether there is a public health risk associated with the compounded human drug product; and (2) whether any public health risk associated with the product is adequately contained.

3. ~~Based on findings from an investigation of a complaint about drug products compounded by a pharmacist and distributed outside the State~~After the Board's investigation, if the complaint is ~~found~~ substantiated~~to be valid~~, the ~~State of [insert State]~~ Board ~~of Pharmacy~~, in accordance with and as permitted by State law, will take the action that the State considers to be appropriate and warranted to ensure that the relevant compounding pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the complaint, including the risk that future similar complaints may occur.

4. The Board will maintain records of the complaint, its investigation, and any response to or action taken as a result of the complaint, beginning when the State receives notice of the complaint. The Board will maintain these records for at least three (3) years. The three-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action. The Board will share the results of its investigation that with FDA as permitted under State law ~~3.~~

~~4~~5. The ~~State of [insert State] Board of Pharmacy~~ will by email (StateMOU@fda.hhs.gov)~~notify~~ provide FDA ~~by sending an email to StateMOU@fda.hhs.gov~~ with the information described in section III.c.1.a of this MOU as soon as possible, but no later than 3 business days after receiving and ~~investigating~~ assessing ~~any~~ the complaint~~relating to a drug product compounded by a pharmacist and distributed outside the State involving a serious adverse drug experience or serious product quality issue~~. ~~After this notification, the State will share with FDA the results of the investigation that it conducted, if permitted under State law. See Appendix A for definitions of *serious adverse drug experience* and *serious product quality issue.*~~

6. If the ~~the State of [insert State] Board of Pharmacy~~ receives ~~a a~~ complaint of a serious adverse drug experience or a serious product quality issue relating to human drug products compounded by a ~~complaint involving an adverse experience or product quality issue relating to a drug compounded by~~ a physician and distributed outside the State, the ~~[insert State]~~ Board ~~of Pharmacy~~ will notify the appropriate State Agency responsible for regulating the practice of medicine~~physician practice and licensure/registration~~ ~~regulator of~~

~~physician compounding~~ within the State. ~~If the complaint involves a serious adverse drug experience or serious product quality issue, t~~The ~~State~~ Board will also notify FDA of the complaint by sending an email to StateMOU@fda.hhs.gov. ~~with the information in section III.c.1.a of this MOU as soon as possible, but no later than 3 business days, after receiving the complaint.~~

~~5~~7. The FDA will notify the ~~[insert State]~~ Board ~~of Pharmacy~~ by email **(insert state-specific email address)** of any action taken by the FDA in response to ~~the~~ complaints submitted to the FDA by ~~[insert state]~~the Board ~~of Pharmacy~~, including the decision of the FDA not to pursue further action.

~~0. The State of [insert State] will maintain records of the complaint, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the State receives notice of the complaint. The State will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.~~

e~~b~~. Interstate Distribution of Inordinate Amounts of Compounded Human Drug Products ~~Interstate~~

1. For purposes of this MOU, a pharmacy ~~or physician~~ has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products distributed interstate during any calendar month is greater than 50 percent of the number of prescription orders for compounded human drug products distributed ~~or dispensed~~ both intrastate and interstate by such pharmacy ~~or physician~~ during that month.

2. The Board will determine whether a pharmacy had distributed an inordinate amount of compounded human drug product interstate in either of the following circumstances: (a) the Board receives a complaint as defined in Section III.a.1; or (b) during a regular inspection of a pharmacy that distributes compounded human drug product interstate, the Board identifies a serious product quality issue with compounded human drug product distributed interstate by the pharmacy. In these circumstances, the Board will make its inordinate amount determination for the calendar month in which it received the complaint or conducted the inspection. ~~The [insert State] Board of Pharmacy, as part of regular inspections and/or its investigation of a pharmacy based on a complaint concerning a compounded drug product distributed interstate, will determine whether inordinate amounts of compounded drug products were distributed interstate by such pharmacy. On an annual basis (at minimum), the State of [insert State] will identify, using surveys, reviews of records during inspections, or other mechanisms available to the State, compounding pharmacies that distribute inordinate amounts of compounded drug products interstate by collecting information regarding the total number of~~

~~prescription orders for compounded drug products distributed or dispensed intrastate and the total number of prescription orders for compounded drug products distributed interstate~~.

~~3. If the State of [insert State] becomes aware of a physician who is distributing compounded drug products interstate, the State will coordinate with the appropriate regulator of physician compounding within the State to determine, using surveys, reviews of records during inspections, or other mechanisms available to the State, whether the physician distributes inordinate amounts of compounded drug products interstate by collecting information regarding the total number of prescription orders for compounded drug products distributed or dispensed intrastate and the total number of prescription orders for compounded drug products distributed interstate.~~

~~4~~3. When acting under Section III.b.2, if the Board identifies a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, it ~~For pharmacies or physicians that have been identified as distributing inordinate amounts of compounded drug products interstate involving a serious adverse drug experience or serious product quality issue, the [insert] State Board of Pharmacy also will~~will also~~l collect information regarding the~~determine the total number of prescription orders for sterile compounded human drug products distributed outside the State during the calendar month in which the Board received the complaint or conducted the inspection; ascertain the number and identity of States in which the compounding pharmacy ~~or physician~~ is licensed or ~~number of States~~ into which the compounding pharmacy ~~or physician~~ distributes compounded human drug products; and determine whether the ~~[insert State] Board of Pharmacy inspected for and found during its most recent inspection that the compounding~~ pharmacy ~~or physician~~ distributed compounded human drug products without valid prescription orders for individually identified patients.

~~5~~4. The ~~[insert State]~~ Board ~~of Pharmacy~~ will, within 30 days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, notify FDA by email (~~sending an email to~~ StateMOU@fda.hhs.gov) ~~within 30 days of identifying a pharmacy or physician within its jurisdiction that has distributed inordinate amounts of compounded drug products interstate involving a serious adverse drug experience or serious product quality issue~~ and will include the information described in section III.c.1.b of this MOU.

~~d~~c. Submission and Disclosure of Information

1. When submitting information to StateMOU@fda.hhs.gov regarding Section III.a.1 complaints ~~complaints relating to compounded drug products distributed outside the State~~ or ~~regarding distribution of inordinate amounts of drugs interstate involving a serious adverse drug experience or serious product quality issue involving a serious adverse~~

~~drug experience or serious product quality issue~~Section III.b.2 determinations, the following minimum information will be included:

a. Complaints:

i. Name and contact information of the complainant, if available;

ii. Name and address of the pharmacy~~/physician~~ that is the subject of the complaint;

iii. Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;

iv. The ~~[insert State]~~ Board ~~of Pharmacy~~'s ~~initial~~ assessment ~~after investigation,~~ of the validity of the complaint ~~relating to a compounded drug product compounded by a pharmacist and distributed outside the State involving a serious adverse drug experience or serious product quality issue~~, if available; and

v. Description ~~and date~~ of any actions the ~~[insert State]~~ Board ~~of Pharmacy~~ has taken at the time of the submission to address the complaint.

b. Inordinate Amount Determinations:

i. Name and address of the pharmacy~~/physician~~ that distributed inordinate amounts of compounded human drug products ~~compounded by a pharmacist and distributed~~ outside the State ~~involving a serious adverse drug experience or serious product quality issue compounded drug products interstate~~;

ii. The total number of prescription orders for compounded human drug products linked ~~involving~~to a serious adverse drug experience or serious product quality issue the pharmacy distributed or dispensed outside the State~~intrastate~~;

iii. The total number of prescription orders for compounded human drug products the pharmacy distributed outside the State~~interstate~~;

iv. The total number of prescription orders for sterile compounded human drug products the pharmacy distributed outside the State ~~interstate~~;

v. The number and identity of States in which the compounding pharmacy ~~or physician~~ is licensed or into which the pharmacy ~~or physician~~ distributes compounded human drug products, and

vi. Whether the ~~[insert State] Board of Pharmacy inspected for and found during its most recent inspection~~determined that the ~~compounding~~ pharmacy ~~or physician~~ distributed compounded human drug products without valid prescription orders for individually identified patients.

2. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 or commissioning of officials under 21 CFR 20.84 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement, or commissioning terms, will govern FDA's sharing of the following types of information:

- Confidential commercial information, such as information that would be protected from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));

- Personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or

- Information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

FDA agrees that information provided to FDA by the ~~State of [insert State] Board of Pharmacy~~ will only be disclosed consistent with applicable Federal law and regulations governing the disclosure of such information, including, but not limited to, the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the ~~State of [insert State] Board of Pharmacy~~ retains the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or prevent the ~~State of [insert State] Board of Pharmacy~~ from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the ~~[insert name of State agency] Board of Pharmacy~~ affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the ~~State~~ Board no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the ~~State~~ Board will notify FDA.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration Center
for Drug Evaluation and Research
Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
Email: StateMOU@fda.hhs.gov

[State] Board of Pharmacy
TBD

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

a When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 30-day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

b. If the ~~[insert State]~~ Board ~~of Pharmacy~~ does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded drug products distributed outside the State, the MOU may be terminated upon 30-days' notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the ~~[insert State]~~ Board of Pharmacy ~~will~~ notify all licensed pharmacists~~,~~ and pharmacies~~, and physicians~~ within the State of the termination and advise them that as of 30 days from the date of the posting of the termination notice, compounded drug products may be distributed (or caused to be distributed) out of the State only in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by the licensed pharmacy ~~or physician~~ (section 503A(b)(3)(B)(ii) of the FD&C Act).

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR THE ~~STATE OF~~ [insert State] BOARD OF PHARMACY
By (Type Name)	By (Type Name)
Title	Title
Date	Date

Appendix A. Definition of Terms Used in the MOU

- **Adverse Drug Experience**: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).

- ~~**Distribution:** *Distribution* means that a compounder has sent a drug product out of the facility in which the drug was compounded. Such distribution may include, but is not limited to, delivery or shipment to a physician's office, hospital, or other health care setting for administration, and dispensing the drug product by sending it to a patient for the patient's own use.~~

  ~~Note: To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU will not alter this condition.~~

- **Product Quality Issue** : Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriologica l contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.

- **Serious Adverse Drug Experience**: Any adverse drug experience (as defined above) occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

- **Serious Product Quality Issue**: Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).