MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the [insert State Board of Pharmacy or other appropriate State agency] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate[1] and the appropriate investigation by the [insert State Board of Pharmacy or other appropriate State agency] of complaints relating to human drug products compounded in [insert State] and distributed outside such State.[2] 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 under section 503B of the FD&C Act.

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));

[1] For purposes of this MOU, see the definitions of "inordinate amounts" and "distribution of compounded human drug products interstate" (also referred to as "distributed interstate") in Appendix A.

[2] As described herein, the State Board of Pharmacy or other appropriate State agency signatory is agreeing to take certain actions as described in Section III below. For example, if a State Board of Pharmacy signs the MOU, the State Board of Pharmacy agrees to take the actions described in Section III below with respect to drugs compounded by pharmacies in that State; in addition, the State Board of Pharmacy agrees that if it receives information about complaints or becomes aware of information about drugs compounded by physicians in the State and distributed interstate, it will forward the information to FDA and the appropriate State regulator of physicians as described in Section III.

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)).

b. To qualify for these exemptions, a compounded human drug product must, among other things,[3] 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 drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State (section 503A(b)(3)(B)(i)); or

2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded 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, in consultation with the National Association of Boards of Pharmacy (NABP), for use by the States in complying with section 503A(b)(3)(B)(i). This MOU is the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

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

1. The [insert State Board of Pharmacy or other appropriate State agency] will investigate complaints of adverse drug experiences and product quality issues[4] relating to human drug products compounded at a pharmacy in [insert State] and distributed outside the State. Any investigations will be performed pursuant to the [insert State Board of Pharmacy or other appropriate State agency]'s established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of this MOU.

[3] 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 does not alter this condition.
[4] For purposes of this MOU, see the definitions of "adverse drug experience" and "product quality issue" in Appendix A.

2. Any investigations performed by the [insert State Board of Pharmacy or other appropriate State agency] under this MOU will include taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.

3. After the [insert State Board of Pharmacy or other appropriate State agency]'s investigation, if the complaint is substantiated, the [insert State Board of Pharmacy or other appropriate State agency], in accordance with and as permitted by State law, will take the action that the [insert State Board of Pharmacy or other appropriate State agency] considers to be appropriate and warranted to ensure that the relevant 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 problem, including the risk that future similar problems may occur.

4. The [insert State Board of Pharmacy or other appropriate State agency] will maintain records of the complaint about adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the [insert State Board of Pharmacy or other appropriate State agency] receives notice of the complaint. The [insert State Board of Pharmacy or other appropriate State agency] 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.

5. As soon as possible, but no later than 5 business days after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will, by submission to an Information Sharing Network[5] or by email to StateMOU@fda.hhs.gov, provide FDA with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.i-iii).[6]

[5] For purposes of this MOU, see the definitions of "serious adverse drug experience," "serious product quality issue," and "Information Sharing Network" in Appendix A.

[6] The information includes the following: (i) Name and contact information of the complainant, if available; (ii) Name and address of the pharmacy that is the subject of the complaint; and (iii) Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

6. After the [insert State Board of Pharmacy or other appropriate State agency] concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will share with FDA, as described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.iv-v),[7] the results of the investigation as permitted by State law.

7. If the [insert State Board of Pharmacy or other appropriate State agency] receives a complaint involving an adverse drug experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will also notify FDA by submission to an Information Sharing Network or by sending an email to StateMOU@fda.hhs.gov with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.2.a.-c), if available, as soon as possible, but no later than 5 business days, after receiving the complaint.

b. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate[8]

1. For purposes of this MOU, a pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of:

(i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus

(ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the

[7] The information includes: (i) [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and (ii) Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

[8] The distribution of inordinate amounts of compounded human drug products interstate is a threshold for the [insert State Board of Pharmacy or other appropriate State agency] to identify and report certain information to FDA, not a limit on the distribution of compounded human drug products interstate.

facility in which they were compounded during that same calendar year.

Figure 1. Calculating an Inordinate Amount

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.

2. On an annual basis, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [insert State Board of Pharmacy or other appropriate State agency], pharmacies that distribute inordinate amounts of compounded human drug products interstate.

3. For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using data submitted to an Information Sharing Network or other available mechanisms, during that same calendar year:
    a. the total number of prescription orders for sterile compounded human drugs distributed interstate;
    b. the names of States in which the pharmacy is licensed;
    c. the names of States into which the pharmacy distributed compounded human drug products; and
    d. whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

4. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, notify FDA of such pharmacy, through an Information Sharing Network or by email to StateMOU@fda.hhs.gov, and will include the

information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.b).

5. If the [insert State Board of Pharmacy or other appropriate State agency] becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a physician who is distributing any amount of compounded human drug products interstate, also notify FDA by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov.

c. Submission and Disclosure of Information
    1. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a pharmacy and distributed outside the State, or regarding distribution of inordinate amounts of human drug products compounded by a pharmacy interstate, the following minimum information will be included. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

        a. Complaints:

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

            ii. Name and address of the pharmacy 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. [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and

            v. Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

        b. Inordinate Amounts:

i. Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;

ii. The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year;

iii. The number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year;

iv. The total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;

v. The total number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year;

vi. The names of States in which the pharmacy is licensed and the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and

vii. Whether the [insert State Board of Pharmacy or other appropriate State agency] inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients during that same calendar year.

2. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a physician, or regarding distribution of any amount of human drug products compounded by a physician interstate, the following minimum information will be included, if available. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

   a. Name and contact information of the complainant or notifier;

   b. Name and address of the physician that is the subject of the complaint or notification; and

c. Description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint or notification.

3. 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 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement 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 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 [insert State Board of Pharmacy or other appropriate State agency] will only be disclosed consistent with applicable Federal law and regulations governing the disclosure of such information, including 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 [insert State Board of Pharmacy or other appropriate State agency] retain 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 [insert State Board of Pharmacy or other appropriate State agency] 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 State Board of Pharmacy or other appropriate State agency] 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 [insert State Board of Pharmacy or other appropriate State agency] no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the [insert State Board of Pharmacy or other appropriate State agency] will notify FDA within 60 calendar days of the change in legal authority.

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

[Insert State Board of Pharmacy or other appropriate State agency and its contact information]

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 60 calendar day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

b. If the [State Board of Pharmacy or other appropriate State agency] does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded human drug products distributed outside the State, the MOU may be terminated upon a 60 calendar day 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 or other appropriate State agency] will notify all pharmacies that compound drug products in the State and notify the State authority that licenses or regulates physicians of the termination and advise them that as of 60 calendar days from the date of the posting of the termination notice, compounded human 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 [insert State Board of Pharmacy or other appropriate State agency]
By (Type Name)	By (Type Name)
Title	Title
Date	Date

Appendix A. Definition of Terms for the Purposes of this 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 of compounded human drug products interstate**: Means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded.

- **Information Sharing Network:** An information sharing network designated by FDA for purposes of this MOU to collect, assess, and allow review and sharing of information pursuant to this MOU.

- **Inordinate Amounts**: A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.[9]

- **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 bacteriological 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 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

[9] 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.

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).

Memorandum of Understanding Addressing Certain Distributions of Compounded Drugs: Questions and Answers

FDA is working to respond to questions from states regarding the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (/media/143283/download) between state boards of pharmacy or other state agencies and FDA. This web page will be updated as we receive additional questions. Please email questions to compounding@fda.hhs.gov (mailto:compounding@fda.hhs.gov).

1. **Will states have an opportunity to negotiate the language of the MOU?**

   No. FDA has made the standard MOU available for signature. Section 503A 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 states. Developing individualized MOUs would create a patchwork of regulation of distribution of compounded drugs interstate and it would be impractical to have individual MOUs with each state.

   The MOU describes, in brackets, the state in the agreement as "State Board of Pharmacy or other appropriate State agency." The bracketed language appearing in the MOU is intended to be substituted with the appropriate name and contact information of the state.

2. **Can the state solely rely on pharmacies entering information into an information sharing network to identify pharmacies that distribute inordinate amounts of compounded human drug products interstate under the MOU?**

   By signing the MOU, the state is agreeing to identify pharmacies that distribute inordinate amounts of compounded drugs interstate. However, the MOU provides flexibility in how the state does this, including use of tools like an information sharing network, such as the one established in cooperation with NABP. If a state that chooses to use an information sharing network is uncertain whether the information it contains is complete, the state may verify information through other means, such as during inspections. FDA will continue to work with states to address questions regarding reporting expectations under the MOU.

3. **What will FDA do with information submitted by the states under the MOU?**

   Protecting patients is our top priority. Information submitted by the states will help inform FDA about potential for patient harm, including whether additional federal oversight is warranted. The information submitted by the states also will help inform the agency's risk-based inspection priorities.

4. **What happens if a state does not fulfil the agreements under the MOU?**

   The MOU may be terminated upon a 60-calendar day notice of termination if a state does not adhere to the MOU provisions.

5. **Can states use their established processes to investigate complaints of adverse drug experiences and drug quality issues?**

   Yes, states can use their established processes as long as those policies and procedures do not conflict with the terms of the standard MOU. The MOU indicates any state investigation will be performed according to the state agency's established investigatory policies and procedures, including those related to prioritizing complaints.
   For example, using established procedures, a state board of pharmacy or other appropriate state agency may review an incoming complaint describing an adverse drug experience and determine the complaint does not warrant further investigation. In other cases, a state board of pharmacy or other appropriate state agency may determine that an incoming complaint contains insufficient information and investigate further to determine appropriate action.

6. **Can a state that is prohibited by a state law from disclosing a complainant's name and contact information fulfil the agreed upon data reporting under the MOU?**

   Yes. Under the MOU, the state is agreeing to report the name and contact information of the complainant, if available, to FDA. If providing this information is prohibited by state law, FDA does not consider it to be "available" for purposes of the MOU.

7. **Does "prescription order" in the MOU include new and refill prescription orders?**

   As stated in the September 10, 2018, Federal Register Notice (https://www.federalregister.gov/documents/2018/09/10/2018-19461/memorandum-of-understanding-addressing-certain-distributions-of-compounded-drug-products-between-the)proposing this MOU, "For purposes of this MOU, each refill is considered to be a new prescription order."

TEXAS STATE BOARD OF PHARMACY

June 15, 2020

The Honorable Russell Vought
Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Submitted via: https://www.regulations.gov/comment?D=FDA-2018-N-3065-0046

RE: Comments on Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the States and the Food and Drug Administration; Revised Draft; Availability (OMB Control Number 0920-0800; Docket ID: FDA-2018-N-3065)

Dear Director Vought:

This letter is to express concerns with the information collection that has recently been submitted to Office of Management and Budget (OMB) by the Food and Drug Administration (FDA) for review under the Paperwork Reduction Act dealing with the "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between [insert State of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration" (MOU). The MOU will require substantial inspection, data tracking, reporting and recordkeeping requirements on boards of pharmacy and other agencies in states that sign the MOU, so the FDA estimates of the burden for those requirements are critical.

The Texas State Board of Pharmacy has not been formally surveyed or otherwise directly contacted regarding FDA's collection of information for the MOU. Instead, the notice of the collection of information filed with OMB suggests that FDA has based their estimates of both how many states will sign the MOU and what the burden on those states will be on a handful of comments from state boards. From these comments, FDA estimates the average numbers for how many adverse event reports states will receive and how many pharmacies will trigger the 50% threshold on out-of-state distributing and dispensing drugs, which then requires tracking, reporting and recordkeeping. An accurate information collection by FDA would have involved actually surveying states in writing, and as result, the lack of accurate information may have resulted in a serious underestimation of the burden the MOU will have for boards. The estimate of the number of states that will sign the MOU could also be inflated. The burden on larger states that sign the MOU, like Texas, will undoubtedly be several times greater than the averages in FDA's estimates.

FDA disagrees with comments they received that the MOU amounts to an unfunded mandate because it is "voluntary". However, FDA's defines the term "distribution" in the MOU to include patient specific dispensing. As a result, if a state does not sign, the economic impact on pharmacies and the healthcare impact on their out-of-state patients would be considerable. It would be critical that FDA conduct a comprehensive collection of information on the MOU so that OMB, as well state boards of pharmacy, state legislatures, pharmacy stakeholders and the public can have a more complete picture of what state resources will be necessary to meet the MOU's requirements.

We also have specific concerns regarding the content of two sections of the MOU.

1. Section III.a.5 provides:

> As soon as possible, but no later than 5 business days after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will, by submission to an Information Sharing Network5 or by email to StateMOU@fda.hhs.gov, provide FDA with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.i-iii).

This provision should be changed to require the submission as soon as possible, but no later than 5 business days after *discovering* that a complaint involves a serious adverse drug experience or serious product quality issue. Complaints are often submitted without complete information regarding the circumstances, including whether the incident involved a serious adverse drug experience or serious product quality issue and whether drug product compounded at a pharmacy and distributed outside the State. As written this section would potentially require the agency to report a complaint before identifying that the complaint met the requirements for reporting.

2. Section III.b.3.d provides:

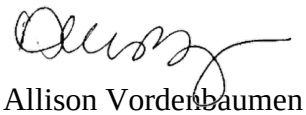
> 3. For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using data submitted to an Information Sharing Network or other available mechanisms, during that same calendar year:
> . . .
> d. whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

This section is confusing and in conflict with the stated purpose of the MOU. If a pharmacy distributes compounded human drug products without valid prescription orders for individually identified patients, then it would be compounding drugs as a 503B outsourcing

facility and would fall outside the scope of the MOU which states that it does not apply to 503B facilities. Further, the Texas State Board of Pharmacy does not regulate outsourcing facilities.

I appreciate the opportunity to provide comments. Thank you for your consideration of our input. Please do not hesitate to contact me with any questions or concerns.

Sincerely,



Allison Vordenbaumen Benz, R.Ph., M.S
Executive Director/Secretary

TEXAS STATE BOARD OF PHARMACY

Issues Relating to the MOU with FDA on Distribution of Compounded Drug Products

The U.S. Food and Drug Administration (FDA) published the final standard Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) on October 26, 2020. The MOU establishes an agreement between state boards of pharmacy and the FDA regarding the interstate distribution of inordinate amounts of compounded drug products and appropriate investigation of complaints related to such compounding.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) sets a five percent limit on compounded drugs distributed outside the state by a pharmacy located in a state that has not entered into the MOU. The MOU includes dispensing of patient specific prescriptions in its definition of distribution. If a state signs the MOU, the limit does not apply. However, the MOU defines the threshold limits for when the state must report any pharmacies distributing an "inordinate amount" of compounded human drug products interstate.

The MOU also sets out the requirements for the states regarding conducting investigations and reporting such information to the FDA about pharmacies that distribute compounded drugs interstate.

The FDA has given state boards of pharmacy until October 25, 2021, to sign the MOU before it intends to enforce the five percent limit in section 503A of the FD&C Act in states that have not signed the final MOU.

The following issues could present challenges to the Texas State Board of Pharmacy (TSBP) in terms of signing the MOU and complying with its requirements:

1. *Reporting Distribution of Inordinate Amounts*

The reporting requirement requires that TSBP obtain information from the pharmacies licensed by the agency. The National Association of Pharmacy Boards (NABP) has developed a voluntary reporting system for pharmacies to report the data that is necessary to make the determination of whether a pharmacy is distributing an "inordinate amount" of compounded human drug products interstate, which is defined at 50%. There are no statutory requirements for requiring such reporting by pharmacies to an outside entity. If TSBP attempts to mandate reporting to an outside entity by rule, this may be considered an overreach beyond the agency's statutory authority.

Potential issues could arise with pharmacies not wanting to share information that could be considered sensitive commercial information. If a pharmacy does not report to NABP, TSBP remains responsible for collecting the data and reporting the pharmacies that meet the threshold. Such a situation would require substantially increased inspections for compliance. Even if pharmacies comply with the submission to NABP, the agency would still be responsible for reviewing the information and approving it for submission to the FDA.

No funding for additional resources, including staff positions, that would be required to handle this additional workload has been appropriated to TSBP. An unfunded mandate of this magnitude creates a substantial administrative burden and could significantly affect the other operations of the agency.

2. *Investigation and Reporting of Adverse Events*

The MOU requires TSBP to investigate any complaints about a drug compounded at a pharmacy and distributed out of state and to share information about all serious adverse events related to compounded drug products distributed out of state within five business days of receipt of a complaint by TSBP. This short deadline is problematic since often the agency has not determined the nature of a complaint and whether it would indeed need to be reported within five days of receipt of a complaint. Complaints often contain incomplete information and require preliminary investigation before such a determination can be made.

Additionally, in order to comply with the MOU, TSBP would be required to violate the Texas Pharmacy Act, Occupations Code §555.010, which prohibits revealing the identity of the complainant, and §565.055, which prohibits the agency from disclosing confidential investigative information in all but limited, enumerated circumstances. FDA has recently published guidance regarding this issue of releasing the complainant's name to FDA on its website that "the state is agreeing to report the name and contact information of the complainant, if available, to FDA. If providing this information is prohibited by state law, FDA does not consider it to be 'available' for purposes of the MOU."

3. *Legal Authority Affirmation*

The MOU states that TSBP "now possesses and will maintain … the legal authority … and resources necessary to effectively carry out all aspects of this MOU," which may not be feasible due to the issues described herein.

4. *Implications of Not Signing by TSBP*

If TSBP does not sign the MOU, pharmacies would be limited to distributing (which includes dispensing to a specific patient) no more than 5% outside of the state. The result could have a significant impact on out of state patients and pharmacies which operate under this type of business model.

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

April 27, 2021

Frances Gail Bormel, JD, RPh
Acting Director, Office of Compounding Quality and Compliance
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Sent via email: Frances.Bormel@hhs.fda.gov

Re: Request to Delay Enforcement of Section 503A(b)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act

Dear Ms Bormel:

The National Association of Boards of Pharmacy® (NABP®) writes to respectfully request that Food and Drug Administration (FDA) delay enforcement of Section 503A(b)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act until October 2022. Section 503A(b)(3)(B)(ii) reads:

> SEC. 503A. PHARMACY COMPOUNDING.
>
> (b) Compounded Drug.--
>
> (3) Drug product.--A drug product may be compounded under subsection (a) only if--
>
> (B) such drug product is compounded in a State--
>
> (ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded 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. [Page 111 STAT. 2330]

As you know, NABP, founded in 1904, represents the pharmacy regulatory and licensing authorities in all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, The Bahamas, and all 10 Canadian provinces. NABP's mission is to serve as the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

In recent weeks, NABP has received comments from multiple member boards of pharmacy that the timeline is too short for them to take the action needed to sign the MOU by October 2021 and have asked about FDA delaying enforcement.

The majority of boards cite the burden that the coronavirus disease 2019 (COVID-19) pandemic has placed on them, causing a backlog in most, if not all, board activities and resulting in the need for boards to prioritize COVID-19-related actions above everything else.

Some boards also cite issues beyond those related to COVID-19. Several states have indicated that regulatory changes, which involve lengthy processes and require extensive public comment periods, are needed. Others have indicated that statutory amendments are necessary, and the legislatures are placing a great deal of focus on COVID-19-related legislation. In addition, states where legislatures only meet biennially, eg, Montana, Nevada, North Dakota, Texas, may not have appropriate changes in place until 2022 or even 2023.

Additionally, the potential lack of access for patients who rely on pharmacies that are located in states that cannot sign the MOU is of great concern to NABP and its member boards. In fact, at least one state has no in-state compounding pharmacies and its patients rely exclusively on interstate shipment for their needed medications. As a result, an October 2021 enforcement date may cause an interruption in therapy for these and other patients nationwide.

To summarize, NABP anticipates that an enforcement delay will give many states the time needed to take the necessary actions to sign the MOU. As you know, NABP is strongly supportive of the work that FDA has done to protect patients from high-risk compounders and would like as many states as possible to join in this effort. Association staff is hard at work developing the Information Sharing Network and will soon be onboarding several states that have decided to sign the MOU. NABP is pleased that patients in these states will soon benefit from the work put into this effort.

Thank you for your attention to this matter. NABP hopes that FDA will consider this request.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Lemrey “Al” Carter, PharmD, MS, RPh
Executive Director/Secretary

cc: NABP Executive Committee

Alliance for Pharmacy Compounding

November 9, 2020

Allison Vordenbaumen Benz
Executive Director / Secretary
Texas State Board of Pharmacy
333 Guadalupe, Ste #3-500
Austin, TX 78701

RE: FDA's Final MOU on Interstate Distributions of Compounded Drug Products

Dear Allison:

As you may be aware, on October 26, 2020, the Office of Management and Budget (OMB) cleared the Food and Drug Administration's (FDA's) Memorandum of Understanding (MOU) on interstate distributions of compounded drug products under the Paperwork Reduction Act – and on the following day FDA posted the final MOU in the Federal Register and made it available for states to sign. The Notice of Availability can be found here (*hyperlink)* and the final MOU can be found here (*hyperlink)*. The notice indicates that states will have one year to sign the MOU before FDA begins enforcing a statutory five percent cap on interstate distributions – defined by FDA to include traditional dispensing – from pharmacies in states that do not sign the MOU.

When the final MOU was sent to OMB in May of this year, the Alliance for Pharmacy Compounding (APC) joined other stakeholders, including major national pharmacy organizations (National Community Pharmacists Association, American Pharmacists Association, National Alliance of State Pharmacy Associations), Members of Congress, multiple state boards of pharmacy, and many individual pharmacists and pharmacy owners to express serious concerns that FDA had not met the requirements of the Paperwork Reduction Act to do a collection of information on the administrative and financial burdens the MOU's unfunded mandates would place on states. As many stakeholders pointed out, the collection of information in this particular case was critically important because the burden and cost of the unfunded mandates on state boards of pharmacy relate directly to how many states will sign the MOU.

Pharmacies in states that cannot sign – due to restrictions in state law, or because they don't have the financial resources to meet the MOU's mandates, or they choose not to sign because of the requirements it will place on state agencies and pharmacies in their state – will be capped at distributing no more than five percent of their compounded drug products interstate. Because FDA has redefined in the MOU the key term of distribution to include the patient-specific dispensing of compounded drugs, pharmacies in states that don't sign the MOU will be capped at "distributing" or "dispensing" no more than five percent of their compounded drugs out of state. This has the potential to create an enormous patient access problem for the millions of Americans who rely on medications compounded at out-of-state pharmacies. This is why a true collection of information by FDA about the impact of the MOU on each state and the status of legal authority, financial capability and overall likelihood of each state to sign the final MOU was so important.

Unfortunately, instead of surveying each state about these important questions, FDA simply asked for comments from states and from the few they got, gleaned national state averages about the burden the FDA estimates will be placed on state agencies. Amazingly, although the information submitted to OMB from FDA estimates a total annual time burden (in hours) of the MOU on states at 7,789, *it also asserts*

$0 in annual cost burden (in dollars) of the MOU on the states. FDA's estimate that 45states will sign the final MOU is not supported by any survey of the states or empirical evidence and is inconsistent with NABP's estimate and comments both FDA and OMB have received directly from state boards of pharmacy. For these reasons, APC and many other stakeholders asked OMB to reject the MOU under the Paperwork Reduction Act and send it back to the FDA for a true collection of information about the burden of the MOU on state agencies and whether states intended to sign the now finalized MOU. Unfortunately, OMB chose to ignore all of this stakeholder input and clear the MOU without change, triggering the 365-day clock for states to decide whether or not to sign the MOU.

It is particularly troubling that FDA would finalize this MOU without going through the notice and comment rulemaking process under the Administrative Procedures Act, as clearly called for in the statutory language of section 503A of the Food, Drug and Cosmetic Act (FDCA) that establishes the MOU requirement. This is unfortunately part of a larger pattern of FDA implementing and enforcing the compounding provisions of the FDCA, as amended by the Drug Quality and Security Act (DQSA) of 2013, through informal, non-binding guidance documents rather than going through the more rigorous rulemaking process that is intended to provide more stakeholder input and greater transparency and accountability for federal agencies implementing the laws passed by Congress.

APC believes that had this MOU gone through the rulemaking process as clearly called for in the statute, a final MOU would have been developed that had broad stakeholder support and that all or nearly all 50 states would sign. Instead, in defiance of Congress, FDA short-circuited the process to finalize a substantively flawed MOU that redefines key statutory terms in an attempt to give the agency authority over the patient-specific dispensing of compounded drugs, which as you know is traditionally regulated under state law. We are concerned that a full collection of information would show that many more than FDA's estimate of five states cannot or will not sign this MOU – and that an entirely avoidable access crises is brewing for the patients who rely on pharmacies in those states for their compounded medications. Indeed, a federal lawsuit has already been filed by a coalition of several compounding pharmacies, seeking declaratory relief that the MOU should be vacated because it did not go through rulemaking as called for in the statute and because it clearly exceeds the statutory authority granted to FDA by Congress.

States that sign the MOU will be required to finance the additional staffing needed to gather intrastate and interstate dispensing and distribution data from all compounding pharmacies in their state and evaluate that data to determine which pharmacies trigger the MOU's reporting requirements. States that sign the MOU will further be required to investigate adverse event reports, report data to the FDA, and maintain records. Pharmacies in states that are unable or unwilling to sign the MOU are statutorily prohibited from "distributing" more than five percent of their compounded drugs interstate. In the MOU the FDA directs states to use "surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available" to determine which pharmacies in their state have distributed more than 50 percent of their compounded drugs out of state.

While the outcome of this lawsuit or other potential litigation related to the MOU is uncertain, APC remains committed to working with pharmacy stakeholders to provide much-needed public information about the impact the MOU will have on states that sign and the pharmacies in those states, as well as the impact it will have on the pharmacies that don't sign the MOU and the out-of-state patients those pharmacies serve. We are committed to continuing to strive for a workable final MOU that gives FDA the data they need to track inordinate interstate shipments of compounded drugs without unduly burdening states or inappropriately capping patient-specific dispensing. We believe more public

information about the current MOU is needed to accomplish this goal. **To that end, we respectfully ask that you or your Board's legal counsel take a few minutes to complete our brief survey, either online at www.a4pc.org/stateMOUsurvey or enclosed here (to be returned to us by fax or email).**

Thank you in advance for your participation in this important collection of information on the MOU that has unfortunately become necessary due to FDA's failure to complete one pursuant to the Paperwork Reduction Act. Should you have any questions or concerns, please do not hesitate to contact me directly at scott@a4pc.org or 404-844-8607.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
scott@a4pc.org

ENCLOSED: Questionnaire

Alliance for Pharmacy Compounding

STATE BOARD OF PHARMACY QUESTIONNAIRE

ON FDA'S MOU ON INTERSTATE DISTRIBUTIONS OF COMPOUNDED MEDICATIONS

Please complete the questionnaire below no later than November 30, 2020 if possible and fax it to the Alliance for Pharmacy Compounding at (281) 495-0602 or scan and email it to info@a4pc.org. Or if you prefer, you may complete the questionnaire online at www.a4pc.org/stateMOUsurvey. Thank you.

1. STATE NAME:
2. STATE BOARD OR AGENCY NAME:
3. YOUR NAME:
4. YOUR TITLE:
5. YOUR EMAIL ADDRESS:
6. Under your state's law, does the state board of pharmacy have the legal authority to sign the MOU with FDA? If not, is there another agency in your state that does? If so which one?

7. If the answer to question #1 is no, what action would be necessary to give your Board or another state agency the legal authority to sign the MOU? (e.g. a change to state law, a proposed regulation, a change to Board rules)

8. 3. How many pharmacies in your state do you estimate are currently distributing and dispensing more than 50 percent of their compounded drugs out-of-state?

9. How many annual manpower hours do you estimate it would take your Board to collect and evaluate data on intrastate and interstate shipments of compounded drugs from pharmacies licensed in your state?

10. How many additional annual manpower hours do you estimate would be required for your Board to meet the MOU's requirements to investigate adverse events (including additional inspectors) related to compounded drugs shipped interstate from pharmacies in your state?

11. How many additional annual manpower hours do you estimate would be required for your Board to meet the MOU's reporting and recordkeeping requirements?

12. Do you anticipate that the MOU would require your Board to hire additional full or part-time employees? If so, how many?

13. Roughly, what do you estimate the overall annual financial burden (in dollars) to your state would be to comply with the mandates associated with the MOU?

14. What amount, if any, has your state budgeted for fiscal year 2021 to meet the mandates of the MOU?

15. Does your state intend to sign the final MOU?

Return completed questionnaire by fax to the Alliance for Pharmacy Compounding at (281) 495-0602 *or scan and email it to info@a4pc.org no later than NOVEMBER 30, 2020 if possible.*

If you have questions, please contact APC's David Pore at dpore@hslawmail.com.

Pharmacy Solutions

1921 W. Pioneer Pkwy
Arlington, TX 76013
Phone: 817.274.0050
Fax: 817.860.6083
RXCompound.com

February 17,2021

To members of the Texas Board of Pharmacy:

My name is Tom Siegenthaler, RPh. I have been licensed to practice pharmacy in the great State of Texas since June 25, 1980. I opened an independent pharmacy in 1990, and have provided medications, compounded and sterile compounded for patients in Texas and other states.

I own Pharmacy Solutions, a compounding pharmacy in Arlington, Texas. We are currently licensed in and serve patients in 30 states, with licenses pending in several others. We dispense customized compounded preparations to about 8500 patients. We ship about 10 percent of our compounded preparations out of state – all pursuant to a prescription.

I'm writing to tell you that your decision, as our state board of pharmacy, about whether to sign FDA's Memorandum of Understanding with states has potentially catastrophic implications for my pharmacy and other Texas compounding pharmacies like mine, not to mention for the patients we serve. Many of our patients are cancer patients and depend on us to provide medications both regular and compounded to treat their illness.

First, *please be aware that the MOU only applies to human compounding, not animal compounding*.

The MOU has serious flaws. It conflates definitions of 'distribute' and 'dispense' in a way Congress never anticipated. As a result, in states that sign the MOU, FDA will gain oversight of certain aspects of traditional dispensing, which has long been the purview of state boards of pharmacy, NOT a federal agency. In addition, FDA seriously underestimated the administrative burden on state boards that sign the MOU – the costs of staffing, reporting, etc. required of states in order to comply. The MOU creates, in effect, an unfunded mandate on states that sign.

But there are also problems – potentially greater ones – for states that DON'T sign:

If the Texas board does not sign the MOU, my compounding pharmacy will be limited to shipping NO MORE THAN 5% of our compounded preparations out of state. For many, many compounders – including me – that 5% cap will impede countless patients from getting their medications. It could well put some compounders out of business and result in lost jobs (and tax revenue) in our state. That's an unfortunate position state boards of pharmacy have been

Pharmacy Solutions

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Arlington, TX 76013
Phone: 817.274.0050
Fax: 817.860.6083
RXCompound.com

put in by FDA – making a decision that could hurt local economies, not to mention patient care. (This 2020 op-ed by Virginia Congressman Morgan Griffith makes that point well.)

So, what am I asking of you?

Take this issue seriously. Consult with compounding pharmacy owners. The MOU is deeply flawed, and both NABP and FDA need to hear from you about your concerns NOW, not later. If they don't hear from you, there's no chance the MOU can be amended and improved. So please write to NABP and FDA.

And what happens if FDA is unwilling to make changes? I'll be asking you to sign the MOU, and so will other compounders, because, as I've said, that 5% cap on out-of-state shipments that will be imposed if you don't sign will be the death knell for many compounders. I do understand your role as a regulatory agency is to protect consumers. But when pharmacies can't stay in business, patients in-state and out-of-state can't access the medications they need. How does that protect consumers?

I'd welcome an opportunity to meet with the board to brief you about this coming train-wreck that is FDA's MOU. Feel free to contact me. But in any case, please pay attention to this issue. The stakes are quite high for those you regulate and the patients we serve.

Sincerely,

Tom Siegenthaler, RPh, FACA

Tom's cell 817-925-4242

Owner

Pharmacy Solutions

February 19, 2021

To members of the Texas Board of Pharmacy:

My name is Mike Sands and I'm the Co-Founder & CEO of SandsRx Pharmacy in Wylie, TX. We serve patients in the 17 different states that we're licensed in. We dispense customized compounded preparations to approximately 1,650 patients. We also ship approximately **10%** of our compounded preparations out of state – all pursuant to a prescription.

I'm writing to tell you that your decision, as our state board of pharmacy, about whether to sign FDA's Memorandum of Understanding with states has potentially catastrophic implications for my pharmacy and other Texas compounding pharmacies like mine, not to mention for the patients we serve.

WE NEED YOU TO PLEASE SIGN THE MOU.

First, *please be aware that the MOU only applies to **human compounding,** not animal compounding*.

The MOU has serious flaws. It conflates definitions of 'distribute' and 'dispense' in a way Congress never anticipated. **As a result, in states that sign the MOU, FDA will gain oversight of certain aspects of traditional dispensing, which has long been the purview of state boards of pharmacy, NOT a federal agency**. In addition, FDA seriously underestimated the administrative burden on state boards that sign the MOU – the costs of staffing, reporting, etc. required of states in order to comply. The MOU creates, in effect, an unfunded mandate on states that sign.

But there are also problems – potentially greater ones – for states that DON'T sign:

If the board does not sign the MOU, my compounding pharmacy will be limited to shipping NO MORE THAN 5% of our compounded preparations out of state. For many, many compounders – including me – that 5% cap will impede countless patients from getting their medications. It could well put some compounders out of business and result in lost jobs (and tax revenue) in our state. That's an unfortunate position state boards of pharmacy have been put in by FDA – making a decision that could hurt local economies, not to mention patient care. (This 2020 op-ed by Virginia Congressman Morgan Griffith makes that point well.)

So what am I asking of you?

Take this issue seriously. Consult with compounding pharmacy owners. The MOU is deeply flawed, and both NABP and FDA need to hear from you about your concerns NOW, not later. If they don't hear from you, there's no chance the MOU can be amended and improved. So please write to NABP and FDA.

And what happens if FDA is unwilling to make changes? I will be asking you to sign the MOU, and so will other compounders. **The reason being is that 5% cap on out-of-state shipments that will be imposed, if you don't sign, will be the end of existence for many compounders.** I understand your role as a regulatory agency is to protect consumers. However, when pharmacies can't stay in business, patients in-state and out-of-state can't access the medications they need, how does that protect consumers?

I would welcome an opportunity to meet with the board to brief you about this coming train-wreck that is FDA's MOU. Feel free to contact me. But in any case, please pay attention to this issue. The stakes are quite high for those you regulate and the patients we serve.

Sincerely,

Mike Sands
Co-Founder & CEO
SandsRx Pharmacy
4 Regency Drive
Wylie, TX 75098
www.sandsrx.com

alliance for natural health USA

Alliance for Natural Health USA
1011 E Jefferson St #204
Charlottesville, VA 22902
(800) 230-2762
www.anh-usa.org

February 22, 2021

To the members of the Texas State Board of Pharmacy:

On behalf of the Alliance for Natural Health USA (ANH), I am writing to urge you to seriously consider deep flaws with the FDA's Memorandum of Understanding concerning compounded medications, and to contact the agency with your concerns.

ANH is a nonprofit organization representing one million consumers and healthcare practitioners across the U.S. ANH protects the right of natural health practitioners to practice, and the right of consumers to choose the healthcare options and treatment modalities they prefer, including complementary and alternative medicine. We believe a system that is single-mindedly focused on "treating" sick people with expensive drugs, rather than maintaining healthy people, is neither practical nor economically sustainable.

Compounded medications are a key component of natural healthcare, as they are tailored to individual patient needs.

I'm writing to tell you that your decision, as the state board of pharmacy, about whether to sign FDA's Memorandum of Understanding with states has potentially catastrophic implications for access to compounded medications in your state.

The MOU has serious flaws. It conflates definitions of 'distribute' and 'dispense' in a way Congress never anticipated. As a result, in states that sign the MOU, FDA will gain oversight of certain aspects of traditional dispensing, which has long been the purview of state boards of pharmacy, NOT a federal agency. In addition, FDA seriously underestimated the administrative burden on state boards that sign the MOU – the costs of staffing, reporting, etc. required of states in order to comply. The MOU creates, in effect, an unfunded mandate on states that sign.

But there are also problems – potentially greater ones – for states that DON'T sign:

If your state board does not sign the MOU, compounding pharmacies will be limited to shipping NO MORE THAN 5% of compounded preparations out of state. For many, many compounders, that 5% cap will impede countless patients from getting their medications. It could well put some compounders out of business and result in lost jobs (and tax revenue) in your state. That's an unfortunate position state boards of pharmacy have been put in by FDA – making a decision that could hurt

local economies, not to mention patient care. (This 2020 op-ed by Virginia Congressman Morgan Griffith makes that point well.)

I urge you to consult with compounding pharmacy owners. The MOU is deeply flawed, and both NABP and FDA need to hear from you about your concerns now, not later. If they don't hear from you, there's no chance the MOU can be amended and improved. So please write to NABP and FDA.

What happens if FDA is unwilling to make changes? I'll be asking you to sign the MOU because that 5% cap on out-of-state shipments that will be imposed if you don't sign will be the death knell for many compounders. I do understand your role as a regulatory agency is to protect consumers. But when pharmacies can't stay in business, patients in-state and out-of-state can't access the medications they need. How does that protect consumers?

Thank you for your consideration.

Sincerely,

Gretchen DuBeau, Esq.
Executive and Legal Director
Alliance for Natural Health USA

PHYSICIANS
PREFERENCE
PHARMACY

February 24, 2021

2021 FEB 25 PM 4:21

TX PHARMACY BOARD

To the Members of the Texas Board of Pharmacy:

With this correspondence I am writing to tell you that your decision, as our state board of pharmacy, about whether to sign FDA's Memorandum of Understanding (MOU) with states has potentially catastrophic implications for my pharmacy and other Texas compounding pharmacies, as well as the thousands of patients we serve.

I own **Physicians Preference Pharmacy International, LLC, (PPPI)** a compounding pharmacy in Katy, Texas (license 32372). We are currently licensed in and serve patients in 47 states. We dispense customized compounded preparations to approximately 5000 patients. We ship approximately 23% of our compounded preparations out of state – all pursuant to a prescription. Since 1989, we have served over 33,000 patients at the **Hotze Health & Wellness Center** from all over the United States and they have used **PPPI** which is affiliated with **Hotze Health & Wellness Center.**

First, please be aware that the MOU only applies to human compounding, not animal compounding.

The MOU has serious flaws. First, it conflates definitions of 'distribute' and 'dispense' in a way Congress never anticipated. As a result, in states that sign the MOU, the FDA will gain oversight of certain aspects of traditional dispensing, which has long been the purview of state boards of pharmacy, not a federal agency. Second, the FDA seriously underestimated the administrative burden on state boards that sign the MOU – the costs of staffing, reporting, etc. required of states in order to comply. The MOU creates, in effect, an unfunded mandate on states that sign.

There are also problems, potentially greater ones, for states that don't sign the MOU:

If the Texas board does not sign the MOU, then **PPPI** will be limited to shipping no more than 5% of our compounded preparations out of state. For many compounders that 5% cap will stop countless patients from getting their medications. It will put many compounders out of business and result in lost jobs and tax revenue in our state. The FDA has put the state boards of pharmacy in a difficult position as this decision hurts local economies and patient care. (This 2020 op-ed by Virginia Congressman Morgan Griffith makes that point well.)

Please take this issue seriously and consult with compounding pharmacy owners. Both the NABP and FDA need to hear from you about your concerns immediately. If they do not hear from you, then there is no chance the MOU can be amended and improved. So I strongly encourage you to please write to NABP and FDA.

If the FDA is unwilling to make changes then I will be asking you to sign the MOU, and so will other compounders, because that 5% cap on out-of-state shipments that will be imposed if you do not sign will be the death knell for many compounders. While I understand your role as a regulatory agency is to protect consumers, when pharmacies cannot stay in business, the patients

20214 Braidwood Drive, Suite 140, Katy, Texas 77450
281.828.9088 toll free 877.640.5248

PhysiciansPreferenceRX.com

in-state and out-of-state cannot access the medications they need. How does that protect the consumer?

I would welcome an opportunity to meet with you to discuss this approaching train wreck that is FDA's MOU. You can call my direct line at my office at 281.698.8679 or text me at 832.364.9503. The stakes are extremely high for myself, other compounders, and the patients we serve.

With much appreciation for your consideration of my request, I remain, as always,

Sincerely yours,

Steven F. Hotze, M.D.
Owner
Physicians Preference Pharmacy International, LLC

April 27, 2021

Allison Vordenbaumen Benz, Executive Director / Secretary
Texas Board of Pharmacy
333 Guadalupe, Suite #3-500
Austin, TX 78701

Dear Allison Vordenbaumen Benz,

We, the undersigned organizations, strongly urge your state board of pharmacy to take action immediately in determining if it can sign the FDA's Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) before the October 2021 deadline. If there are concerns about or impediments to signing by the October 2021 deadline, we urge you to contact the FDA *as soon as possible* to express your state's concerns and to request at least a two-year extension of the signing deadline, to October 2023. A letter to the FDA requesting such an extension was submitted April 16, 2021 and a copy of that correspondence is included here.

Already, several state boards of pharmacy have raised issues about the potential conflicts between the MOU and existing state laws regarding confidentiality of information. It is important that your board of pharmacy analyze now any legal restrictions which may exist under state law and take action to remedy those restrictions as quickly as possible. Some states have already determined corrective action cannot take place by the October 2021 deadline and will need to request an extension. If this is the case for your state, we urge you to echo to FDA our request for a two-year extension of the signing deadline.

The consequences of not signing the MOU are significant:

- For states that **do not sign** the MOU, a pharmacy in that state cannot send more than five percent of its human compounded prescriptions to patients out of state, which has significant impacts on the viability of compounding pharmacies and patients who live near state borders, have two residences, live in rural areas, or require a specialized compound from an out of state pharmacy for treatment.

- For states that **do sign** the MOU, a pharmacy can continue to fulfill the compounded needs of all their patients; however, those pharmacies that dispense/distribute more than fifty percent of their human compounded prescriptions out of state will be required to submit additional data to the state board of pharmacy. This additional information will be shared by the board of pharmacy with the FDA.

Please speak with compounders in your state about the implications of the MOU on their patients and practice. Clearly, there are negative implications for signing and not signing. Given the upcoming October 2021 deadline and the devastating impacts not signing the MOU would have on patients who rely on compounded treatments, we urge you to sign the MOU by October 2021 – or if unable to do so due to conflicts of law, to request at least a two-year extension to October 2023 from the FDA. If you have further questions, please contact Ronna Hauser, NCPA VP Policy & Government Affairs Operations, at ronna.hauser@ncpa.org.

Sincerely,

Alliance for Pharmacy Compounding (APC)
American Pharmacists Association (APhA)
National Community Pharmacists Association (NCPA)
PCCA

CC: National Association of Boards of Pharmacy

April 16, 2021

Dockets Management Staff: Docket No. [FDA-2015-N-0030]
Food and Drug Administration 5630
Fishers Lane, Room 106
Rockville, MD 20852

Submitted Electronically to FDA Docket No. [FDA-2015-N-0030]

The undersigned organizations represent thousands of pharmacy compounding professionals. We write today regarding the FDA's final Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) with the states regarding interstate distributions of compounded drugs. For the reasons discussed below, we respectfully request that the FDA delay enforcement of the final MOU until at least October 26, 2023.

We are concerned that multiple state boards of pharmacy, including but not limited to those in large states like Texas and Florida, have recently concluded that it will be necessary for their respective state legislatures to amend state law in order for the boards of pharmacy to be able to comply with the final MOU's requirements. Specifically, both Texas and Florida have state laws that protect the confidentiality of complaint information submitted to their state boards of pharmacy, and both boards have received legal opinions that those laws would need to be changed before the board could attest to the ability to comply with the final MOU.

To date, in some states the relevant laws have not been changed and it is unlikely that changes will be made and implemented before the October 26, 2021 enforcement date. Some states have biennial or part-time legislative sessions that do not align with the FDA's deadline for states to sign the final MOU. Florida is in the final two weeks of their legislative session, with no legislation pending to address the final MOU, and the next legislative session there does not begin until January 2022. Likewise, Texas is in the final six weeks of their biennial legislative session and the next legislative session in that state does not convene until January 2023.

According to the National Association of Boards of Pharmacy's FDA Compounding MOU Project data, Alabama, New Mexico, Wyoming, Idaho, and Tennessee have also indicated they are unable or unwilling to sign the final MOU. We understand that multiple other states are facing similar legal hurdles and budgetary concerns and are preoccupied with the COVID-19 pandemic as well. Therefore, these states will not likely be able to meet the FDA's deadline to sign the final MOU. States' boards have also expressed concerns about how many additional inspectors and/or other full-time employees will be needed to meet the final MOU's requirements.

Enforcement of a five percent cap beginning in October of this year will result in an unnecessary disruption of health care for thousands of patients and will put an enormous strain on the pharmacies that serve them. Patients who rely on compounded medications from pharmacies in states that cannot, or do not sign the final MOU by the October 26, 2021 deadline will be penalized by disruption

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Thank you in advance for your consideration of this request.

If you have questions or would like to discuss the matter, please contact APC's Scott Brunner at scott@a4pc.org or at (404) 844-8607.

Sincerely,

Alliance for Pharmacy Compounding
American Pharmacists Association
National Alliance of State Pharmacy Associations
National Community Pharmacists Association

CC: National Association of Boards of Pharmacy

April 27, 2021

Jennifer Falkenrath, Bureau Manager, Div. of Occupational & Professional Licensing
Utah Board of Pharmacy
PO Box 146741
Salt Lake City, UT 84114-6741

Dear Jennifer Falkenrath,

We, the undersigned organizations, strongly urge your state board of pharmacy to take action immediately in determining if it can sign the FDA's Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) before the October 2021 deadline. If there are concerns about or impediments to signing by the October 2021 deadline, we urge you to contact the FDA *as soon as possible* to express your state's concerns and to request at least a two-year extension of the signing deadline, to October 2023. A letter to the FDA requesting such an extension was submitted April 16, 2021 and a copy of that correspondence is included here.

Already, several state boards of pharmacy have raised issues about the potential conflicts between the MOU and existing state laws regarding confidentiality of information. It is important that your board of pharmacy analyze now any legal restrictions which may exist under state law and take action to remedy those restrictions as quickly as possible. Some states have already determined corrective action cannot take place by the October 2021 deadline and will need to request an extension. If this is the case for your state, we urge you to echo to FDA our request for a two-year extension of the signing deadline.

The consequences of not signing the MOU are significant:

- For states that **do not sign** the MOU, a pharmacy in that state cannot send more than five percent of its human compounded prescriptions to patients out of state, which has significant impacts on the viability of compounding pharmacies and patients who live near state borders, have two residences, live in rural areas, or require a specialized compound from an out of state pharmacy for treatment.

- For states that **do sign** the MOU, a pharmacy can continue to fulfill the compounded needs of all their patients; however, those pharmacies that dispense/distribute more than fifty percent of their human compounded prescriptions out of state will be required to submit additional data to the state board of pharmacy. This additional information will be shared by the board of pharmacy with the FDA.

Please speak with compounders in your state about the implications of the MOU on their patients and practice. Clearly, there are negative implications for signing and not signing. Given the upcoming October 2021 deadline and the devastating impacts not signing the MOU would have on patients who rely on compounded treatments, we urge you to sign the MOU by October 2021 – or if unable to do so due to conflicts of law, to request at least a two-year extension to October 2023 from the FDA. If you have further questions, please contact Ronna Hauser, NCPA VP Policy & Government Affairs Operations, at ronna.hauser@ncpa.org.

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American Pharmacists Association (APhA)
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April 16, 2021

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Alliance for Pharmacy Compounding
American Pharmacists Association
National Alliance of State Pharmacy Associations
National Community Pharmacists Association

CC: National Association of Boards of Pharmacy

April 27, 2021

Carrie Phillips, Executive Director
Vermont Board of Pharmacy
89 Main St, Third Floor
Montpelier, VT 05620-3402

Dear Carrie Phillips,

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April 16, 2021

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Alliance for Pharmacy Compounding
American Pharmacists Association
National Alliance of State Pharmacy Associations
National Community Pharmacists Association

CC: National Association of Boards of Pharmacy

April 27, 2021

Caroline Juran, Executive Director
Virginia Board of Pharmacy
Perimeter Center, 9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Caroline Juran,

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Alliance for Pharmacy Compounding
American Pharmacists Association
National Alliance of State Pharmacy Associations
National Community Pharmacists Association

CC: National Association of Boards of Pharmacy

April 27, 2021

Lauren Lyles-Stolz, Executive Director of Pharmacy Quality and Assurance Commission
Washington Board of Pharmacy
PO Box 47852
Olympia, WA 98504-7852

Dear Lauren Lyles-Stolz,

We, the undersigned organizations, strongly urge your state board of pharmacy to take action immediately in determining if it can sign the FDA's Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) before the October 2021 deadline. If there are concerns about or impediments to signing by the October 2021 deadline, we urge you to contact the FDA *as soon as possible* to express your state's concerns and to request at least a two-year extension of the signing deadline, to October 2023. A letter to the FDA requesting such an extension was submitted April 16, 2021 and a copy of that correspondence is included here.

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National Alliance of State Pharmacy Associations
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April 27, 2021

Michael Goff, Executive Director & CSMP Administrator
West Virginia Board of Pharmacy
2310 Kanawha Blvd E
Charleston, WV 25311

Dear Michael Goff,

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April 27, 2021

Christian Albouras, Executive Director
Wisconsin Board of Pharmacy
4822 Madison Yards Way
Madison, WI 53705

Dear Christian Albouras,

We, the undersigned organizations, strongly urge your state board of pharmacy to take action immediately in determining if it can sign the FDA's Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) before the October 2021 deadline. If there are concerns about or impediments to signing by the October 2021 deadline, we urge you to contact the FDA *as soon as possible* to express your state's concerns and to request at least a two-year extension of the signing deadline, to October 2023. A letter to the FDA requesting such an extension was submitted April 16, 2021 and a copy of that correspondence is included here.

Already, several state boards of pharmacy have raised issues about the potential conflicts between the MOU and existing state laws regarding confidentiality of information. It is important that your board of pharmacy analyze now any legal restrictions which may exist under state law and take action to remedy those restrictions as quickly as possible. Some states have already determined corrective action cannot take place by the October 2021 deadline and will need to request an extension. If this is the case for your state, we urge you to echo to FDA our request for a two-year extension of the signing deadline.

The consequences of not signing the MOU are significant:

- For states that **do not sign** the MOU, a pharmacy in that state cannot send more than five percent of its human compounded prescriptions to patients out of state, which has significant impacts on the viability of compounding pharmacies and patients who live near state borders, have two residences, live in rural areas, or require a specialized compound from an out of state pharmacy for treatment.

- For states that **do sign** the MOU, a pharmacy can continue to fulfill the compounded needs of all their patients; however, those pharmacies that dispense/distribute more than fifty percent of their human compounded prescriptions out of state will be required to submit additional data to the state board of pharmacy. This additional information will be shared by the board of pharmacy with the FDA.

Please speak with compounders in your state about the implications of the MOU on their patients and practice. Clearly, there are negative implications for signing and not signing. Given the upcoming October 2021 deadline and the devastating impacts not signing the MOU would have on patients who rely on compounded treatments, we urge you to sign the MOU by October 2021 – or if unable to do so due to conflicts of law, to request at least a two-year extension to October 2023 from the FDA. If you have further questions, please contact Ronna Hauser, NCPA VP Policy & Government Affairs Operations, at ronna.hauser@ncpa.org.

Sincerely,

Alliance for Pharmacy Compounding (APC)
American Pharmacists Association (APhA)
National Community Pharmacists Association (NCPA)
PCCA

CC: National Association of Boards of Pharmacy

April 16, 2021

Dockets Management Staff: Docket No. [FDA-2015-N-0030]
Food and Drug Administration 5630
Fishers Lane, Room 106
Rockville, MD 20852

Submitted Electronically to FDA Docket No. [FDA-2015-N-0030]

The undersigned organizations represent thousands of pharmacy compounding professionals. We write today regarding the FDA's final Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) with the states regarding interstate distributions of compounded drugs. For the reasons discussed below, we respectfully request that the FDA delay enforcement of the final MOU until at least October 26, 2023.

We are concerned that multiple state boards of pharmacy, including but not limited to those in large states like Texas and Florida, have recently concluded that it will be necessary for their respective state legislatures to amend state law in order for the boards of pharmacy to be able to comply with the final MOU's requirements. Specifically, both Texas and Florida have state laws that protect the confidentiality of complaint information submitted to their state boards of pharmacy, and both boards have received legal opinions that those laws would need to be changed before the board could attest to the ability to comply with the final MOU.

To date, in some states the relevant laws have not been changed and it is unlikely that changes will be made and implemented before the October 26, 2021 enforcement date. Some states have biennial or part-time legislative sessions that do not align with the FDA's deadline for states to sign the final MOU. Florida is in the final two weeks of their legislative session, with no legislation pending to address the final MOU, and the next legislative session there does not begin until January 2022. Likewise, Texas is in the final six weeks of their biennial legislative session and the next legislative session in that state does not convene until January 2023.

According to the National Association of Boards of Pharmacy's FDA Compounding MOU Project data, Alabama, New Mexico, Wyoming, Idaho, and Tennessee have also indicated they are unable or unwilling to sign the final MOU. We understand that multiple other states are facing similar legal hurdles and budgetary concerns and are preoccupied with the COVID-19 pandemic as well. Therefore, these states will not likely be able to meet the FDA's deadline to sign the final MOU. States' boards have also expressed concerns about how many additional inspectors and/or other full-time employees will be needed to meet the final MOU's requirements.

Enforcement of a five percent cap beginning in October of this year will result in an unnecessary disruption of health care for thousands of patients and will put an enormous strain on the pharmacies that serve them. Patients who rely on compounded medications from pharmacies in states that cannot, or do not sign the final MOU by the October 26, 2021 deadline will be penalized by disruption

of care and inability to receive therapy from their pharmacy of choice. States should be given more time to amend their laws and budget the necessary funds so they can sign and comply with the final MOU.

For these reasons, we respectfully request FDA delay its enforcement of the final MOU until, at least, October 26, 2023.

Thank you in advance for your consideration of this request.

If you have questions or would like to discuss the matter, please contact APC's Scott Brunner at scott@a4pc.org or at (404) 844-8607.

Sincerely,

Alliance for Pharmacy Compounding
American Pharmacists Association
National Alliance of State Pharmacy Associations
National Community Pharmacists Association

CC: National Association of Boards of Pharmacy

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: Texas State Board of Pharmacy – Compounding Advisory Group

FROM: Lemrey "Al" Carter, Executive Director/Secretary

DATE: June 22, 2021

RE: Response to Request for Public Comments Regarding the Food and Drug Administration Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products

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The National Association of Boards of Pharmacy® (NABP®) strongly encourages the Texas State Board of Pharmacy to sign the Food and Drug Administration (FDA) Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU). NABP trusts that participation in the MOU will improve public protection by gathering and sharing compounding pharmacy data and fostering better and more targeted regulation and oversight of compounding pharmacies.

As you know, NABP, which was founded in 1904, represents the pharmacy regulatory authorities in all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, The Bahamas, and all 10 Canadian provinces. NABP's mission is to serve as the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

NABP is aware of resource concerns related to the obligations that a state takes on by signing the MOU and we are confident that we can assist. Over the past year, NABP has been working with FDA to develop an Information Sharing Network (ISN) that signatory boards can use to submit, manage, and share data in compliance with the terms of the MOU. The ISN, which builds upon facility profiles found in NABP e-Profile Connect, is expected to be launched in July 2021.

NABP is also aware of the concern regarding the submission of complaint information to the ISN when it is prohibited from disclosure by state law. To clarify, under the MOU, states agree to report to FDA the name and contact information of the complainant, *if available*. FDA has stated that it does not consider the information to be "available" if providing the information is not allowed under state law.

Finally, NABP is concerned about the potential lack of access to necessary compounded medications if states with many compounding pharmacies that ship interstate, such as Texas, do not sign the MOU. In fact, at least one state has indicated to NABP that it has no in-state compounding pharmacies and its patients rely solely on nonresident pharmacies, including 17 pharmacies located in Texas, for their compounded medications. Thus, NABP considers it imperative that Texas sign the MOU.

NABP is strongly supportive of the outstanding work that the Texas State Board of Pharmacy has done, and continues to do, to protect patients who receive compounded drug products. We believe that signing the MOU will enhance these efforts.

Please see the attached documents for background information on the project as well as model regulatory language for you to consider if you would like to make submission of data to the ISN mandatory in your state.

Attachments

cc: NABP Executive Committee

Frequently Asked Questions

Following are answers to frequently asked questions regarding this data sharing project. Question categories include data/information sharing, board investigations, pharmacy participation, project audits, and Food and Drug Administration's (FDA's) memorandum of understanding (MOU). Refer to FDA's frequently asked questions about the MOU for more information. If you have any additional questions, see the Compounding Pharmacy Information Sharing Project overview page or contact prof-affairs@nabp.pharmacy.

Data/Information Sharing

What information will be provided to FDA through the Information Sharing Network developed by NABP?

Upon approval by a board of pharmacy, the system will provide FDA with:

- Information about compounders for which the number of prescription orders for compounded drug products distributed interstate is greater than 50% of the number of prescription orders for compounded drug products distributed or dispensed both intrastate and interstate by such compounder; and
- Information provided by a board of pharmacy about:
  - complaints of serious adverse drug experiences and product quality issues relating to human drug products compounded at a pharmacy and distributed interstate;
  - complaints regarding an adverse drug experience or product quality issue relating to human drug products compounded by a physician and distributed interstate; and
  - notifications about distribution of any amount of human drug products compounded by a physician and distributed interstate.

What volume of compounded human drug products distributed interstate is considered an inordinate amount?

A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50% of the sum of:

1. the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; and

2. the number of prescription orders for compounded human drug products that were dispensed (eg, picked up by a patient) at the facility in which they were compounded during that same calendar year.

The distribution of inordinate amounts of compounded human drug products interstate is a threshold for the board of pharmacy to identify and report certain information to FDA, not a limit on the distribution of compounded human drug products interstate. Pharmacies whose data are reported to FDA will not necessarily be subject to inspection by FDA.

Does "prescription order" in the MOU include new and refill prescription orders?

As stated in the September 10, 2018, Federal Register Notice proposing this MOU, "For purposes of this MOU, each refill is considered to be a new prescription order."

What compounded drug products are *not* covered by the MOU?

Such products include:

- drugs intended for veterinary use
- repackaged drug products
- radiopharmaceuticals
- biological products subject to licensure under section 351 of the Public Health Service Act
- drugs compounded by outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act

What specific information will boards of pharmacy submit to the Information Sharing Network about compounding pharmacy complaints?

Regarding complaints relating to human drug products compounded by a pharmacy and distributed outside a state, boards of pharmacy will submit the following information:

- Name and contact information of the complainant, if available
- Name and address of the pharmacy that is the subject of the complaint
- Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint
- The board's assessment of whether the complaint was substantiated, if available
- Description of any actions that the board has taken to address the complaint

What specific information will boards of pharmacy submit to the Information Sharing Network about compounding physician complaints and notifications?

Regarding complaints relating to human drug products compounded by a physician, or regarding the distribution of any amount of human drug products compounded by a physician and distributed outside a state, boards of pharmacy will submit the following information, if available:

- Name and contact information of the complainant or notifier
- Name and address of the physician who is the subject of the complaint or notification
- A description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint or notification

Will NABP provide training on the use of the Information Sharing Network?

Yes. Additional information on training and data entry instructions will be forthcoming. You can also review these resources about the Information Sharing Network:

- Download the information sheet for a breakdown of the process for data entry and data flow through the network
- Watch the recent webinar, *Preparing for FDA's Compounding MOU*, to understand how the MOU can better position your board to address patient safety and improve communication between FDA and all boards of pharmacy

What is included in "the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year?"

This statement refers to the number of prescription orders that were shipped or mailed out of the facility, *regardless of whether the products went in state or out of state.*

Note that this is added to "the number of prescription orders for compounded human drug products that were dispensed (eg, picked up by a patient) at the facility in which they were compounded during that same calendar year" to calculate the **total** number of prescription drug orders dispensed/distributed. This total is used as the denominator to determine the inordinate amount percentage.

What is included in "the total number of prescription orders for compounded human drug products distributed interstate during that same calendar year?"

This statement refers to the number of prescription orders that were sent (or caused to be sent) *out of the state* in which the drug was compounded.

This number is used as the numerator to determine the inordinate amount percentage. Then, the calculation is made. If the result is greater than 50%, the amount is considered inordinate, and the data needs to be sent to FDA. (The calculation is shown at the top of page 6 of the MOU.)

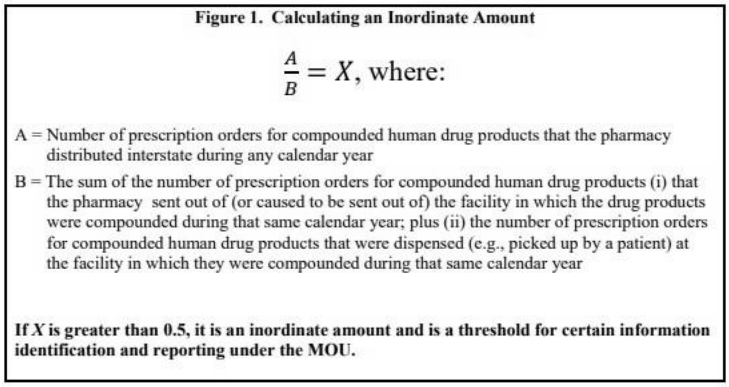

Figure 1. Calculating an Inordinate Amount

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.

Board Investigations

What types of complaints does the MOU obligate the board of pharmacy to investigate?

The board of pharmacy or state agency **will investigate complaints of adverse drug experiences and product quality issues relating to human drug products compounded at a pharmacy** in that state and distributed outside the state.

- An adverse drug experience is 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)).
- A product quality issue is 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 bacteriological 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.

Any investigations will be performed pursuant to the board of pharmacy or state agency's established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of the MOU.

For example, using established procedures, a state board of pharmacy or other appropriate state agency may review an incoming complaint describing an adverse drug experience and determine the complaint does not warrant further investigation. In other cases, a state board of pharmacy or other appropriate state agency may determine that an incoming complaint contains insufficient information and investigate further to determine appropriate action.

Any investigations performed by the board of pharmacy or state agency under the MOU will include taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.

There is no obligation for the board of pharmacy to investigate complaints regarding compounding physicians.

The MOU requires the board to report a variety of information within a certain number of business days after receipt. When does that timeline begin in a situation where the umbrella agency, rather than the board, receives the information initially?

The timeline begins when the agency that signs the MOU, be it the umbrella agency or the board, receives the information.

Pharmacy Participation

Why would a pharmacy voluntarily enter the requested information?

The information requested in the MOU will be incorporated into the application for many NABP accreditation and inspection programs, including Verified Pharmacy Program (VPP). As a result, all applicants seeking accreditation or a VPP inspection will voluntarily submit the requested information – regardless of whether their primary intent is to participate in the pilot project. Compounding pharmacies also will be able to enter the requested information, outside of the VPP application process, for a chance to receive a VPP inspection at no cost to them. The VPP inspection in this scenario will be adapted to serve the dual purpose of a traditional blueprint inspection and an audit for the pilot project. If pharmacies that submit the requested information through the NABP program application are chosen for an audit, they will receive either a refund or a future VPP inspection at no cost to them.

Some pharmacies already have a profile in NABP's e-Profile Connect system and would only need to provide the additional information related to compounding. Others would need to create a new profile. All entities providing the requested data would be entered into the pool of possible compounding pharmacies to be audited through a VPP inspection.

Under the pilot project, what will NABP do with the information that the pharmacies provide?

NABP will consult with FDA to select 150 eligible pharmacies to be audited for the project. The pharmacies will be prioritized based on factors including the volume of compounded drug products distributed interstate and other considerations. Those selected to be audited will receive a VPP inspection developed for entities engaged in sterile compounding. These VPP inspections will be modified to gather the additional information needed for the project. NABP will engage its team of seasoned and knowledgeable surveyors to conduct the audits, after providing them with the appropriate training to gather the necessary information.

How do compounding pharmacies submit the requested data?

Pharmacies that already have a business e-Profile can log into their account and add the information in the Compounding Details tab. If you do not yet have an e-Profile for your business, you will need to create one before you can enter the requested data. For more details, review the Instructions for Entering Pharmacy Compounding Data.

How many pharmacies are expected to voluntarily submit their information?

Participation by compounding pharmacies is voluntary; therefore, a specific number of pharmacies submitting information has not been determined. NABP plans to conduct 150 pharmacy audits over the course of the pilot program to evaluate the system and assess the information it produces.

Will the free VPP inspection still be available after the pilot project is over?

The funding from FDA includes the cost of these inspections. Thus, once the funding has been exhausted, VPP will no longer be available free of charge.

Project Audits

What will the audits entail?

The audits will, among other things, assess the accuracy of the information provided, including the total number of prescription orders for compounded drug products distributed interstate and distributed or dispensed intrastate, and whether the pharmacy distributes compounded drugs without patient-specific prescriptions, such as for office stock. Audits also will evaluate the compounding facility for issues such as those related to production quality.

What will NABP do with the audit findings?

NABP will conduct research to analyze the information that the pharmacies self-reported in the data system, as compared with the audit findings. The analysis will assess the quality and reliability of the data collected in the system. This research will provide the following information:

- an assessment of the extent of interstate distribution of compounded drugs;
- a descriptive analysis of the characteristics of compounders engaging in interstate distribution, including the number of states into which they distribute compounded drugs, scale of production, distribution of office stock, and production quality factors;
- an assessment of the prevalence of data inaccuracies;
- an assessment of remaining data gaps and other factors that may inform risk-based oversight; and
- an analysis of complaints submitted to the Information Sharing Network.

How will NABP determine which pharmacies to audit?

NABP will select pharmacies for audits in consultation with FDA, prioritizing pharmacies based on several factors, including the volume of compounded drug products distributed interstate.

FDA MOU

Can the state solely rely on pharmacies entering information into the Information Sharing Network to identify pharmacies that distribute inordinate amounts of compounded human drug products interstate under the MOU?

By signing the MOU, the state is agreeing to identify pharmacies that distribute inordinate amounts of compounded drugs interstate. However, the MOU provides flexibility in how the state does this, including use of tools like NABP's Information Sharing Network. If a state that chooses to use the Information Sharing Network is uncertain whether the information it contains is complete, the state may verify information through other means, such as during inspections. FDA will continue to work with states to address questions regarding reporting expectations under the MOU.

What will FDA do with information submitted by the states under the MOU?

Protecting patients is our top priority. Information submitted by the states will help inform FDA about potential for patient harm, including whether additional federal oversight is warranted. The information submitted by the states also will help inform the agency's risk-based inspection priorities.

What if a board that signs the MOU does not or cannot comply with the MOU?

There are no penalties associated with non compliance; however, FDA may move forward with terminating the MOU following a 60-calendar-day notice, which will result in enforcement of the 5% limitation on interstate distribution of compounded human drugs by pharmacies.

Will boards have an opportunity to negotiate the language of the MOU?

No, FDA has made the standard MOU available for signature. Section 503A of the FD&C Act directs FDA to develop, in consultation with NABP, a standard MOU for use by states. Developing individualized MOUs would create a patchwork of regulation of distribution of compounded drugs interstate and it would be impractical to have individual MOUs with each state.

Can a state that is prohibited by a state law from disclosing a complainant's name and contact information fulfill the agreed upon data reporting under the MOU?

Yes. Under the MOU, the state is agreeing to report the name and contact information of the complainant, if available, to FDA. If providing this information is prohibited by state law, FDA does not consider it to be "available" for purposes of the MOU. In addition, NABP's Information Sharing Network will allow boards to select whether to make this information accessible to other boards.

Can states now sign the MOU and, if so, have any states done so?

The final MOU was released in October 2020; therefore, states can now sign. One year after the release date, FDA will begin enforcing the 5% limitation on interstate distribution. See the MOU participation map for the latest updates.

SUGGESTED REGULATORY LANGUAGE

Definitions.

"NABP Information Sharing Network"[1] means the information sharing network developed by NABP that collects, assesses, and allows review and sharing of compounding pharmacy and physician information as described in the MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION.

"Person" means an individual, corporation, subsidiary, partnership, association, organization, affiliate organization, or any other legal entity, including government.

OPTION 1

Notification.

(a) On an annual basis, and within 90 days of the beginning of the calendar year, all licensed Persons shall report to the NABP Information Sharing Network the following:

(1) Whether the licensed Person participates in the following activities during the identified calendar year:
   (i) Human drug compounding – sterile;
   (ii) Human drug compounding – nonsterile;
   (iii) Patient-specific compounding; and
   (iv) Non-patient-specific compounding.

(2) If a licensed Person is compounding sterile or nonsterile human drug products and is prompted by the NABP Information Sharing Network[2], the licensed Person shall also provide for the identified calendar year the following information[3]:
   (i) Number of prescription orders for compounded human drugs the licensed Person sent out of the facility;
   (ii) Number of prescription orders for compounded human drugs dispensed at the facility; and
   (iii) Total number of prescription orders for compounded human drugs distributed interstate.

(3) If prompted by the NABP Information Sharing Network[4], the licensed Person shall provide the following additional information:

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[1] The information sharing network was built by NABP pursuant to the NABP-FDA Cooperative Agreement to Develop a System for the Collection, Management, and Sharing of Information on Compounding Pharmacies Distributing Interstate.

[2] The Information Sharing Network will prompt the licensed Person for this information if the licensed Person indicates that it is compounding sterile or nonsterile human drug products.

[3] These three data points will allow the Information Sharing Network to determine whether the licensed Person is distributing inordinate amounts of compounded human drug products interstate, as described in the MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION.

[4] The Information Sharing Network will prompt the licensed Person for this additional information if it calculates that the licensed Person has distributed inordinate amounts of compounded human drug products interstate as described in the MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE US FOOD AND DRUG ADMINISTRATION.

(i) Number of prescription orders for sterile compounded human drugs distributed interstate;
(ii) Names of states into which the licensed Person distributed compounded human drugs during the year; and
(iii) Whether compounded human drugs are distributed without patient-specific prescriptions.

OPTION 2

(a) Between January 1 and March 31 of each year, any pharmacy permitted by the Board that has prepared, labeled, or dispensed any compounded drug to any patient or other person, either within or outside [Insert State] during the immediately preceding calendar year must update all information regarding its services the National Association of Boards of Pharmacy's e-Profile Connect system at www.dashboard.nabp/pharmacy.

To: Allison Vordenbaumen Benz, Executive Director
Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-500

From: Drs. Kasra Amirdelfan, Anjum Bux, Ramsin Benyamin, Michael A. Fishman, Salim Hayek, Sean Li, Ali Nairizi, Yeshvant A. Navalgund, Anish Patel, Dawood Sayed, Peter Staats, Ricardo Vallejo

Date: June 22, 2021

Re: Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the Texas Board of Pharmacy and the U.S. Food and Drug Administration

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Dear Ms. Vordenbaumen Benz:

As clinicians devoted to finding the best solutions for our patients, we are also dedicated to supporting patient care and patient access to alternatives to high doses of opiates. Alternatives that improve quality, safety, outcomes and reduce healthcare costs. To that end, we write to strongly encourage the Texas State Board of Pharmacy to enter into the Memorandum of Understanding ("MOU") between Texas and the US Food and Drug Administration ("FDA"). By signing the MOU, Texas and the Texas State Board of Pharmacy will ensure that 503A pharmacies continue to serve patients nationwide with high quality compounded drugs to meet unmet needs.

Physicians prescribe and implant intrathecal pain pumps for patients with severe chronic pain. Pain pumps help lessen chronic pain and muscle spasticity caused by cerebral palsy, multiple sclerosis, stroke, brain injury, spinal cord injuries cancer and several other systemic conditions. This method of delivery also helps avoid the abuse and diversion that have plagued the use of oral opioids. Because the pump delivers medication directly to the spinal area, side effects are significantly reduced as compared to oral opioids and patients need only receive 1/100th to 1/300th of the typical oral dose.

Texas based compounding pharmacies have helped coordinate the care of patients receiving intrathecal pain medications for decades. Texas is home to pharmacies that provide home infusion or other specialty compounding services to patients in other states, often pursuant to longstanding patient, pharmacist, and provider relationships.

Unfortunately, if the Texas State Board of Pharmacy chooses not to enter into the MOU with FDA, pharmacies located in the Texas will be subject to the FDCA's 5 percent interstate distribution limitation. The 5 percent limit would all but eliminate access to these critical medications and have a significant adverse effect on patients. It may cause several patients to explant the pump and return to high-risk oral opioids and less effective, higher cost treatments.

Accordingly, we strongly encourage the Texas State Board of Pharmacy to adopt the MOU so that compounding pharmacies in Texas will be able to continue to serve the patients who rely on them. In addition, we believe entering into the MOU would serve an important function in advancing what we believe is a shared mission by Texas, FDA, and compounding pharmacies—to provide patients with access to the high-quality compounded medications they need as well as help deter the abuse of systemic opioids and help mitigate the ongoing opioid epidemic.

We appreciate consideration and look forward to working with you in the future.

Sincerely,

Kasra Amirdelfan, M.D.
Director of Medical Research
Interventional Spine & Pain Medicine
IPM Medical Group, Inc.
Vice President of Clinical Affairs
American Society of Pain and Neuroscience (ASPN)
Walnut Creek, Brentwood, Oakland, CA

Dr. Ramsin Benyamin
President and Founder, Millennium Pain Center
President, American Society of Interventional Pain Physicians
Clinical Assistant Professor of Surgery, College of Medicine, University of Illinois, Champaign-Urbana
Member, Guidelines Committee, American Society of Interventional Pain Physician
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Regional Director: National Spine & Pain Centers
Managing Partner: Center for Pain Management
Diplomat, American Board of Anesthesiology
ABA Certified Pain Medicine Specialist
Fellow, American Society of Anesthesiologists

Jason E. Pope MD, DABPM, FIPP
President, California Society of Interventional Pain Physicians
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Board, WV Society of Interventional Pain Physicians
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Medical Director, Interventional Pain, Asher Spine Center
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AIS HealthCare® Patient. Care. Trust.

To: Allison Vordenbaumen Benz, Executive Director
Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-500

From: Charles R. Bell, Jr.
President and Founder
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RE: FDA Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products

Dear Texas Board of Pharmacy:

On May 13, 2020, the U.S. Food and Drug Administration ("FDA") issued for public viewing a final version of its "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the Texas Board of Pharmacy and the U.S. Food and Drug Administration" ("MOU").[1] AIS Healthcare ("AIS") is writing to strongly encourage the Texas Board of Pharmacy to enter into the MOU with FDA to help ensure that pharmacies like AIS can continue to serve patients nationwide with compounded drugs to meet their unmet medical needs.[2] Below, we describe (I) AIS's compounding operations and facilities, (II) the MOU and 5 percent statutory limitation, (III) the importance of entering into the MOU for patient access to compounded drugs and economic integrity of pharmacies in Texas and (IV) how the MOU can improve federal, state, and pharmacy collaboration aimed at safeguarding the quality of compounded drugs being distributed across state lines.

I. AIS's Compounding Operations and Facilities

With state-of-the-art pharmacies in Texas, Maryland, Mississippi, Georgia, Florida and Alabama, AIS provides substantial value and industry-leading quality to patients, providers and payors by providing patient specific compounded medications to treat a wide array of disease states. Specific to Texas, our Dallas pharmacy provides compounded medications to patients across the country that are used in implanted pumps to treat underlying chronic pain and/or spasticity caused by trauma, cancer, multiple sclerosis, brain and spinal cord injuries, etc. AIS is the largest provider in this critical space, licensed to operate in all 50 states, and is the only Home Infusion Therapy Provider accredited by both URAC and ACHC. Filling more than 140,000 intrathecal prescriptions and serving more than 33,000 intrathecal patients annually, AIS is a leading national home infusion therapy provider of specialized, patient-specific specialty compounded drug products for patients across the country. Combined, our US pharmacies provide almost 200,000 prescriptions to approximately 60,000 intrathecal, IG and ophthalmology patients

[1] Final Standard MOU Addressing Certain Distributions of Compounded Human Drug Products - Not for Implementation (May 13, 2020), https://www.regulations.gov/document?D=FDA-2018-N-3065-0045.

[2] FDA will make the MOU available to the States for signature once the Office of Management and Budget clears the MOU pursuant to the Paperwork Reduction Act. *See* FDA, *FDA Announces Latest Step Toward Finalizing Memorandum of Understanding with States Addressing Compounded Drug Distribution, While Preserving Access* (May 28, 2020), https://www.fda.gov/news-events/fda-voices/fda-announces-latest-step-toward-finalizing-memorandum-understanding-states-addressing-compounded.

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in all 50 states. Our medications are compounded pursuant to patient-specific that exceed the quality standards set forth in United States Pharmacopeia Chapter <797>. AIS puts patients first and their well-being is at the heart of everything we do.

II. Interstate distribution under the MOU and the 5 percent limitation

Section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA") describes the conditions that must be met for drug products compounded by a licensed pharmacist in a state licensed pharmacy or federal facility, or by a licensed physician, to qualify for exemptions from three requirements of the FDCA: sections 501(a)(2)(B) (current good manufacturing practice), 502(f)(1) (labeling with adequate directions for use), and 505 (premarket approval). One of the conditions that must be met to qualify for the exemptions 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 an MOU, the licensed pharmacist, licensed pharmacy, or licensed 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.[3]

FDA addressed "inordinate amounts" in the final MOU (subsection 1) in a manner that would not impose a limitation on interstate distribution.[4] FDA adopted this approach in response to comments on an interpretation of "inordinate amounts" in an earlier MOU draft that would have limited interstate distribution of compounded drugs to 30 percent. In the final MOU, reaching "inordinate amounts," which FDA has defined to mean the distribution of more than 50 percent of a pharmacy's compounded drug products interstate, triggers certain state reporting obligations.[5] According to the FDCA, however, if a compounder is located in a state that has not entered into the MOU, it is bound by the 5 percent limitation on interstate distribution discussed in subsection (2).

If a state Board of Pharmacy enters into the MOU, it would agree to investigate and report to FDA certain adverse events and product quality concerns associated with compounded drug products that resident pharmacies distribute interstate. In addition, the Board would take certain steps to determine, on an annual basis, which pharmacies distribute "inordinate amounts"—defined in the MOU as more than 50

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[3] FDCA § 503A(b)(3)(B).

[4] MOU Part III.b

[5] *See* MOU note 8 ("The distribution of inordinate amounts of compounded human drug products interstate is a threshold for the [insert State Board of Pharmacy or other appropriate State agency] to identify and report certain information to FDA, not a limit on the distribution of compounded human drug products interstate.").

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percent—of its compounded drug products interstate. Upon identifying such a pharmacy, the Board would submit certain information to FDA, including: (a) total number of prescription orders for sterile compounded human drugs interstate; (b) names of states in which the pharmacy is licensed; (c) names of states into which the pharmacy distributed compounded human drug products; and (d) whether the state inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients. The MOU provides for a state to identify this information by any available mechanism, such as data submitted to an Information Sharing Network that is being developed by NABP in collaboration with FDA.[6]

It is noteworthy that the final MOU addresses a number of the comments that states submitted on their own behalf, or that the National Association of Boards of Pharmacy ("NABP") submitted based on feedback from the states. For example, in contrast to previous drafts, the final MOU imposes no obligation on the Texas Board of Pharmacy to determine if a physician distributes inordinate amounts of compounded drugs interstate or to collect information about such a physician. Instead, the Board would simply notify FDA if aware of a physician who engages in interstate distribution. Further, revisions reflected in the final MOU provide more flexibility on investigations and reporting of adverse drug experiences and product quality concerns. FDA increased the timeframe to report to FDA from three days to five days and indicated that states should investigate the complaints according to their own procedures, provided there is no conflict with the MOU.

FDA also adopted AIS's recommendation that the Agency provide a longer period for states to consider whether to sign the MOU before it begins to enforce the 5 percent limitation.[7] In materials accompanying drafts of the MOU, FDA had stated that it was considering a 180-day timeframe.[8] For the final MOU, it increased the timeframe to 365 days.[9] It is our understanding that FDA may consider extending the time period for another year; however, we ask that Texas help lead the way and sign now. We believe this would give certainty to patients, physicians and pharmacies.

III. Entering into the MOU is crucial for the viability of pharmacies in Texas and patient access to compounded drug products.

As stated above, if the Texas State Board of Pharmacy chooses not to enter into the MOU with FDA, pharmacies located in Texas will be subject to the FDCA's 5 percent interstate distribution limitation. FDA understands the 5 percent limitation to apply to all drug products that a pharmacy sends out of state, which, according to the Agency, must be based on the receipt of valid patient-specific

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[6] *FDA in Brief: FDA awards grant for information-sharing system and research of interstate distribution of compounded drugs, as part of agency's effort to help address risks with poor-quality compounded drugs* (Oct. 2, 2019), https://www.fda.gov/news-events/fda-brief/fda-brief-fda-awards-grant-information-sharing-system-and-research-interstate-distribution.

[7] Comment from AIS to Docket No. FDA-2018-N-3065, "Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the States and U.S. Food and Drug Administration; Revised Draft; Availability" (Aug. 8, 2019),

[8] 83 Fed. Reg. 45,632 (2018).

[9] 85 Fed. Red. 28,962 (2020).

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prescriptions.[10] The 5 percent limit would cripple the businesses of AIS and many other similarly situated specialty pharmacies. In doing so, it would have an adverse effect on patients and negatively impact the Texas economy.

AIS is first and foremost a home infusion pharmacy. Comments that the National Home Infusion Association ("NHIA") submitted to FDA's docket illustrate the adverse impact that the 5 percent limit would have for patients of specialty pharmacies such as ours. The comment explains that

> [m]any home infusion providers are located near state borders and fill prescriptions for individualized compounded drugs to patients who reside in a neighboring state. For these pharmacies, the provision of infusion therapy across state lines to individual patients has become routine practice. Patients with highly specialized therapies for rare disorders and patients in rural areas near state lines may not have access to an in-state home infusion provider who can meet their needs.[11]

Compounding pharmacies also produce specialty drugs for chemotherapy, ophthalmology, pain management, wound care, urological care, and more. Many of these pharmacies ship drugs to patients and providers throughout the country. The Alliance for Pharmacy Compounding and Letco Medical report that 88 percent of U.S. pharmacies operate under section 503A and nearly 5 percent operate both a 503A facility and outsourcing facility; of those, just under half—nearly 44 percent—are licensed to ship interstate.[12] Texas is home to AIS and possibly other pharmacies that provide home infusion or other specialty compounding services to patients in other states, often pursuant to longstanding patient, pharmacist, and provider relationships.

The COVID-19 outbreak has also illustrated the importance of unrestricted interstate distribution of compounded drug products. As an example, AIS has provided hospitals in other states with supplies of fentanyl needed to place COVID-19 patients on ventilators. Hospitals' supplies of fentanyl have been dwindling due to the surge of COVID-19 patients on ventilators.[13] If our pharmacy were restricted to 5 percent interstate distribution, we would not be able to supply the fentanyl to hospitals in other states as we have, despite the desperate, otherwise unfulfilled, need. New emergencies are most certain to occur in the future, making it crucial that compounding pharmacies stand ready and able to supply medically necessary compounded drugs nationwide.

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[10] *See* FDCA § 503A(a) (requiring that compounding occur after, or limited quantities before, the receipt of a valid prescription for an identified individual patient).

[11] Comment from NHIA to 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" (Dec. 10, 2018).

[12] Alliance for Pharmacy Compounding, *What is Compounding*, https://www.a4pc.org/APC/About/What-is-compounding-/APC/About/What-is-compounding-.aspx?hkey=3822cc79-8504-48c2-9579-2e9ff57a5c72 (last viewed May 27, 2020).

[13] NPR, *U.S. May Get More Ventilators But Run Out of Medicine for COVID-19 Patients* (Apr. 4, 2020), https://www.npr.org/2020/04/04/826961777/u-s-may-get-more-ventilators-but-run-out-of-medicine-for-covid-19-patients.

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Although secondary to the patient access and safety issues, it is also important to reflect on the adverse impact that a 5 percent limitation would have on businesses in Texas and the Texas economy. If compounding pharmacies that once engaged in a substantial amount of interstate business can no longer ship more than 5 percent of their drug products interstate, such a restriction may cause some pharmacies to shutter their doors permanently, thus eliminating supportive economic components of the Texas economy and curtailing patient access to needed and life-saving medications. Alternatively, pharmacies may have no choice but to relocate to other States that have entered into the MOU. Either pathway could result in a substantial decrease in jobs and revenue for Texas.

Finally, it is important to note that it may be challenging for pharmacies to register with FDA as an outsourcing facility to avoid the conditions in section 503A on interstate distribution. Outsourcing facilities can engage in multi-state distribution of unlimited quantities of compounded drug products, but a number of states do not allow resident outsourcing facilities to engage in patient-specific compounding or non-resident outsourcing facilities to dispense compounded drugs to patients in their states.

IV. Entering Into the Final MOU Would Facilitate Federal/State/Pharmacy Collaboration To Help Ensure Drugs Distributed Interstate Are Compounded Under High Quality Conditions

AIS prides itself on its measures to not just meet, but to exceed, drug production standards applicable to 503A pharmacies. Our company recognizes that many of the drug products that we produce, including pain medications for intrathecal administration, require the greatest assurance of sterility. It is our view that patients are most protected when FDA and the States collaborate to efficiently and effectively utilize their resources to engage in robust oversight of compounding pharmacies, particularly those that compound high risk products. The MOU is an important tool to help further that objective. When States identify resident compounding pharmacies that distribute the majority of their drug products interstate and inform FDA of those that ship large volumes of sterile drug products throughout the country, FDA can focus its inspectional resources on such entities to help ensure that they meet applicable quality standards. In addition, by investigating complaints associated with compounded drugs distributed interstate and reporting to FDA any that constitute serious adverse drug experiences or serious product quality concerns, FDA and the State can rapidly react to emerging issues before they cause serious harm.

V. Conclusion

We strongly encourage you to adopt the MOU so that compounding pharmacies in Texas, like AIS, will be able to continue to serve the patients who rely on them. In addition, we believe entering into the MOU would serve an important function in advancing what we believe is a shared mission by Texas, FDA, and compounding pharmacies like AIS—to provide patients with the high-quality compounded medications they need.

Sincerely,

Charles Bell

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President and Founder
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