



NABP

National Association of
Boards of Pharmacy

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Mount Prospect, IL 60056

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: December 13, 2018

RE: Comments to FDA from NABP on the Revised Draft Standard Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the States and US Food and Drug Administration

Attached please find NABP's comments to the US Food and Drug Administration (FDA) on its revised draft standard memorandum of understanding (MOU) entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the US Food and Drug Administration." As background, on September 10, 2018, FDA announced the availability of the revised draft standard memorandum of understanding for public comment. Special thanks for all the comments submitted within the limited timeframe. NABP included almost all of the comments provided by the member jurisdictions either in the body of the redlined MOU or cover memo document.

In summary, the attached redlined version of the MOU does the following:

- Identifies the state board of pharmacy as the contracting agency with FDA, as opposed to the State.
- Clarifies that the MOU addresses compounded *human* drug products.
- Clarifies that the use of the word "distribution" is separate and distinct from, and should not be used in relation to, the word "distribution" as it is used in Part H, Section 360(e)(e)(e) of the FD&C Act (pertaining to the definition of distribution as it applies to the pharmaceutical industry supply chain).
- Regarding the investigation of complaints related to compounded drug products distributed outside the state:
 - Adds the qualification that investigations will be performed pursuant to board investigatory policies and procedures, including those related to prioritizing complaints.
 - For drug products compounded by a physician and distributed outside the state, the original MOU requires the state (board) to report such complaints to the regulator of physician compounding (clarified to be the *state agency responsible for regulating the practice of medicine*) and to notify the FDA if such complaint involves a *serious adverse drug experience* or a *serious product quality issue*. As the board of pharmacy lacks jurisdiction to investigate such complaints, it will not be in a position to make such a determination, therefore, the text was edited to require the board to simply notify FDA of any such complaints.
 - Adds the requirement that the FDA notify the board of any action taken by FDA in response to complaints submitted, including the decision to not pursue further action.
 - Regarding submission of information to the FDA, clarifies that the board may not have the name and contact information of the complainant.
- Regarding the interstate distribution of inordinate amounts of compounded drug products:
 - Removes all references to drug products compounded by physicians.

- Identifies the circumstances under which a board will determine whether a pharmacy had distributed an inordinate amount of compounded drug products interstate:
 - When the board receives a complaint related to drug products compounded by a pharmacist and distributed outside the state by a pharmacy and the complaint is determined to be related to a serious adverse drug experience or serious product quality issue; or
 - During a regular inspection of a pharmacy that distributes compounded drug products interstate, and the board identifies a serious product quality issue with compounded drug products distributed interstate.
- Notes that the board may also use other mechanisms to identify compounding pharmacies that distribute inordinate amounts of compounded drug products interstate.
- Removes the requirement that boards collect information regarding the total number of prescription orders for sterile compounded drugs outside the state.

Additionally, the redlined MOU contains minor grammatical edits.

If you have any questions or comments, please contact execoffice@nabp.pharmacy. More information on this topic may be found at <https://www.federalregister.gov/documents/2018/09/10/2018-19461/memorandum-of-understanding-addressing-certain-distributions-of-compounded-drug-products-between-the>.

Attachments

cc: NABP Executive Committee



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TO: US Food and Drug Administration
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: December 10, 2018
RE: NABP Comments on the Revised Draft Standard Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the States and US Food and Drug Administration

The National Association of Boards of Pharmacy (NABP) appreciates the opportunity to submit comments concerning the “Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration” (MOU). NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health. Founded in 1904, NABP aims to ensure the public’s health and safety through its pharmacist license transfer and pharmacist competence assessment programs, as well as through its accreditation programs such as the Verified Internet Pharmacy Practice Sites®, Verified-Accredited Wholesale Distributors®, and DMEPOS.

In anticipation of submitting these comments and based upon input from its member boards of pharmacy, those responsible for the regulation of compounding, NABP developed a redlined version of the MOU and circulated it to the boards for their review and feedback. Approximately half of the US jurisdictions provided generally favorable feedback to the redlined version of the MOU. These jurisdictions also indicated that they may be able, and therefore are far more likely, to approve and sign an MOU similar to NABP’s redlined version rather than the MOU that was published in the Federal Register on September 10, 2018.

Distribution

NABP was informed by approximately twenty states that the MOU presented a serious conflict because of the use of the term “distribution.” These states maintain that the act of distribution does not include “dispensing,” nor should the use of the term “distribution” in the MOU be misconstrued to reference the act of “dispensing” or provide the FDA with regulatory authority over the act of “dispensing.”

NABP attempted to correct this conflict in the redlined version of the MOU circulated to the states by inserting a footnote into the redlined MOU:

“The definition of interstate ‘distribution’ in this MOU is separate and distinct from, and should not be used in relation to, the term ‘distribution’ as it is used in Part H, Section 360(e)(e)(e) of the FD&C

Act (pertaining to the definition of distribution as it applies to the pharmaceutical distribution supply chain).”

As one state specifically noted to NABP:

“ . . . The terms are universally understood to be mutually-exclusive, and they are defined as mutually-exclusive throughout State and Federal law and regulation, as well as NABP’s model guidance. Footnotes recognizing the error do nothing to correct it. Dispensing is not distribution and should not figure in assessments of interstate distribution.”

The FDA responded to this conflict in the Federal Register, Volume 83, No. 175 noting that “if we were to interpret the word ‘distribution’ to apply only if a drug is provided without a prescription, it would mean that drug products compounded under section 503A of the FD&C are excluded from regulation under the MOU . . .”

In responses to NABP, the aforementioned states believe that if the terminology is not corrected, the MOU is essentially null and void and has no application to pharmacies that compound products under section 503A of the Food, Drug and Cosmetic Act (FD&C Act). NABP understands the distinction between and the differences that exist in federal and state statutes and regulations with the two terms. NABP also acknowledges that the FDA’s interpretation of the term “distribution” is present throughout the DQSA and a foundational consideration. NABP is submitting the redlined version of the MOU with the language proposed to the states and alerting the FDA that the language will not ameliorate a significant number of states’ concerns. Further, based upon the input from a number of states, unless the language in the MOU is corrected, a number of state boards of pharmacy will not be able to or will refuse to sign the MOU.

Inordinate Amount Determination

Another area of note from the states are the provisions regarding the “Inordinate Amount Determination.” States’ comments included but were not limited to, requests that the information should be limited to sterile drug products, questions concerning if the appropriate determinants are used to calculate the percentage, whether a percentage and/or if 50% is the most appropriate measure, and the date selected for the annual report.

NABP’s Redlined MOU

The attached redlined version of the MOU does the following:

- Identifies the state board of pharmacy as the contracting agency with FDA, as opposed to the State.
- Clarifies that the MOU addresses compounded *human* drug products.
- Regarding the investigation of complaints related to compounded drug products distributed outside the state:
 - Adds the qualification that investigations will be performed pursuant to board investigatory policies and procedures, including those related to prioritizing complaints.
 - For drug products compounded by a physician and distributed outside the state, the original MOU requires the state (board) to report such complaints to the regulator of physician compounding (clarified to be the *state agency responsible for regulating the practice of medicine*) and to notify the FDA if such complaint involves a *serious*

adverse drug experience or a *serious product quality issue*. As the board of pharmacy lacks jurisdiction to investigate such complaints, it will not be in a position to make such a determination, therefore, the text was edited to require the board to simply notify FDA of any such complaints.

- Adds the requirement that the FDA notify the board of any action taken by FDA in response to complaints submitted, including the decision to not pursue further action.
- Regarding submission of information to the FDA, clarifies that the board may not have the name and contact information of the complainant.
- Regarding the interstate distribution of inordinate amounts of compounded drug products:
 - Removes all references to drug products compounded by physicians.
 - Identifies the circumstances under which a board will determine whether a pharmacy had distributed an inordinate amount of compounding drug products interstate:
 - When the board receives a complaint related to drug products compounded by a pharmacist and distributed outside the state by a pharmacy and the complaint is determined to be related to a serious adverse drug experience or serious product quality issue; or
 - During a regular inspection of a pharmacy that distributes compounded drug products interstate, and the board identifies a serious product quality issue with compounded drug products distributed interstate.
 - Notes that the board may also use other mechanisms to identify compounding pharmacies that distribute inordinate amounts of compounded drug products interstate.
 - Removes the requirement that boards collect information regarding the total number of prescription orders for sterile compounded drugs outside the state.

Additionally, the redlined MOU contains minor grammatical edits.

Thank you again for the opportunity to submit comments.

Attachment

cc: Executive Officers – State Boards of Pharmacy
NABP Executive Committee

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

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the ~~State of~~ [insert State] Board of Pharmacy (“Board”) and the U.S. Food and Drug Administration (FDA) regarding the interstate distribution¹ of inordinate amounts² of compounded human drug products ~~interstate~~ and the appropriate investigation by the Board State of [insert State] of complaints relating to human drug products compounded in such State and distributed outside such State. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities.

II. BACKGROUND

- a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist ~~or licensed physician~~ to be exempt from three sections of the FD&C Act requiring:
1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));
 2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and
 3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).

¹The definition of interstate distribution in this MOU is separate and distinct from, and should not be used in relation to, the term distribution as it is used in Part H Section 360(e)(e)(e) of the FD&C Act (pertaining to the definition of distribution as it applies to the pharmaceutical distribution supply chain). See Appendix A for the definition of interstate distribution.

²The 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. See Part III.b.1 of this MOU for the definition of inordinate amounts.

- b. To qualify for these exemptions, among other things, a compounded human drug product must meet the conditions in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:
1. Has entered into an MOU [developed in consultation with the National Association of Boards of Pharmacy (NABP)] with FDA that addresses the interstate distribution of inordinate amounts⁺ of compounded human drug products ~~interstate~~ and provides for appropriate investigation by ~~a State agency~~ the Board of complaints relating to compounded human drug products distributed by a licensed pharmacist or licensed pharmacy outside such State (section 503A(b)(3)(B)(i)); or
 2. Has not entered into an MOU with FDA and the licensed pharmacist, or licensed pharmacy, ~~or licensed physician~~ distributes (or causes to be distributed) compounded human drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy ~~or physician~~ (section 503A(b)(3)(B)(ii)).
- c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i). The content of this MOU conforms to the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

- a. Investigation of Complaints Relating to Compounded Drug Products Distributed Outside the State
1. ~~Appropriate agencies of the State of [insert State] Board~~ will investigate complaints of adverse drug experiences and product quality issues received relating to human drug products compounded by a pharmacist or pharmacy and delivered by interstate distribution, ~~and distributed outside the State by a pharmacy.~~ ~~Primary responsibility for investigating complaints involving drug products compounded by a pharmacist will generally lie with the [insert State Board of Pharmacy or other appropriate State agency].~~ Complaints relating to compounded drug products distributed outside the State that will be investigated include reports received by the State Board concerning adverse drug experiences ~~or product quality issues associated with drugs compounded by a pharmacist.~~ Any investigations will be performed pursuant to the Board's established investigatory policies and procedures, including those related to prioritizing complaints. See Appendix A for definitions of *adverse drug experiences* and *product quality issues*.
 2. Any investigations performed by the ~~State of [insert State] Board~~ under this MOU will include, but are not limited to, taking steps to

assess (1) whether there is a public health risk associated with the compounded human drug product; and (2) whether any public health risk associated with the product is adequately contained.

3. ~~Based on findings from an investigation of a complaint about drug products compounded by a pharmacist and distributed outside the State~~After the Board's investigation, if the complaint is ~~found to be valid~~substantiated, the ~~State of [insert State]~~ Board, in accordance with and as permitted by State law, will take the action that the State considers to be appropriate and warranted to ensure that the ~~relevant~~compounding pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the complaint, including the risk that future similar complaints may occur.
4. The Board will maintain records of the complaint, its investigation, and any response to or action taken as a result of the complaint, beginning when the State receives notice of the complaint. The Board will maintain these records for at least three (3) years. The three-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.
5. The ~~State of [insert State]~~ Board will, by email (to StateMOU@fda.hhs.gov), notify provide FDA ~~by sending an email to StateMOU@fda.hhs.gov~~ with the information described in section III.c.1.a of this MOU as soon as possible, but no later than 3 business days after receiving and assessing any a Section III.a.1 complaint ~~complaint relating to a drug product compounded by a pharmacist and distributed outside the State~~to involveing a serious adverse drug experience or serious product quality issue. After ~~this notification~~the Board concludes its investigation of a Section III.a.1 complaint assessed to involve a serious adverse drug experience or serious product quality issue, the ~~State~~ Board will share with FDA the results ~~of the investigation that it conducted as permitted by state law~~. See Appendix A for definitions of *serious adverse drug experience* and *serious product quality issue*.
6. If the ~~State of [insert State]~~ Board receives complaint involving an adverse experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State, the ~~State~~Board will notify the appropriate State agency responsible for regulating the practice of medicine, regulator of physician compounding within the State. ~~If the complaint involves a serious adverse drug experience or serious product quality issue,~~†The ~~State~~ Board will also notify FDA of the complaint by sending an email to StateMOU@fda.hhs.gov with the information in section III.c.1.a of this MOU as soon as possible, but no later than 5 business days, after receiving the complaint.
- 6.7. The FDA will notify the Board by email (insert state-specific email

address) of any action taken by the FDA in response to complaints submitted to the FDA by the Board, including the decision of the FDA not to pursue further action.

~~7. The State of [insert State] will maintain records of the complaint, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the State receives notice of the complaint. The State will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.~~

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

1. For purposes of this MOU, a pharmacy ~~or physician~~ has engaged in an inordinate amount of interstate distribution of distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products ~~distributed interstate~~ delivered by interstate distribution during any calendar month is greater than 50 percent of the number of prescription orders for compounded human drug products ~~distributed or dispensed both intrastate and interstate by such pharmacy or physician~~ delivered by intrastate distribution³ and interstate distribution during that same calendar month.
2. The Board will determine whether a pharmacy has engaged in an inordinate amount of interstate distribution of compounded human drug products in either of the following circumstances: (a) the Board receives a complaint as defined in Section III.a.1 and assesses the complaint to involve a serious adverse drug experience or a serious product quality issue under Section III.a.4; or (b) during a regular inspection of a pharmacy that distributes compounded human drug products interstate, the Board identifies a serious product quality issue with compounded human drug products distributed interstate by the pharmacy. In these circumstances, the Board will make the Section III.b.1 inordinate amount calculation for the calendar month in which it received the complaint or conducted the inspection. ~~On an annual basis (at minimum), the State of [insert State] will~~ The Board may also use other mechanisms to identify, using surveys, reviews of records during inspections, or other mechanisms available to the State, compounding pharmacies that distribute inordinate amounts of compounded drug products interstate, ~~by collecting information regarding the total number of prescription orders for compounded drug products~~

³The definition of *intrastate distribution* in this MOU is separate and distinct from, and should not be used in relation to, the term *distribution* as it is used in Part H Section 360(e)(e)(e) of the FD&C Act (pertaining to the definition of distribution as it applies to the pharmaceutical distribution supply chain). See Appendix A for the definition of *intrastate distribution*.

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

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

43. When acting under Section III.b.2, if the Board identifies a pharmacy that has delivered inordinate amounts of compounded human drug products by interstate distribution, it ~~For pharmacies or physicians that have been identified as distributing inordinate amounts of compounded drug products interstate, the State also will~~ also collect information regarding the total number of prescription orders for sterile compounded drugs distributed outside the State; ascertain the number ~~each~~ of States in which the compounding pharmacy or physician is licensed or number of States into which the compounding pharmacy or physician distributes compounded human drug products; and, as well as determine whether the State ~~inspected for and found during its most recent inspection that the compounding pharmacy or physician distributed compounded human drug products without valid prescription orders for individually identified patients.~~

54. The State Board will, within 30 days of identifying a pharmacy that has delivered inordinate amounts of compounded human drug products by interstate distribution, notify FDA, by email, (sending an email to StateMOU@fda.hhs.gov) within 30 days of identifying a pharmacy or physician within its jurisdiction that has distributed inordinate amounts of compounded drug products interstate and will include the information described in section III.c.1.b of this MOU.

c. Submission and Disclosure of Information

1. When submitting information to StateMOU@fda.hhs.gov under Section III.a.4 or Section III.b.2 regarding complaints relating to compounded drug products distributed outside the State or regarding distribution of inordinate amounts of drugs interstate determinations, the following minimum information will be included:

a. Complaints:

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

- ii. Name and address of the pharmacy/~~physician~~ that is the subject of the complaint;
- iii. Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;
- iv. ~~The State Board's initial~~ assessment of the validity of the complaint ~~relating to a compounded drug product distributed outside the State~~, if available; and
- v. Description ~~and date~~ of any actions the State Board has taken at the time of the submission to address the complaint.

b. Inordinate Amount Determinations:

- i. Name and address of the pharmacy/~~physician~~ that ~~distributed~~ delivered inordinate amounts of compounded human drug products ~~interstate~~ by interstate distribution;
- ii. The total number of prescription orders for compounded human drug products ~~distributed or dispensed~~ intrastate ~~delivered by intrastate distribution~~;
- iii. The total number of prescription orders for compounded human drug products ~~the pharmacy distributed~~ interstate ~~delivered by interstate distribution~~;
- ~~iv. The total number of prescription orders for sterile compounded drug products distributed interstate;~~
- ~~v.iv.~~ A list of States in which the ~~compounding~~ pharmacy ~~or physician~~ is licensed or into which the pharmacy ~~or physician~~ distributes compounded human drug products, and
- ~~v.v.~~ Whether the State Board ~~inspected for and found during its most recent inspection~~ determined that the ~~compounding~~ pharmacy ~~or physician~~ distributed compounded human drug products without valid prescription orders for individually identified patients.

2. On or about [pick a date] each year, the Board will submit to an annual report to FDA containing the following information:

a. A list of each pharmacy in the State that compounds human drug product and that is licensed in multiple states;

b. Each such pharmacy's self-report of the total number of compounded human drug product prescriptions delivered to patients the previous calendar year.

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

- Confidential commercial information, such as information that would be protected from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));
- Personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or
- Information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

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

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the ~~State of [insert State]~~ Board

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

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

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

~~[State] Board of Pharmacy~~
TBD

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

VI. PERIOD OF AGREEMENT

- a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 30-day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.
- b. If the ~~State Board~~ does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded drug products distributed outside the State, the MOU may be terminated upon 30-days' notice of termination.

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

VII. APPROVALS

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

Appendix A. Definition of Terms Used in the MOU

- **Adverse Drug Experience:** Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).
- **Interstate Distribution:** ~~*Distribution-Interstate distribution* means that a pharmacy or pharmacist has, pursuant to a patient-specific prescription order as required by section 503A(a) of the FD&C Act, compounded a human drug product and delivered it by any means to the patient, the patient's agent, or the patient's health care provider in another state. ~~compounder has sent a drug product out of the facility in which the drug was compounded. Such distribution may include, but is not limited to, delivery or shipment to a physician's office, hospital, or other health care setting for administration, and dispensing the drug product by sending it to a patient for the patient's own use.~~~~
- ~~Note: To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU will not alter this condition.~~
- **Intrastate Distribution.** ~~*Intrastate distribution* means that a pharmacy or pharmacist has, pursuant to a patient-specific prescription order as required by section 503A(a) of the FD&C Act, compounded a human drug product and delivered by any means to the patient, the patient's agent, or the patient's health care provider within the state in which the pharmacist or pharmacy is located.~~
- **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 (as defined above) occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result

in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

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