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Preparing for FDA's Compounding MOU

NABP Home Study Continuing Pharmacy Education Webinar

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About This Home Study Webinar

Food and Drug Administration's (FDA's) Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) on compounded human drug products can help reduce the risk of injury to patients by improving oversight of compounding pharmacies.

Related to Section 503A of the Federal Food, Drug, and Cosmetic Act, the MOU acts as an agreement between the state boards of pharmacy and FDA to collect information about the distribution of inordinate amounts of compounded human drugs, as well as complaints about compounders. The MOU better positions regulators to address patient safety and improve communication between FDA and boards.

At the end of this webinar, participants will be able to:

1. Summarize the evolution of FDA's data collection requirements under the MOU.
2. Define "inordinate amounts" of compounded human drug products.
3. Explain when boards must to report inordinate amounts to FDA as required by the MOU.
4. Describe the National Association of Boards of Pharmacy (NABP) Information Sharing Network.
5. Discuss how the NABP Information Sharing Network can streamline the data sharing process and help boards meet data reporting obligations.

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Financial Disclosures

Jack W. "Jay" Campbell IV declares that neither he nor any immediate family member has a current affiliation or financial arrangement with any organization that may have a direct interest in the subject matter of this continuing pharmacy education (CPE) activity.

Melissa Madigan declares that she has a current affiliation or financial relationship with an organization that may have a direct interest in the subject matter of this program as an employee of the National Association of Boards of Pharmacy (NABP).

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Preparing for FDA's Compounding MOU

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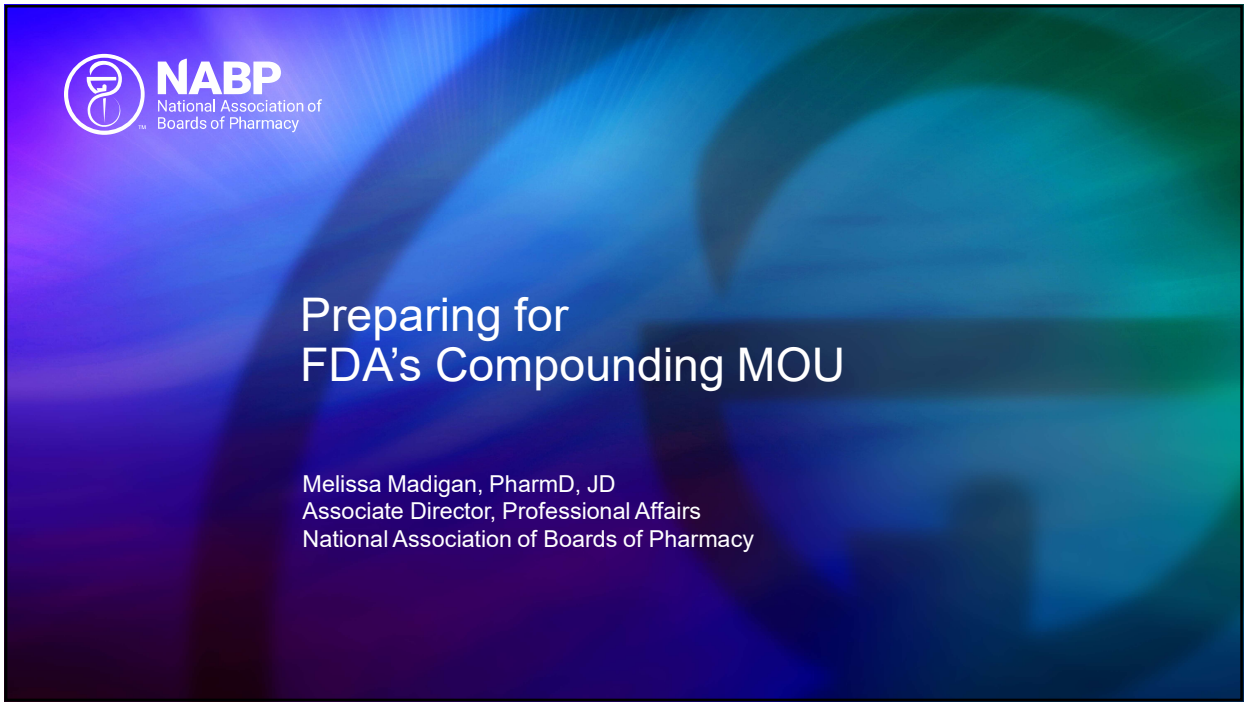

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FDA's Compounding MOU Raises Questions Among Boards of Pharmacy

The impending implementation of the Food and Drug Administration (FDA) "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products" (MOU) has introduced many questions among the state boards of pharmacy.

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Questions Include:

- When will the MOU be finalized?
- What obligations will it place on the boards of pharmacy?
- How will it impact state oversight of 503A pharmacies?
- What information will be required to collect and share?
- What IT and personnel resources will be needed?
- What mechanism will be used to collect, manage, and share information?
- When does a board need to share complaints regarding compounders with the FDA?
- Do "prescription orders" include new and refill prescription orders?
- What will FDA do with submitted information?
- What happens if a state doesn't comply with the MOU?
- Regarding submission of complaint information, should the board include protected health information (PHI), such as patient names or other identifiers? Or should PHI be redacted?

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What Information Must Boards of Pharmacy Flag for FDA?

- Certain compounding pharmacy data.
- Complaints about compounding pharmacies.
- Certain complaints about compounding physicians.
- Certain information about compounding physicians distributing interstate.

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What Information Must Boards of Pharmacy Flag for FDA? (cont.)

Per the MOU, boards must identify for FDA:

- Pharmacies that are compounding human drug products and distributing "inordinate amounts" interstate.*
- Complaints of serious adverse experiences or quality issues relating to human drug products compounded by pharmacies and distributed interstate.
- Complaints of adverse experiences or quality issues relating to human drug products compounded by a physician and distributed interstate.
- Information relating to the distribution interstate of any amount of compounded human drug products by physicians.

* The distribution of inordinate amounts 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 products interstate.

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Regarding Inordinate Amounts:

- Boards will determine if a pharmacy is compounding inordinate amounts using either:
  - surveys,
  - reviews of records during inspections,
  - information-sharing network (NABP's system), or
  - other available mechanisms.
- The MOU does not require the board to input compounding pharmacy data into the information-sharing network.
- The MOU allows the board to meet its obligation to determine compounding of inordinate amounts solely through use of the information-sharing network.

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NABP Develops System for Collecting and Sharing Information Specified in the MOU

- The information-sharing network is being developed using a grant provided by FDA to NABP.
  - Grant is for a pilot project to build a network and evaluate its accuracy and usefulness.
- FDA recognized there is no centralized system to collect and share data from compounding pharmacies distributing interstate, and thus the grant was established.
- FDA is eager to partner with NABP and boards to protect patients from high-risk compounders.
- FDA agrees the network will be a key to assisting boards in their efforts to comply with the MOU, understanding the lack of board resources.

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How Is NABP Building the New Information Sharing System?

- NABP is adapting its existing NABP e-Profile Connect data management system to meet the needs of the new information-sharing network.
  - To enable the collection, management, and sharing of information pertaining to compounders.
- NABP e-Profile Connect provides state boards of pharmacy with information on each individual pharmacist, technician, student/intern, and facility in the system.

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System Will Provide New Capabilities for Boards of Pharmacy

- Expands current NABP e-Profile Connect system.
- Adds data fields outlined in the MOU to the pharmacy facility profiles found in the NABP e-Profile Connect system.
- Allows boards and pharmacies to enter data.
- Boards will be able to review and annotate information provided by licensees and upload documents, including complaints and inspection forms.

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Implementation Begins With Pilot Project

- Development of the new information-sharing network began in June 2020 as part of the three-year pilot project.
- Implementation of the network is expected to begin in early 2021 with the collection of information from compounding pharmacies.
- Boards of pharmacy will have access to this information and the ability to supplement it soon after pharmacies can begin inputting data.
- At the conclusion of the pilot project, NABP will evaluate the usability of the network and the accuracy of the information collected during the pilot and present a final analysis to FDA.

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System Will Identify Certain Data for FDA

- The system will notify boards about pharmacies whose submitted data show that they are distributing inordinate amounts of compounded human drugs interstate.
- The system will require boards of pharmacy to approve the submission of such data to FDA prior to it being transmitted.

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What Information Will Be Collected From Pharmacies?

Regarding the distribution or dispensing of compounded human drug products, the system will collect the following information from the pharmacy:

- Name and address of state-licensed entity
- Whether the pharmacy participates in the following activities during an identified calendar year:
  - Human drug compounding – sterile
  - Human drug compounding – nonsterile
  - Patient-specific compounding
  - Non-patient-specific compounding

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If a Pharmacy Is Compounding Sterile or Nonsterile Human Drug Products, the Following Information Will Also Be Collected or Calculated:

- Number of prescription orders for compounded drugs the pharmacy sent out.
- Number of prescription orders for compounded drugs dispensed at the facility.
- Total number of prescription orders for compounded drugs sent out or dispensed at the facility.*
- Total number of prescription orders for compounded drugs distributed interstate.
- Percentage of compounded drugs distributed interstate.*

* Calculated by the system.

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Also to Be Collected:

- Number of prescription orders for sterile compounded drugs distributed interstate.
- Names of states in which pharmacy is licensed.
- Names of states into which pharmacy distributed compounded drugs during the year.
- Whether compounded drugs are distributed without patient-specific prescriptions.

If the board has the compounding pharmacy data referenced here, the board will be able enter it into the facility's e-profile.

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Notifying FDA of Inordinate Amounts

Within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drugs interstate during the identified calendar year, and upon approval by the board, the system will provide FDA with the following information about such pharmacies:

1. Name and address of the pharmacy.
2. The number of prescription orders for compounded human drugs that the pharmacy sent out of (or caused to be sent out of) the facility in which the drugs were compounded.
3. The number of prescription orders for compounded human drugs that were dispensed (eg, picked up by the patient) at the facility in which they were compounded.

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Notifying FDA of Inordinate Amounts (cont.)

4. The total number of prescription orders for compounded human drugs distributed interstate.
5. The total number of prescription orders for sterile compounded human drugs distributed interstate.
6. The names of the states in which the pharmacy is licensed.
7. The names of the states in which the pharmacy distributed compounded human drugs.
8. Whether the board inspected for and found during its most recent inspection that the pharmacy distributed compounded human drugs without valid prescription orders for individually identified patients.

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Notifying FDA of Pharmacy Complaints

Regarding complaints involving a serious adverse drug experience or serious product quality issue related to human drug products compounded by a pharmacy and distributed outside the state, the board will enter into the system:

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

The board will also be able to upload a copy of the complaint or other relevant documents.

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Notifying FDA of Pharmacy Complaints (cont.)

Transmission of complaint information from system to FDA:

- As soon as possible after, but no later than five business days after, receiving the complaint and, upon approval by the board, the system will provide FDA with the information found in items 1 – 3.
- After the board concludes its investigation of the compliant, and upon approval by the board, the system will provide FDA with the information found in items 4 – 5.

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Notifying FDA of Complaints and Notifications About Physicians

Regarding complaints involving an adverse drug experience or product quality issue related 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, the board will enter into the system:

1. Name and contact information of the complainant or notifier.
2. Name and address of the physician who is the subject of the complaint or notification.
3. 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.

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Notifying FDA of Complaints and Notifications About Physicians (cont.)

Transmission of physician complaint information from system to FDA:

- Regarding complaints against physicians, as soon as possible but no later than five business days after receiving the complaint, and, upon approval by the board, the system will transmit such complaint to FDA. In addition, the board must notify the state regulator of physicians.

Transmission of physician notification information from system to FDA:

- Regarding the distribution of any amount of compounded products interstate by a physician, within 30 business days of identification of such physician and upon approval by the board, the system will transmit this information to FDA. In addition, the board must notify the state regulator of physicians.

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Collection of Data From Pharmacies Will Be Through Two Pathways

1. Requesting compounding data through any application for one of the National Association of Boards of Pharmacy® (NABP®) pharmacy accreditation programs, **except** for the DMEPOS Pharmacy Accreditation program, or through the Verified Pharmacy Program® (VPP®) inspection application. The pharmacy will pay the regular accreditation or inspection application fee.
2. The data fields will be available through the pharmacy's NABP e-profile. The pharmacy will set up an NABP e-profile or access its already-established NABP e-profile, then insert the data. There is no charge for this.

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How Will NABP Encourage Pharmacies to Volunteer Requested Information?

- All pharmacies seeking accreditation will voluntarily submit the requested information – regardless of whether their primary intent is to participate in the pilot project.
- Compounding pharmacies can enter the requested information outside of the accreditation application process.
- All pharmacies submitting the requested data will have the opportunity to receive a VPP inspection at no cost to them.

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How Will the System Meet the Goal of Improving Compounding Pharmacy Oversight?

- Enable the collection, management, and sharing of information regarding compounding pharmacies in the United States.
- Provide boards of pharmacy with a tool to report compounding pharmacy information to FDA, giving access to data that will inform oversight determinations.
- Enable boards of pharmacy to better prioritize their resources to address compounding pharmacies that pose the highest risk to patients.
- Foster better, more targeted oversight of compounding pharmacies.

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Project Provides Transparency to Support Data-Driven Policy Decisions

- Boards of pharmacy and FDA will gain a better understanding of the interstate distribution of compounded drugs, including significant compliance issues.
- Boards of pharmacy and FDA will be better positioned to advance public health protections associated with compounded drugs.
- Boards of pharmacy will gain an ongoing means of reporting information relating to compounding pharmacies to FDA.
- FDA will gain improved visibility to determine whether additional federal oversight is warranted.

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Feedback From Boards Has Been Positive

- Vast majority of boards are in the process of determining whether to sign the MOU.
- Several boards have said they will surely sign the MOU.
- Some boards have said they do currently require or are considering requiring pharmacies to report data to the system.
- Very few have said they will not sign the MOU.
- NABP is in conversations with several boards about sharing compounding pharmacy data they already collect.

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Informational Resources

NABP's new website has a page dedicated to this project:

- Background and details on the project.
- Link to MOU.
- FAQs.
- Slide deck.

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Thank You!

Questions? Contact
help@nabp.pharmacy

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