Commission SBAR Communication

Agenda Item/Title: FDA Memorandum of Understanding Update

Date SBAR Communication Prepared: May 27, 2021

Reviewer: Lauren Lyles-Stolz, PharmD, Executive Director

Link to Action Plan:

☒ **Action** ☐ **Information** ☒ **Follow-up** ☐ **Report only**

Situation: (Briefly describe the current situation. Give a clear, succinct overview of pertinent issues)

The commission should decide whether to approve, reject, or continue to evaluate next steps regarding the FDA's Memorandum of Understanding (MOU). The commission has until October 27th, 2021 before the FDA limits interstate distribution of compounded human drug products to 5 percent of the total prescription orders dispensed or distributed by a pharmacy. If the FDA MOU is signed then this limit is not applicable.

Commission staff distributed a survey to compounding pharmacies in Washington State to assess the perceived impact.

Background: (Briefly state the pertinent history):

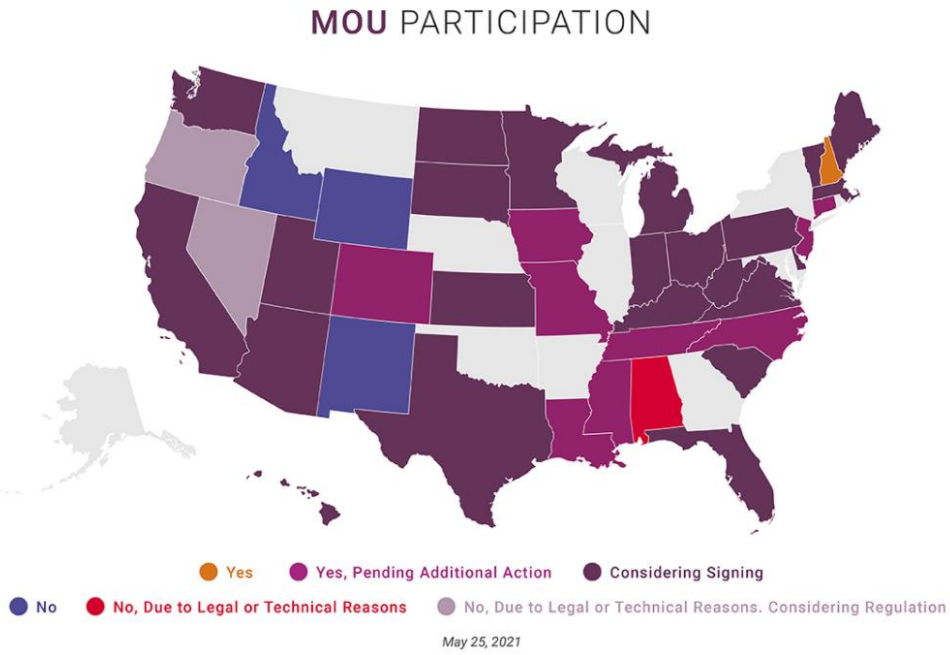
While the commission has several rules in place to ensure the safety of compounded drug products (see WAC 246-945-100, WAC 246-945-410, WAC 246-945-490, and RCW 18.64.270), compounded drug products are not approved by the FDA for quality and safety. As such, the FDA issues an MOU as an agreement which states may enter regarding the distribution of inordinate amounts of compounded human drug products and the investigation of complaints related to human compounded drug products. As described in the Federal Food, Drug, and Cosmetic Act, the FDA works with the National Association of Boards of Pharmacy (NABP) in developing the MOU. The MOU 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" (MOU, Sec. I).

The FDA defines "inordinate amounts" 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" (MOU, Appendix A).

Further, the FDA clarifies that "interstate distribution" 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" (MOU, Appendix A).

In a more recent letter from NABP as well as discussed during this year's annual conference, NABP is also requesting that FDA delay enforcement of Section 503A(b)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act. According to NABP, they anticipate that an enforcement delay will give many states the time needed to take the necessary actions to sign the MOU. Additionally, they noted that some boards also cited 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 these legislatures are placing a great deal of focus on COVID-19-related legislation. In addition, states where legislatures only meet biennially (e.g., Montana, Nevada, North Dakota, Texas) may not have appropriate changes in place until 2022 or even 2023.

While NABP is waiting on a response from the FDA, they continue to work on developing the Information Sharing Network in order to onboard states that have decided to sign the MOU. They also have a map available on their website where you can view the status of other states' current thinking of signing the FDA MOU. Currently, 10 states have stated they are signing or signed the FDA MOU while 22 are still considering signing (including WA). Four states have stated they are not signing the FDA MOU and there is currently no data available for the other states.



There are several considerations for the commission to consider regarding the MOU. Rejecting to adopt the MOU would limit interstate distribution of compounded drug products to 5 percent of the total prescription orders dispensed or distributed by a

compounding pharmacy (MOU, Sec. II.b.2). Limiting distribution may come with operational costs and barriers to pharmacies for the commission to consider.

Assessment: (Summarize the facts and give your best assessment. What is going on? Use your best judgment)

Commission staff distributed a survey (see SBAR Appendix 1) to compounding pharmacies in Washington to assess the perceived impact of not signing the FDA MOU. Out of the 116 respondents who completed the survey in total, 75 reported that they were affiliated with 503A compounding facilities that also distribute compounded drug products outside of Washington State. The below table shows the results based on those 75 respondents. Based on the FDA MOU Survey results, 98.3% of compounding pharmacies (59 out of 60 respondents) that distribute 5% or more human compounded drug products reported that not signing the FDA MOU would have a negative impact on patient care and their pharmacy practice. Respondents also provided comments for the commission to consider elaborating on their responses (see SBAR Appendix 2, Appendix 3). Notably, 100% of respondents who reported distributing more than 50% human compounded drug products stated not signing would have a negative impact. Only 33.3% of those who reported distributing less than 5% felt that not signing the FDA MOU would result in a negative impact.

Table: Perceived Impact of Not Signing FDA MOU on Compounding Pharmacies in WA

Percent Compounded Product Dist. Outside WA	Number Who Responded "Yes" to Negative Impact	Total in Subgroups	Percentage in Subgroups Who Responded "Yes" to Negative Impact
<5% Distributed	5	15	33.3%
5-50% Distributed	48	49	98%
>50% Distributed	11	11	100%
Grand Total	***64***	***75***	***85.3%***

Note: Table only includes those who are affiliated with a 503A compounding facility that distribute product outside of WA State

Recommendation: (What actions are you asking the commission to take? What do you want to happen next?

After discussing the MOU, the commission may choose to adopt the following options in part or in whole. It is recommended that the commission come to a decision within 365 days of the MOU's publication.

OPTION 1: Approve the MOU.

OPTION 2: Reject the MOU. This determination would limit interstate distribution of compounded drug products to 5 percent of the total prescription orders dispensed or distributed by a pharmacy.

OPTION 3: The commission can direct PQAC staff to write to the FDA requesting delayed enforcement of Section 503A(b)(3)(B)(ii) of the Federal Food, Drug, and Cosmetic Act until more states are able to establish a pragmatic path forward (e.g., rulemaking, guidance, etc.) to uphold the FDA MOU.

Follow-up Action: (Next Steps After the meeting – Document the commission's decision and/or any additional steps or follow-up requested; such as, report back in 6-months, etc.).

Depending on the options identified above, the PQAC team will proceed as directed and communicate to licensees through GovDelivery.

FDA MOU Survey Questions

Question 1: Does your pharmacy provide compounded medications?

Yes
No

Question 2: How would you classify your type of compounding pharmacy? See FD&C Act Provisions that Apply to Human Drug Compounding for examples.

503A, patient prescription specific compounding
503B, FDA registered outsourcing pharmacy

Question 3: Do you dispense or distribute human compounded prescription medications interstate or outside of Washington State?

Yes

No

Question 4: What percentage of compounded human drug products does your pharmacy distribute to patients outside of Washington State? The percentage should be based on total prescription orders.

<5%
5-50%
>50%

Question 5: If PQAC does not enter into an MOU with FDA, this would limit interstate or out-of-state distribution of compounded human drug products to a maximum of 5% of the total prescription orders dispensed or distributed by a compounding pharmacy. Would this negatively impact patient care and your pharmacy practice?

Yes (Please explain in the space provided below)

No

Question 6: Please add additional concise comments that the commission should consider before determining to sign or not sign the FDA MOU. (Comment shouldn't exceed one paragraph).

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Agenda Item/Title: **Suspicious Orders and Zero Reports**

Date SBAR Communication Prepared: **05/26/2021**

Reviewer: **Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission**

Link to Action Plan:

☒ **Action** ☒ **Information** ☐ **Follow-up** ☐ **Report only**

Situation: (Briefly describe the current situation. Give a clear, succinct overview of pertinent issues)

Pharmacy Quality Assurance Commission (commission) staff have encountered operational challenges related to zero order reporting under WAC 246-945-585 Wholesaler – Suspicious orders and due diligence, specifically as it relates to compliance tracking.

As stated in WAC 246-945-585(1), wholesalers shall design and operate a system to identify and report suspicious orders of controlled substances and drugs of concern to the commission.

The commission can consider modifications to the rule to mitigate operational challenges encountered by staff. In addition, if the commission considers rulemaking, staff have identified other potential technical fixes to also consider.

Background: (Briefly state the pertinent history):

The requirement for wholesalers to report suspicious orders of controlled substances or drugs of concern is new in chapter 246-945 WAC. Previous WAC only required reporting on precursor substances. The requirements in WAC 246-945-585 were developed from work done with the Office of the Attorney General as requested by the Washington State Opioid Response Workgroup.

WAC 246-945-585 both requires that wholesalers report suspicious orders to the commission as well as engage in due diligence to identify customers who might be diverting controlled substances or drugs of concern. The language in WAC 246-945-585 mirrors what is in the NABP's Model State Pharmacy Act and Model Rules. The reports that must be submitted to the commission are suspicious orders within 5 business days of identification (WAC 246-945-585(1)(a)) or "zero" reports when no suspicious orders have been identified (WAC 246-945-585(1)(b)). Zero reports must be submitted within 15 business days after the end of the calendar month. If wholesalers do not distribute controlled substances or drugs of concern (WAC 246-945-585(1)(c)), they may apply for an exemption from reporting. Additionally, wholesalers are required to electronically report any customer that is believed to be engaged in diversion, including those that they refuse to sell to, within 30 days of the refusal, cessation, or identification (WAC 246-945-585(5)).

Assessment: (Summarize the facts and give your best assessment. What is going on? Use your best judgment)

The requirement for wholesalers to electronically report suspicious orders and zero reports went into effect on July 1st, 2020. However, the commission exercised enforcement discretion to not find licensees deficient for failure to comply through May 31, 2021.

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Staff have been working through the implementation of a suspicious order and zero order process and system to ensure compliance to the new rules. While there is now a process for submitting the suspicious orders to Health Systems Quality Assurance Complaint Intake, the monitoring and tracking of licensees submitting zero reports (meaning without a suspicious order activity) has presented operational challenges.

There are currently over 1,300 licensed wholesalers in Washington, meaning there will be a high volume of monthly zero reports for commission staff to process. An internal survey program has been identified and a questionnaire developed for the monthly zero reports. However, the operational process to cross-reference each wholesaler submitting one of the required monthly reports (suspicious or zero) will require labor-intensive tracking. Additionally, an email address is required to utilize the above-referenced computer program tracking the wholesalers that have not completed the zero order questionnaire. Currently, there are approximately 500 licensees without an email address on file. (Providing an email address is voluntary and not mandated.) In addition, the survey program does not automatically synchronize with the department's internal licensing and regulatory database.
While there is a transition from the current licensing and regulatory database (ILRS) to a new modernized, efficient system (HELMS), it is unknown at this time if the new system will be better equipped to accommodate the zero/suspicious order report compliance tracking. PQAC staff are already in discussion with the HELMS implementation team to determine the feasibility of tracking through HELMS, but the target implementation date for HELMS is approximately July of 2022.

If the commission authorizes rulemaking to address identified limitations, there are also potential technical revisions to WAC 246-945-585 to consider.

Recommendation: (What actions are you asking the commission to take? What do you want to happen next?

OPTION #1 – ZERO REPORT TECHNICAL LANGUAGE RULE REVISIONS (revisions in red font):

The commission can consider the following all or in part:

- Suspicious orders will be sent to HSQA complaint intake at hsqacomplaintintake@doh.wa.gov (i.e. no change to the suspicious order requirement)
- Amend WAC 246-945-585 through rulemaking. Subsection (1)(b) could be modified to require a wholesaler to complete a zero report each month and store it in a readily retrievable manner subject to the records retention provision in WAC 246-045-020 (rather than submitted monthly to PQAC). Possible language for Subsection(1)(b) is as follows:
  - Zero reports shall be ~~submitted~~ completed and retained in accordance with WAC 246-945-020 if no suspicious orders have been identified in a calendar month. These reports shall be ~~submitted~~ completed within fifteen business days of the end of the calendar month.
- Potential technical edits to the language are as follows:
  - 246-945-585(5)(c) Customer DEA registration number if applicable.
  - 246-945-585(6) All licensed wholesalers ~~shall~~ may submit all reports to the commission in a DEA ARCOS format where applicable.
- Enforcement Discretion for submission of zero reports for 12 months (June 1, 2022) or until the rulemaking is complete.

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OPTION #2 – CONTINUE COLLECTION OF ZERO REPORTS AND SUSPCIOUS ORDERS (**NO** COMPLIANCE TRACKING)

- Edits to technical language as referenced in option #1.
- Suspicious orders will be sent to HSQA complaint intake at hsqacomplaintintake@doh.wa.gov (i.e. no change to the suspicious order reporting requirement).
- The link to the zero report questionnaire will be posted on a GovDelivery each month for wholesalers who are not exempt to complete (link and instructions on website as well).
- A GovDelivery will be posted on the 10th of the month reminding wholesalers to complete questionnaire if they have not done so.
- The zero report questionnaire has a field to enter an email address which will assist in potential future compliance tracking utilizing the current system (approximately 500 wholesalers are in PQAC's internal licensee system with no email address on file).
- PQAC Program Manager Joanne Miller will work with the credentialing department to include information needed to ensure tracking (email address to send zero report reminders and link) and add zero report questionnaire information on renewal notices for September 30, 2021.
- Continue to investigate the capabilities of the new licensing and regulatory database (HELMS). This will be a future option as the HELMS implementation is projected to "go live" in approximately July of 2022.

Follow-up Action:

If option #1 is selected, the PQAC team will draft a guidance document or policy statement outlining the enforcement discretion and projected timeline. This document will be sent as a communication through GovDelivery.

If option #1 is selected, the PQAC team will create a template document which may be used to assist wholesalers in the tracking of zero order reporting. Staff will also initiate rulemaking if authorized.