FDA MOU Survey Discussion and Next Steps

Survey Results

On March 18, 2021, the Board issued a quick 5-question survey to all in-state pharmacists and pharmacies to assess the impact of signing the FDA Compounding MOU. The survey closed on April 5, 2021 and received 38 responses.

1. What classification best describes your pharmacy?

Respondent Type	Number of Responses
Independent outpatient pharmacy (1 store)	22
Institutional pharmacy (hospital, LTC, etc.)	5
Small chain pharmacy (2-11 stores)	8
Other (2 specialty pharmacies and 1 anonymous)	3

NOTE: No large chains responded to the survey.

2. What type of compounded human drug products do you distribute?

Type of Drugs Compounded	Number of Responses
Both	9
N/A - We do not distribute compounded drug products*	2
Non-sterile compounded products	23
Sterile compounded products	4

****The two respondents that do not compound drugs did not have an opinion on whether to sign the MOU.***

3. Do you distribute compounded human drug products outside of this state? If yes, indicate how many states. If no, select N/A.

Number of States	Number of Responses
1-10	10
10-20	1
20-30	1
40+	3
N/A - We do not distribute compounded drugs outside of this state	23

4. Do you distribute more than 50% of your compounded human drug prescriptions outside of Ohio?

Response	Number of Responses
No	18
Yes	3
N/A – We do not distribute compounded drugs outside of this state	17

5. Should the State of Ohio Board of Pharmacy sign the FDA Compounding MOU?

Response	Number of Responses
No	3
Yes	12
No opinion at this time	23

Next Steps: Rules for Public Comment

Rule 4729:7-1-02 – Distribution of Compounded Human Drug Products Interstate, Memorandum of Understanding (NEW)

(A) As used in this rule:

(1) "Distribution of compounded human drug products interstate" means that a pharmacy or prescriber has sent (or caused to be sent) a compounded drug product out of the state in which the drug was compounded.

(2) "Information sharing network" means an information sharing network designated by United States food and drug administration and the state board of pharmacy for purposes of collecting, assessing, and allowing review and sharing of information pursuant to the memorandum of understanding.

(3) "Inordinate amounts" means 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 fifty percent of the sum of:

(a) 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

(b) 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.

(4) "Memorandum of understanding" or "MOU" means the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) (effective 11/27/2013). The MOU does not apply to:

(a) Veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262); and

(b) Drugs that are compounded by outsourcing facilities licensed in accordance with division 4729:6 of the Administrative Code.

(B) On an annual basis, a pharmacy located in this state shall report to the board, using an information sharing network, that the licensee distributes inordinate amounts of compounded human drug products interstate.

(C) For in-state pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the in-state pharmacy shall be required to report the following information using an information sharing network approved by the board:

(1) Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;

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

(4) The names of states in which the pharmacy is licensed; and

(5) The names of states into which the pharmacy distributed compounded human drug products.

(D) Upon renewal of a terminal distributor of dangerous drugs licensed in accordance with chapter 4729:5-2 of the Administrative Code, a prescriber located in this state shall report to the board, using an information sharing network, that the licensee distributed in the past twenty-four months or currently distributes compounded human drug products interstate.

(E) Unless otherwise approved by the Board or the Board's executive director, a terminal distributor shall have sixty days following notification by the board to comply with the reporting requirements listed in paragraphs (B) and (C) of this rule.

(F) All information reported to the information sharing network is being conducted in accordance with division (K) of section 4729.54 of the Revised Code.

Rule 4729:7-3-07 – Reporting of Product Quality Issues (NEW)

(A) A prescriber who engages in drug compounding that is licensed as a terminal distributor of dangerous drugs shall report to the state board of pharmacy within seventy-two hours upon discovery, and in a manner determined by the board, any product quality issue attributed to a compounded drug preparation personally furnished by the prescriber.

(1) As used in this paragraph, a product quality issue means any of the following:

(a) Any incident that causes the compounded drug preparation or its labeling to be mistaken for, or applied to, another article;

(b) Contamination of the compounded drug preparation, including but not limited to mold, fungal, bacterial, or particulate contamination; or

(c) Any significant chemical, physical, or other change or deterioration of the personally furnished compounded drug preparation within the compounded drug preparation's assigned beyond-use date.

(2) A product quality issue does not include an isolated allergic reaction to a substance included in a compounded drug preparation.

(B) A prescriber licensed as a terminal distributor of dangerous drugs shall report to the state board of pharmacy within seventy-two hours of issuance or receipt, and in a manner determined by the board, any warning letters, injunctions, or decrees issued in relation to the prescriber by the United States food and drug administration.