

OMB Control No. 0910-0697
Expiration date: 12/31/2020

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Hi Board of Medicine Directors,

It was a pleasure speaking with you on November 1, 2018. During the end of my presentation, I asked a number of questions of you. I would like to follow up and seek some feedback from you.

1. Under your state information sharing laws, do you have the authority and ability to protect non-public information¹ we share with you? In particular, can you protect information that would lead to the identity of the person who voluntarily submitted an adverse event report or product complaint to FDA (e.g., patient, compounder), or the identity of other persons identified in the report or complaint (e.g., healthcare provider)?
2. If your answer to question 1 is yes,
 - a. Can the state medical board² follow up on AE reports and quality complaints without disclosing information to a third party (e.g., a compounder or healthcare provider) that would identify the person who submitted the report or complaint to FDA, or the identity of other persons identified in the report or complaint?
 - i. In addition to a person's name, address, or institution, consider the possibility that other information contained in the report or complaint -- e.g., the date of treatment, the patient's age or description, or other circumstances relating to their treatment -- would lead to the identity of the voluntary reporter or other person.
 - b. To the extent that the answer to question 2.a. is "no", is it useful for the state medical board to get adverse event reports or complaints that include protected information on condition that the state will obtain written consent, as appropriate,

¹ Non-public information includes information that the FDA may not publicly disclose under federal law, and generally includes confidential commercial information and personal information whose disclosure would constitute a clearly unwarranted invasion of personal privacy. NPI also includes confidential predecisional information that the FDA has not released to the public.

² This term generally refers to the state entity that regulates and oversees the licensing of physicians.

before publicly disclosing the identity of a patient, voluntary reporter, or other person named in the report?

- c. Can the state follow up if it is not able to disclose information to third parties that would identify the healthcare provider who submitted an AE report/quality complaint or the compounder that submitted a report/complaint?
3. Regardless of your answer to question 2, is it useful for the state medical board to get adverse event reports or product quality complaints if we provide only publicly available information?
 - a. FDA generally would redact information that would lead to the identity of a patient or voluntary reporter, or of others identified in the report or complaint. If the report was voluntarily submitted to FDA by a compounder, we would generally redact the name of that person or business.
 4. Do you routinely work with the Board of Pharmacy in your state?
 5. Are there other agencies that you work with regarding compounded drug products within your state that would benefit from entering into a 20.88 agreement?
 6. Other comments or concerns?

If there are any questions, please contact Sara Ashton at Sara.Ashton@fda.hhs.gov or 202-308-4098.