



June 5, 2020

Mr. Russel Vought
Director
Office of Management and Budget (OMB)
725 17th Street, NW
Washington, DC 20503

[Submitted electronically to www.reginfo.gov/public/do/PRAMain]

RE: OMB Control Number 0910-0800 (Docket No. FDA-2018-N-3065)

Dear Director Vought:

The undersigned organizations represent thousands of pharmacy compounding professionals who continue to have serious concerns with the Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the [insert State] Board of Pharmacy and the U.S. Food and Drug Administration ("the MOU"). We write to you today regarding the FDA's recent submission of the MOU to OMB for review under the Paperwork Reduction Act of 1995 (PRA).

Three of our organizations (APhA, APC *formerly* IACP, and NCPA) each commented separately on our substantive concerns about the various draft versions of the MOU and have commented jointly in July of 2019 on the most recent draft MOU that was released in September of 2018. The comments of our individual organizations to the September 2018 draft MOU, as well as the joint comment our organizations submitted to that draft are included here for your review.

The final MOU includes a few recommendations from our organizations in relation to the requirements on states (e.g., increasing the reporting threshold from 30% to 50%). However, as you will see, the main substantive concern our organizations and many other stakeholders have is that the previous draft MOU, as well as the final MOU now before you, redefine the key statutory term "distribution" to include the patient-specific "dispensing" of compounded drugs in a way that is inconsistent with the statutory language of Section 503A of the Food, Drug and Cosmetic Act (FDCA) and that will lead to serious access problems for patients who rely on out-of-state pharmacies for their compounded medications.

Today, we write to you to express concern with the fact that FDA's analysis supporting the proposed information collection burden for the final MOU was inadequate to meet the requirements of the Paperwork Reduction Act and should therefore be rejected by OMB and sent back to FDA.

The main purpose of FDA's information collection estimate associated with the MOU was to determine the level of information collection burden on state boards of pharmacy and other state regulatory agencies that would result from the MOU's requirements for investigation, reporting and recordkeeping of adverse event reports involving pharmacies shipping compounded drugs interstate. This information is critical in the context of this particular MOU because the level of burden the MOU's requirements place on states relates directly to the number of states that will sign the MOU. States that sign the MOU will be required to finance the additional staffing needed to gather intrastate and interstate dispensing and distribution data from all compounding pharmacies in their state and evaluate that data to determine which pharmacies trigger the MOU's reporting requirements. States that sign the MOU will further be required to investigate adverse event reports, report data to the FDA, and maintain records. Pharmacies in states that are unable or unwilling to sign the MOU are statutorily prohibited from "distributing" more than five percent of their compounded drugs interstate. Because FDA has redefined the key term "distribution" to include traditional patient-specific "dispensing" of compounded drugs, patients who rely on out-of-state pharmacies in states that do not sign the MOU will see their access to the compounded medications they need greatly restricted. Therefore, it is critical that that FDA conduct a thorough, transparent and accurate assessment of the collection of information to ascertain the true burden of the MOU on each individual state, as well as a detailed and complete assessment of the likelihood that each individual state will sign.

In the MOU the FDA directs states to use "surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available" to determine which pharmacies in their state have distributed more than 50 percent of their compounded drugs out of state. For purposes of their proposed information collection for OMB review, it appears FDA did not survey the individual state boards of pharmacy and other state regulatory agencies that will be impacted by the MOU, but rather, chose to use anecdotal evidence gleaned from the public comments to establish hypothetical averages of the numbers of adverse event reports states will receive and the resulting reporting and recordkeeping manpower burden on the states. Our organizations have confirmed the National Association of Boards of Pharmacy (NABP) is currently in the process of surveying member Boards on the MOU with initial results expected in mid-June. At a minimum, FDA should wait to include this data in any reformulated final MOU. In addition, FDA's proposed information collection does not adequately consider the substantial manpower and resources of the MOU's inspection requirements on the states.

From this incomplete information collection estimate, FDA makes the assumption that 45 states will sign the MOU. Yet, in their comments to the draft MOU, the NABP indicated that at as many as 20 states had serious concerns with the administrative burden and unfunded mandates the MOU would create and were unlikely to sign. The final MOU makes minor changes to the previous draft, increasing to five days from the previously proposed three days states have for reporting adverse events to the FDA. This final MOU also expands from six months to one year the time states are given to consider whether to sign the MOU. FDA also cites the yet-to-be-developed "information sharing network" as an additional improvement to the previous draft. It is our understanding that this "information sharing network," which FDA has contracted with NABP to develop, has not been finalized and will not enter into beta testing until at least the fourth quarter of this year. As such, state boards of pharmacy may very well not have access to this information, on which FDA's incomplete burden analysis relies heavily, before they have to determine whether to sign the MOU.

It is highly unlikely that those minor concessions to the concerns being raised by the states will translate into 45 states signing the MOU. We believe that FDA's inaccurate assessment of the collection of information on the MOU has led to a substantial underestimation of the burden that will be placed on

states that sign and, therefore, a substantial overestimation of the number of states that will sign it. As discussed above, the likely refusal of many states to sign the MOU will have a profoundly negative impact upon patients who rely on out-of-state pharmacies for their compounded drugs. Further, FDA estimates that one state will terminate its participation in the MOU each year. If the burden to the states is as inconsequential as FDA predicts, it is unclear why FDA predicts this contraction in participation, especially given the serious penalties on pharmacies within that state and on patient access to medications if the MOU is not continued.

For these reasons, our organizations believe OMB should not approve FDA's information collection estimates under the PRA related to the MOU and require FDA to conduct a true, transparent evaluation of the collection of information that involves a detailed survey of each state that will produce accurate data for the states, pharmacy stakeholders, patients and the general public about the impact of the MOU. As the negative impact on patients served by out-of-state pharmacies in states that do not sign the MOU will be substantial, FDA should be directed to continue working with stakeholders on a final MOU that all states will commit to sign. As you will see from the enclosed joint comments submitted by our organizations in July of 2019, we suggested revisions that could be made to the requirements on states as well as an alternative definition of "distribution" for purposes of the MOU that we believe would have led to most if not all states signing the MOU, with broad stakeholder support. Unfortunately, FDA has yet to formally respond to these consensus recommendations.

Thank you in advance for your consideration of our request. Should you have questions, please do not hesitate to contact APC Legislative and Regulatory Counsel David Pore at dpore@hslawmail.com and APhA Senior Director Regulatory Policy Michael Baxter at mbaxter@aphanet.org.

Sincerely,

American Pharmacists Association
Alliance for Pharmacy Compounding
National Alliance of State Pharmacy Associations
National Community Pharmacists Association