

Congress of the United States
Washington, DC 20515

June XX, 2021

Dear Acting Commissioner Woodcock,

We write today regarding the FDA's "Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products" (MOU). We commend the Agency's thoughtful deliberation over the past several years to finalize this framework. As you are aware, the MOU was finalized in October of 2020 and has an enforcement date of October 26, 2021, after which pharmacies located in states that do not sign the agreement would be subject to a five percent cap on distributing compounded medications across state lines. This limitation would have dire consequences for the countless patients that rely on compounded medications and for the pharmacies located in states that, for varying reasons, cannot sign the MOU. We are writing to ask for a delay in enforcement of this policy to give the various state boards of pharmacy the necessary amount of time to review and enter into this agreement.

We understand that the National Association of Boards of Pharmacy (NABP), which is specifically mentioned in the underlying federal statute and has partnered with FDA to provide data and information on compliance, has requested a one-year delay in the October 26, 2021 enforcement date. The major pharmacy associations (NCPA, APHA, APC, NASPA), which are assisting states in the effort to get individual state boards of pharmacies to sign the MOU, have requested a two-year delay. Given the years of work that went into finalizing the MOU, we believe that a delay would be prudent to accommodate the needs of states in reviewing and complying with the MOU.

It is our understanding that a significant number of states, including large states like Texas and Florida, have identified obstacles to meeting the October 2021 deadline to sign the MOU based on available resources and state law conflicts. The situation has been greatly exacerbated by the current pandemic where meeting schedules of state boards of pharmacy have been disrupted and other pressing issues have diverted attention. In addition, many states have limited legislative sessions that hinder their ability to change state law quickly in the cases it will be needed to comply with the MOU. We have significant concerns over the potential disruption of access to compounded medications for patients who rely on out of state shipments for their healthcare needs.

We respectfully ask that you consider a delay in enforcement of this policy to give the various state boards of pharmacy the necessary amount of time to review and enter into this agreement. Thank you in advance for your prompt attention to this matter. Please do not hesitate to contact our office if we may be of assistance.

Sincerely,

Neal P. Dunn, M.D.
Member of Congress

Henry Cuellar
Member of Congress