



california **pharmacists** association

January 20, 2021

Maria Serpa, PharmD
Chair, Enforcement and Compounding Committee
Board of Pharmacy
2720 Gateway Oaks Blvd, Ste. 100
Sacramento, CA 95833

Dear Chair Serpa,

The California Pharmacists Association (CPhA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) Final Memorandum of Understanding (MOU) related to compounded drug products.

As you may be aware, the FDA has put both individual Boards of Pharmacy around the nation, as well as pharmacy compounders, in between the proverbial "rock and a hard place" with this MOU. If the Board chooses to sign this MOU, the Board must take measures to report to the FDA any pharmacy which ships over 50% of its total compounded medications out-of-state. If the Board chooses to not sign the MOU, pharmacy compounders may not ship any more than 5% of their total compounded medications out of state. CPhA recognizes that the Board does not currently have staff allocations or financial resources to dedicate to this effort should it choose to sign the MOU. CPhA also recognizes that there will be compounding pharmacies that will be significantly and adversely affected by the hard 5% cap if the Board chooses not to sign, which in turn will result in patient access problems.

In order to make the most informed decision, CPhA respectfully requests the Board to do consider the following:

- 1) The Board should assess what it would need, in terms of staff and resources, if it were to decide to sign the MOU.
- 2) The Board should analyze whether it has the legal authority to enter into the agreement independent of the authority of the Department of Consumer Affairs, the Business, Consumer Services and Housing Agency, and the Legislature. Note: The FDA recognized that not all Boards would have this independent authority, which is why it gave states a deadline, in the event other agencies or legislative bodies need to participate.

CPhA would request that the Board refrain from making any decisions until this information is known. If the Board were to make a decision now, it would be bound by the terms of the choice immediately. There is no need for this, as a decision doesn't have to be made for another ten months.

Should you have any questions about these comments, please feel free to contact me at (916) 779-4519 or at dmartinez@cpha.com. Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Martinez', written in a cursive style.

Danny Martinez
Government Relations and External Affairs Manager
California Pharmacists Association.