

FDA Extends Enforcement of 5 Percent Limit on Out-of-State Distribution of Compounded Human Drug Products

The Food and Drug Administration (FDA) [announced that it has extended the time period](#) for states to decide whether to sign the final standard memorandum of understanding (MOU) entitled “Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the California State Board of Pharmacy and the U.S. Food and Drug Administration” from October 27, 2021 to **October 27, 2022**. Therefore, the FDA will not enforce the 5 percent limit on interstate distribution of compounded human drugs by compounding pharmacies located in states that do not sign the MOU before October 27, 2022.

States may sign the final standard MOU at any time, including after the extension deadline of October 27, 2022. Additional information on the intentions of the California State Board of Pharmacy to enter the MOU are included in the [minutes](#) of the April 2021 Board Meeting.

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