

FDA Responses to Action Items from October 26-27, 2021, Inter-governmental Working Meeting on Drug Compounding

FDA will work with the National Association of Boards of Pharmacy (NABP) to raise state awareness of available trainings sponsored by FDA's Compounding Quality Center of Excellence (COE). FDA will also explore hosting additional training opportunities specifically targeted to state regulators.

FDA continues its work to offer state regulators opportunities to attend courses sponsored by the COE. In particular, FDA has scheduled a special live virtual training on October 27 for state regulators on topics including insanitary conditions and sterility assurance, airflow, and aseptic process simulations offered in three of the COE's on-demand online courses. States will be able to ask questions and engage directly with a panel of FDA experts on these topics.

FDA also worked with NABP to amplify state regulator attendance at the COE annual conference which featured several sessions on current good manufacturing practices and compounding quality.

FDA will continue to work with states and NABP to identify, understand, and enhance pathways for information sharing about adverse events, complaints, and product quality issues related to compounded drugs.

FDA continues to engage with NABP and states about adverse event reporting related to compounded drugs. FDA has developed and launched a Compounding Incidents Program webpage that provides [information](#) about incidents related to compounded drugs, including adverse events, product quality issues, and reporting processes. Additionally, FDA published a related [article and podcast](#) on the Compounding Incidents Program. The 2022 Inter-governmental Working Meeting on Drug Compounding will also include dedicated sessions on this topic including state approaches to reporting of adverse events and complaints.

FDA will explore pathways to facilitate additional dialogue between state regulators of pharmacy, medicine, and nursing regarding oversight of physician compounding practices.

FDA has engaged with NABP, the Federation of State Medical Boards and the National Council of State Boards of Nursing to open a dialogue on compounding outside the pharmacy setting and related physician and nurse practices. Conversations focused on the emerging business model of intravenous (IV) hydration facilities, medical spas, and mobile IV infusion services, and the potential health risks associated with products from these facilities that may be adulterated or do not comply with state and federal laws. FDA also met with several state boards of medicine, nursing, pharmacy, and other state regulatory agencies that work on these matters to learn about varying approaches to oversight. The 2022 Inter-governmental Working Meeting on Drug Compounding will include a dedicated session on this topic.