## Fisher, Alexander

**From:** Kathy Bizarro-Thunberg [redacted]
**Sent:** Tuesday, December 17, 2024 8:58 AM
**To:** [redacted]
**Cc:** Fisher, Alexander
**Subject:** TIME SENSITIVE: Request to address the NH Board of Pharmacy on 12/18



Good morning - I would like to respectfully request that the Board consider discussing at its meeting tomorrow (12/18/24), the FDA's October Guidance For Industry, entitled "Temporary Policies for Compounding Certain Parenteral Drug Products." Since Hurricane Helene took out the Baxer manufacturing plant in North Carolina causing a national crisis on IV solution inventories, the New Hampshire Hospital Association has been meeting with its member hospitals since early October on a weekly basis to share best practices on conservation measures, create situational awareness of everyone's inventory concerns and provide support for crisis events. In light of the fact that Baxter's manufacturing process is taking much longer to come back to pre-hurricane levels and limited allocations remain the norm, many NH hospitals are struggling to find adequate supplies through standard channels and are having to postpone or cancel procedures.

In its October 2024 guidance, the FDA introduced flexibility for licensed pharmacies to compound certain products on a non-patient specific basis provided several requirements are met. One key requirement is:

"Before providing the drug product to the hospital or health system, a State-licensed pharmacy notifies the following State authorities, and the State authorities inform the pharmacy that they do not object to the pharmacy providing the drug product to the hospital or health system without first obtaining a patient-specific prescription...The State authority that regulates pharmacy compounding in the State where the pharmacy is located."

Does the Board have a mechanism by which pharmacies may make such a notification and receive confirmation from the Board that it does not object to the compounding?

Additionally, we are aware of the NH sterile compounding regulations at PH 404.04. Will the Board consider introducing any temporary flexibilities in the permit, FDA registration, and MOU/testing evidence requirements in those regulations for the limited scope of products and duration of time covered in the FDA guidance? Aforementioned FDA guidance may be a valuable tool for New Hampshire health systems to continue to provide patient care and avoid the cancellation of surgical procedures during this national healthcare emergency. We seek the Board's support of this Federal measure to alleviate the IV solution crisis.

Thank you in advance for your consideration. Happy to discuss further with you. Kathy

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