April 27, 2020

RECOMMENDED BOARD OF PHARMACY GUIDELINES FOR OVERSIGHT OF AND COMPLIANCE WITH FDA'S April 2020 "Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency"

The following guidelines are offered to assist state boards of pharmacy in creating a safe, consistent framework for qualified 503A sterile compounders to prepare certain shortage drugs for distribution to hospitals under FDA temporary guidance released April 20, 2020.

1. Sterile compounds *must* come from a pharmacy operating in accordance with USP and state Board rules. *[Note: State boards of pharmacy may choose to allow only PCAB- and NABP-accredited pharmacies to participate under the temporary guidance.]*
2. Hospitals and 503A Pharmacies shall report Notice of Intent to Board of Pharmacy
3. Hospitals should undertake due diligence on 503A pharmacies to verify appropriate quality measures are in place, including but not limited to:
    a. Compounding SOP manual
    b. Training records for SOPs
    c. Recent media fill records and documentation
    d. Drug recall program
    e. Environmental monitoring program
    f. Clean room certification
    g. Most recent Board of Pharmacy inspection report
    h. Third party analytical testing program
4. To provide state regulators accurate reporting and quantifying of compounding under FDA's temporary guidance, the 503A pharmacy shall have in place a system whereby it can readily report via electronic means a record of all medications provided and the health system(s) to which these medications were provided, at a frequency determined by the board.
5. A procedure must be in place for demonstrating that the hospital has actually and appropriately taken possession of a shipment from the 503A pharmacy
6. Orders for C2 shall be recorded on the hospital's DEA 222 form. The pharmacy shall provide the appropriate DEA agent notice of intent to serve as a supplier.
7. In states in which the state Department of Health or other agency oversees a public health emergency task force, the 503A pharmacy should notify the task force about its ability to meet hospital drug needs under the temporary guidance.

8. Labelling provided by the 503A Pharmacy shall include:
    a. Assigned internal identification number (e.g., barcode, prescription, order, or lot number)
    b. Active ingredient(s) and their amounts, activities, or concentrations
    c. Storage conditions if other than controlled room temperature
    d. BUD
    e. Route of administration
    f. Total amount or volume if it is not obvious from the container
    g. If single-dose container, a statement stating such when space permits
    h. If multiple-dose container, a statement stating such
    i. Identification of the outside pharmacy and hospital pharmacy, including DEA numbers if controlled substances were prepared
9. The Hospital pharmacy shall provide the 503A pharmacy a list of patient names, dates of birth, and assigned internal identification number within 30 days after utilization of compounded medications for all patients that received the product.
10. It is recommended that qualified 503A pharmacies submit to the Alliance for Pharmacy Compounding's Compounders' Shortage Drug Source for Hospitals, accessible at www.a4pc.org, names of drugs it is compounding for sourcing by hospitals under FDA temporary guidance and with permission of the state board of pharmacy.

The National Alliance of State Pharmacy Associations (NASPA), founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.
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The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing compounding pharmacists, technicians, educators, students, researchers and suppliers. Compounding exists for patients and animals who are not served by traditional pharmaceutical manufacturers. Every day, APC members play a critical, often life-or-death role in patients' lives, creating essential medications unavailable elsewhere for a range of issues, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, and others.
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