Compounding pharmacies can help alleviate most temporary drug shortages … if empowered to do so.

Alliance for Pharmacy Compounding
Formerly IACP

ISSUE BRIEF:

Patient Access to Urgent-Use Pharmacy Compounding Act of 2023

HR 167 would allow 503As to fill gaps in coverage when 503Bs cannot

If we learned just one thing from the past three years, it's that America's healthcare system isn't structured to accommodate the demands put upon it by a global pandemic. In particular, the drug supply chain failed to function in a way that assured that hospitals and clinics had the drugs they needed to treat the most seriously ill COVID-19 patients. During the worst of the pandemic, hospitals found themselves pleading with manufacturers, suppliers, other health systems, the FDA, 503B outsourcing facilities, and compounding pharmacies for medications to keep those COVID patients alive.

In the midst of that crisis, in consultation with the Alliance for Pharmacy Compounding and other industry groups, FDA promulgated temporary guidance allowing 503A pharmacies to compound 13 COVID medications that were in severe shortage, when those drugs could not be acquired from manufacturers or 503B outsourcing facilities. In a 2021 APC survey, more than 80 pharmacies nationwide reported they had provided compounded versions of those essential drugs to hospitals under the temporary guidance. That guidance had almost certainly saved hundreds of lives, and at a September 2022 industry conference, an FDA official indicated that no adverse events had been reported.

Though that FDA temporary guidance has now been withdrawn, the problem of drug shortages persists – and it extends well beyond the 13 COVID drugs authorized under that temporary guidance document.

Compounding pharmacies are an obvious solution to temporary drug shortages in hospitals and clinics – both traditional compounding pharmacies in the near-term and 503B outsourcing facilities in the longer term. The model for that intentional, cascading *system* in which the A fills the gap until the B can ramp up already exists – not only the model but a record of success. It's precisely what FDA allowed under temporary guidance during the pandemic. At present, FDA seems to tout 503Bs as the sole solution, but without seeming to recognize the lengthy ramp-up time it takes an outsourcing facility to produce drugs in shortage. What about in the interim? Also, the agency very publicly engaged a Chinese manufacturer to provide urgently needed cancer drugs and did so without conversation with or consideration of what 503Bs, much less 503As, could do to help. Yet a solution is right under our noses.

That's why APC urges your support for HR 167, the **Patient Access to Urgent-Use Pharmacy Compounding Act of 2023**, sponsored by Rep. Morgan Griffith (R-VA) and Henry Cuellar (D-TX), which would create a permanent path, within tight regulatory guardrails similar to those in FDA's 2020 temporary guidance document, for 503A pharmacies to provide urgent use and shortage drugs to hospitals and physicians when those drugs cannot be sourced from the manufacturer or a 503B outsourcing facility. The legislation was introduced in early January 2023 and has been referred to the Subcommittee on Health.

THE ISSUE

By publishing its 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 FDA has acknowledged:

1. That urgent patient need should outweigh prescription requirements for 503A compounding, provided that other safeguards are in place.
2. The value of 503A compounding in addressing shortages of critical drug products.

The introduced legislation codifies a policy, largely based on that temporary guidance document, to address both urgent need and drug shortages.

Urgent Need

Physician organizations have noted that the requirement to have a patient-specific prescription for an urgent patient need may in some cases delay and hamper in-clinic care. For instance, ophthalmologists require an inventory of anti-bacterial, anti-fungal, and anti-viral compounded medications to treat eye-infections in immediate circumstances. Delay in providing the medication can result in patient harm. Thus, in limited circumstances, 503A entities should be allowed to compound the drugs without a patient-specific prescription, but then later to ensure that the patient information is married with the particular compounded product.

Related to urgent use, HR 167:

• Modifies the patient prescription requirement.
• Requires the prescriber to certify that the prescriber is unable to obtain the drug as an FDA-approved product or from a 503B entity.
• Only allows for compounding of limited quantities of the drug.
• Only allows the compounded drug to go to the prescriber (not directly to the patient).
• Only allows the administration of the drug by a licensed prescriber in a clinical setting.
• Ensures that patient information is later married with the compounded drug information by requiring:
  - The compounder to label the drug to request the patient information (within 7 days of administration or 7 days of patient discharge of each patient involved).
  - The coupling of the compounded drug information with the patient information, once received.
  - That the compounded product be labeled with a BUD (per USP).

Drug Shortages

With respect to drug shortages, the FDA has noted that it was using its enforcement discretion with respect to the "essentially a copy" requirements, provided that certain conditions are met (i.e., those contained in the temporary guidance document). The proposed legislation would codify that flexibility, while also expanding the definition of drug shortage to include not only the FDA's definition of drug shortage but also ASHP's drug shortage list. The ASHP list encompasses local and regional (not just national) shortages.

Related to drug shortages, HR 167:

• Modifies the patient prescription requirement (when necessary).
• Ensures, when the patient prescription requirement is waived, that the patient information is later married with the compounded drug information by requiring:
  - That the compounder labels the drug to request the patient information (within 7 days of administration or 7 days of patient discharge of each patient involved).
  - That the compounder couples the compounded drug information with the patient information.
• Requires that the compounded product be labeled with a BUD (per USP).
• Expands the definition of shortage to include drugs listed on the FDA or ASHP lists.

THE ASK: Members of Congress must recognize that 503A pharmacies play a safe, valuable role in alleviating temporary drug shortages – especially while 503B outsourcing facilities are ramping up to produce a shortage our urgent us drug under current good manufacturing practices.

- **House Members:** Call the Energy & Commerce Committee and ask that they include HR 167's provisions in any drug shortage or pandemic preparedness package.
- **Senators:** Please introduce a Senate companion bill to HR 167. Please sponsor an effort to include HR 167's provisions in any drug shortage or pandemic preparedness package.

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