New Mexico Regulation and Licensing Department
Board of Pharmacy
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EMERGENCY DISPENSING DECLARATION

Whereas, the U.S. Food & Drug Administration (FDA) has issued a guidance explaining a temporary policy regarding state-licensed pharmacies and federal facilities compounding certain human drugs for hospitalized patients during the COVID-19 public health emergency. This guidance helps address reported issues with accessing certain FDA-approved drugs used for hospitalized patients with COVID-19.

> FDA recognizes that during the COVID-19 public health emergency, even with the recent temporary regulatory flexibility provided to outsourcing facilities, the supply of FDA-approved drugs and drugs compounded by outsourcing facilities may not be sufficient to meet urgent needs for drugs used to treat hospitalized COVID-19 patients. As a temporary measure, with regard to drugs listed in Appendix A, FDA does not intend to take action against state-licensed pharmacies and federal facilities under the circumstances outlined in the guidance for:
>
> - compounding a drug that is essentially a copy of a commercially available drug, or
> - providing a drug to a hospital without first obtaining a patient-specific prescription
>
> Hospitals that cannot obtain FDA-approved drugs and seek to use compounded drugs for their hospitalized patients should first contact outsourcing facilities that produce compounded drugs under more robust quality standards than those made by state-licensed pharmacies or federal facilities.

Beginning May 5, 2020 to continue during the declared state of emergency in New Mexico due to COVID-19, unless otherwise amended:

Pursuant to the Pharmacy Act, NMSA 1978, §§ 61-11-6 A (20) and 61-11-6 B (3), the New Mexico Board of Pharmacy ("board") authorizes the following emergency dispensing procedures:

The board will allow a hospital to obtain pharmacy-compounded sterile preparation under the circumstances and conditions outlined in the FDA guidance document "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 Guidance for Industry," and this emergency dispensing declaration.

Core circumstances and conditions include:

a. The compounded drug product appears on the list in guidance document Appendix A of drugs used for hospitalized patients with COVID-19 and contains only one of the active ingredients listed there.

b. The compounded drug is provided directly to a hospital that informs the pharmacy that:

i. The hospital is treating patients with COVID-19; and

ii. The hospital has made reasonable attempts to obtain, and has not been able to obtain:

1. Adequate supplies of an FDA-approved drug product containing the same active ingredient for the same route of administration, and
2. Adequate supplies of a product made by an outsourcing facility containing the same active ingredient for the same route of administration.

c. The compounded drug product is labeled with a default beyond-use-date (BUD) in accordance with the table in Appendix B, except that the pharmacy uses a shorter BUD where applicable, as specified in the guidance document (literature, or PPE conservation).

d. If the pharmacy and the hospital are not owned and controlled by the same entity, the pharmacy (1) marks the order with a notation indicating that the drug is provided to the hospital to treat patients during the COVID-19 public health emergency; and (2) requests that the hospital provide, to the extent allowed by applicable laws, the records that identify the patients to whom the drugs were administered and document such request within one month of sending the compounded drug to the hospital.

e. Before providing the drug product to the hospital, 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 without first obtaining a patient-specific prescription:

i. The State authority that regulates pharmacy compounding in the State where the pharmacy is located, and,
ii. If different, the State authority that regulates pharmacy compounding in the State where the hospital is located.

- Hospitals, in making reasonable attempts to obtain the drug product as FDA-approved, or from an outsourcing facility should be aware of the following:
  - FDA-approved drug availability may be identified by an expanded search (manufacturers, and wholesale drug distributors).
  - Outsourcing facility availability may be identified using the following resources:
    - A list of board licensed outsourcing facilities is available via: http://verification.rld.state.nm.us/Search.aspx?facility=Y (under license number enter OF*).
    - Alliance for Pharmacy Compounding (compounders' shortage drug source for hospitals) offers a free resource for connecting hospitals with compounders who can provide shortage drugs.
    - Outsourcing Facility Product Reporting Information is available via: https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities.

- Hospitals are to exercise due diligence in determining whether to obtain CSP from a pharmacy. Considerations include:
  - Is the source pharmacy conserving sterile compounding PPE? This shortens the default BUD and is a critical consideration, including in the context of time needed for CSP delivery and administration.

- Has the facility corrected CSP operations deficiencies identified by most recent state or FDA inspection? FDA inspection information is available via: https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions.
- Current environmental monitoring and certification reports.

- Pharmacists and pharmacies are reminded of the requirements of:
  - applicable USP/NF General Chapters numbered below <1000>;
  - 16.19.36 NMAC relating to compounded sterile preparations (CSP); and
  - required maintenance of proper medication storage conditions, including temperature, until the drug is delivered to the hospital.

- Non-resident pharmacies are reminded that the board license type "non-resident sterile" is required prior to shipping any CSP into NM.

Issued: May 5, 2020

Additional resources:

The U.S. Department of Health & Human Services (HHS) Healthcare Emergency Preparedness Information Gateway, ASPR TRACIE, includes novel COVID-19 resources. This includes a **Hospital Disaster Pharmacy Calculator**, which allows hospitals to estimate whether they have adequate supplies of medications for a disaster in stock.

FDA drug shortage information is available via:
https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm