Title: COVID-19 Public Health Emergency: Policy No. I.D.24
Partial Waiver of Outpatient Dispensing Limitations for Hospital Pharmacies

Issued: 11-11-2020
Ratified: 11-18-2020

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1. The Board's rules for hospital pharmacies include a limitation on the dispensing of medications for outpatient use, such that the pharmacy may dispense medications only to certain persons having some connection to the hospital. In particular, Section 1523 provides:

> **§1523. Outpatient Pharmacy Dispensing**
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> A. Hospital outpatient dispensing shall require a separate pharmacy permit for the specialty classification(s) under these regulations. All records including the annual inventory of controlled dangerous substances for the outpatient pharmacy shall be maintained and kept separate and apart from that of the inpatient pharmacy, as the outpatient pharmacy may not acquire drugs through the hospital pharmacy permit under the provisions of the Robinson-Patman Act, 15 USC §13(c).
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> B. Nothing in this section shall prohibit the dispensing of certain prescriptions from the hospital pharmacy, as allowed under the Robinson-Patman Act, 15 USC §13(c), including:
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> 1. dispensing to the hospital inpatient for use in his treatment at the hospital;
> 2. dispensing to the patient admitted to the hospital's emergency facility for use in the patient's treatment at that location;
> 3. dispensing to the hospital outpatient for personal use on the hospital premises;
> 4. dispensing in the context of a genuine take-home prescription, intended for a limited and reasonable time as a continuation of, or supplement to, the treatment that was administered at the hospital to the recipient while an inpatient, an outpatient, or an emergency facility patient if the patient needs that treatment; or
> 5. dispensing to the hospital's physicians, employees, or its students for their personal use or for the personal use of their dependents.
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> AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.
> HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

2. On November 9, 2020, the federal Food & Drug Administration (FDA) issued an **emergency use authorization (EUA)** for the investigational monoclonal antibody therapy bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients. The drug is authorized for patients with positive

results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kilograms (approx.. 88 pounds) and who are at high risk for progressing to severe COVID-19 and/or hospitalization. The drug is to be administered by intravenous infusion for approximately one hour and may be followed by an observation period. Under the EUA, the drug may only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to active the emergency medical system (EMS) as necessary. Facilities must also have space available to administer the medication in a manner that minimizes infection transmission.

3. On November 10, 2020, the U.S. Dept. of Health and Human Services (HHS) announced an **allocation plan** to distribute the first 300,000 doses of the drug to state and territorial health departments which, in turn, will determine which healthcare facilities within their jurisdiction will receive the drug.

4. As provided within the HHS allocation, hospital pharmacies will receive the initial allocations of the drug. Their facilities will then be responsible for administering the drug to eligible patients without regard to whether those patients have any prior connection to the hospital.

5. To facilitate the efficient distribution and administration of the drug to the citizens of Louisiana, the Board has determined it appropriate to partially waive the limitations on dispensing medications to outpatients in its rules for hospital pharmacies. In particular, the Board will exercise enforcement discretion for hospital pharmacies dispensing bamlanivimab or any other medication indicated for the treatment of COVID-19 in non-hospitalized patients.

6. Board First Vice President Marty McKay authorized this interim policy effective November 11, 2021. This policy is scheduled to expire on March 31, 2021 unless terminated or extended by the Board.

7. During their November 18, 2020 meeting, the members voted to ratify this interim policy and extend it to March 31, 2021 unless terminated sooner.