



Louisiana Board of Pharmacy
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MEMORANDUM

To: Licensees & Interested Parties

From: Malcolm J Broussard, Executive Director

Date: April 14, 2020

Re: COVID-19 Guidance Information – Temporary Waiver of 5% Rule on Distribution of Controlled Substances to Other Practitioners

The U.S. Drug Enforcement Administration (DEA) rules, more specifically at 21 CFR 1307.11(A)(1)(iv), permits a DEA registrant to distribute controlled substances to another registrant without being licensed as a distributor as long as those distributions do not exceed 5% of the registrant's total number of dosage units of all controlled substances dispensed and distributed by that registrant during the same calendar year. This so-called "5% rule" is replicated in the Board's rules for controlled substances, more specifically at LAC 46:LIII.2751.A.1.a.iv. Both federal and state provisions require any DEA registrant intending to distribute more than 5% of its controlled substances to other registrants to first obtain the appropriate credential as a distributor.

One of the many consequences of the current public health emergency is the increase in drug shortages, including controlled substances used in the management of sedation for ventilator patients. To facilitate the distribution of controlled substances between registrants during this emergency, the DEA has issued a [temporary waiver](#) of the 5% rule effective retroactively to January 1, 2020. The waiver will terminate upon the end of the public health emergency declared by the Secretary of the U. S. Dept. of Health and Human Services (HHS), unless terminated or withdrawn sooner by the DEA.

The DEA waiver specifically indicates it does not supersede any similar state-imposed restrictions. The Board has determined it appropriate to waive its 5% rule for the same period of time as DEA determines it appropriate for the federal waiver.

The Board reminds its controlled substance licensees of their obligation to maintain accurate records of all dispensing and distribution transactions for controlled substances.

NOTICE: In compliance with Act 256 of the 2019 Louisiana Legislature, the Board gives public notice that any information submitted to the Board may become public record unless specifically exempted by the Public Records Law, R.S. 44:1 *et seq.*

NOTICE: In compliance with Act 655 of the 2018 Louisiana Legislature, the Board gives notice to its licensees and applicants of their opportunity to file a complaint about the Board's actions or procedures. You may submit such complaints to one or more of the following: (1) Louisiana Board of Pharmacy; 3388 Brentwood Dr., Baton Rouge, La 70809; 225.925.6496; info@pharmacy.la.gov (2) Committee on House & Governmental Affairs; La. House of Representatives; PO Box 44486; Baton Rouge, LA 70804; 225.342.2403; h&ga@legis.la.gov (3) Committee on Senate & Governmental Affairs; La. Senate; PO Box 94183; Baton Rouge, LA 70804; 225.342.9845; s&g@legis.la.gov