

Title: COVID-19 Public Health Emergency:
Limitations on Distribution of Controlled Substances

Policy No. I.D.21

Issued: 04-14-2020
Ratified: 05-27-2020
Extended: 11-18-2020

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1. The DEA's rules allow DEA-registered practitioners and pharmacies to distribute controlled substances to each other without holding a registration as a distributor, but limits such distributions to a maximum of five percent of the total number of dosage units of all controlled substances that the registrant dispenses and distributes during that calendar year. Often referred to as the "5% rule", the rule provides that the registrant shall register as a distributor if they have reason to believe their distributions during a calendar year will exceed that 5% threshold.
 2. One solution to the prevailing drug shortage issue is the transfer of controlled substance inventory from a pharmacy to a practitioner or healthcare facility; however, such distributions may result in a registrant exceeding the 5% threshold.
 3. On April 13, the DEA issued a temporary waiver of the 5% rule such that registrants may distribute controlled substances to other registrants without regard to the 5% rule and the necessity to also register as a distributor. The waiver is retroactive to January 1, 2020 and will lapse when the public health emergency declaration is rescinded or terminated. The waiver does not affect the recordkeeping requirements associated with distributions, and those requirements are maintained. Further, the waiver specifically does not preempt any state laws or rules.
 4. The Board President took note of the corresponding 5% rule in the Board's rules for controlled substances, specifically at §2751.A.1.a.iv. The Board President issued a waiver of that rule under the same conditions and timeline as the DEA issued for its waiver.
 5. During their November 18, 2020 meeting, the members voted to extend this interim policy until the conclusion of the public health emergency unless terminated sooner.