



**U. S. Department of Justice**  
Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, Virginia 22152

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*www.dea.gov*

## DEA Registered Practitioners

Dear DEA Practitioner:

Following the nationwide public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, as a result of the Coronavirus Disease 2019 (COVID-19), the Drug Enforcement Administration (DEA) has learned that some DEA-registered practitioners (dispensers), such as hospitals, pharmacies, and physicians, need to distribute controlled substances to other dispensers for the purpose of general dispensing to meet increasing demand that has arisen as a result of the public health emergency. To allow this to occur, DEA is hereby issuing a temporary exception to the pertinent regulation.

### **Background**

The Controlled Substances Act (CSA) establishes different categories of registration as part of the framework of the Act designed to promote effective controls against diversion. 21 U.S.C. 823. Toward that end, persons registered with DEA are authorized only to conduct those activities with controlled substances (such as manufacturing, distributing, and dispensing) to the extent authorized by their registrations. 21 U.S.C. 822(b); 21 CFR 1301.13. Thus, as a general matter, to engage in the distribution of controlled substances, a person must be registered as a distributor. However, the DEA regulations allow a practitioner (who is registered to dispense) to distribute controlled substances to a limited extent to another registered practitioner, such as a hospital, pharmacy, or physician.

As set forth in 21 CFR 1307.11, a practitioner who is registered to dispense may distribute limited amounts of controlled substances to another practitioner for the purpose of general dispensing by the other practitioner to patients, if certain conditions are met. Among these conditions is that the amount a practitioner so distributes to other practitioners during a calendar year cannot exceed five percent of the total number of dosage units of all controlled substances that the practitioner dispenses and distributes during that year. *Id.* at 1307.11(a)(1)(iv). This provision of the regulations is often referred to as the “five percent rule.” This regulation further provides that, if a practitioner has reason to believe that the amount he or she will distribute to other practitioners will exceed this five percent threshold, the practitioner must register as a distributor. 21 CFR 1307.11(b).

Under normal circumstances, DEA would not consider issuing a general exception to the five percent rule as it is essential to the diversion control regime of the CSA to generally limit activities involving controlled substances to those authorized by a person’s registration. However, due to the extraordinary circumstances that have arisen during the COVID-19 pandemic, and to allow for an

adequate and uninterrupted supply of medically necessary controlled substances to patients, DEA will exercise its authority pursuant to 21 CFR 1307.03 and grant an exception to the five percent rule as described below.

### **Temporary Exception**

Pursuant to 21 CFR 1307.03, DEA hereby grants the following temporary exception to 21 CFR 1307.11:

A DEA-registered practitioner that complies fully with all other requirements of 21 CFR 1307.11 may now distribute controlled substances beyond five percent of the total number of dosage units of controlled substances distributed and dispensed during the same calendar year without being required to register as a distributor in order to make such distributions. This exception is in effect until the public health emergency declared by the Secretary of HHS ends, unless DEA specifies an earlier date or otherwise first modifies or withdraws this exception.

Once this exception expires, practitioners must again comply with the five percent rule (and all other aspects of 21 CFR 1307.11).

To simplify matters, DEA will allow timing considerations to work as follows. All distributions made by practitioners from January 1, 2020, until the date this exception ends (see above) will be excluded from consideration in applying the five percent rule. In other words, once this exception ends, practitioners need only consider distributions made from that date through the remainder of the calendar year. For example, if the public health emergency were to end on July 1, 2020 (or if DEA were to end this exception on July 1, 2020), the relevant time period would be from July 1, 2020, through December 31, 2020. In such a scenario, a practitioner who had reason to believe that the total number of dosage units of all controlled substances which will be distributed by him, from July 1, 2020, through December 31, 2020, will exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by him during that same time period (July 1, 2020, through December 31, 2020), the practitioner would be required to obtain a registration to distribute controlled substances.

All DEA-registered practitioners, when distributing controlled substances, must continue to abide by all security, recordkeeping, and other applicable requirements of the DEA regulations. For example, this includes the requirement of only distributing a schedule I or II controlled substance pursuant to an order form. 21 CFR 1307.11(a)(iii). This also includes submitting to DEA a copy of the order for a schedule I or II controlled substance. 21 CFR 1305.13(d) (DEA Form 222) and 1305.29 (electronic orders). These are only examples of some of the still applicable requirements of the DEA regulations.

Please be advised that DEA has also issued a temporary exception to certain aspects of the requirements relating to order forms (DEA Form 222). Details of this exception can be found at [www.deadiversion.usdoj.gov/coronavirus.html](http://www.deadiversion.usdoj.gov/coronavirus.html).

The exception outlined in this letter does not supersede any state rules or regulations that prohibit such distributions. DEA-registered practitioners should consult their state regulatory authorities for any additional state requirements that may apply.

We hope this information is helpful. For information regarding DEA's Diversion Control Division, including contact information for a local field office, please visit [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov). Please contact the Diversion Control Division, Policy Section at (571) 362-3260 if you seek additional assistance regarding this or any other matter.

Sincerely,

William T. McDermott  
Assistant Administrator  
Diversion Control Division

DEA085 – April 13, 2020