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INSIGHT

COVID-19: The Drug Enforcement Administration's Regulatory Role

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The Coronavirus Disease 2019 (COVID-19) pandemic has caused strain on many health care and medical facilities around the country, and some doctors and pharmacists have altered conventional practice to accommodate the needs of patients during this public health emergency. Changed practices include maintaining increased supplies of Schedule II controlled substances needed for intubation at hospitals and increasing the use of telemedicine as an alternative to in-person patient visits with a provider. Such changes require the Drug Enforcement Administration (DEA) to make exceptions to Controlled Substances Act (CSA) regulatory requirements. DEA has made these and other accommodations during the COVID-19 public health emergency.

This Insight focuses on DEA's regulatory role and how related polices have changed in response to the COVID-19 pandemic. The Food and Drug Administration (FDA) also plays a significant role in regulating the nation's drug supply, but is only briefly mentioned here. See other CRS products for discussion of FDA policies.

DEA's Regulatory Role

In addition to criminal enforcement, DEA is charged with enforcing noncriminal regulatory requirements of the CSA. Those requirements provide the statutory framework through which the federal government regulates the lawful production, possession, and distribution of controlled substances. Certain CSA laws and regulations are associated with recent COVID-19-related needs and changes. For a broader discussion of the CSA, see CRS Report R45948, *The Controlled Substances Act (CSA): A Legal Overview for the 116th Congress*.

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Registrants

The CSA requires persons (such as drug manufacturers, wholesale distributors, physicians, pharmacists, and scientific researchers) who handle controlled substances or listed chemicals to register with the DEA. Among other CSA requirements, registrants must maintain detailed records of their controlled substance inventories, establish adequate security controls to minimize theft and diversion, and issue prescriptions according to requirements specific to schedule classification.

Supply of Controlled Substances

The CSA has many supply-related requirements, but a key requirement involving the nation's supply of controlled substances is the establishment of annual quotas. Each year, DEA sets the Aggregate Production Quotas (APQ) for Schedule I and II controlled substances, which determine the annual quantities of those substances available for medical, scientific, and industrial use in the United States. Manufacturers of Schedule I and II controlled substances must register and apply for a quota with DEA. Of particular importance, several Schedule II substances, including fentanyl and hydromorphone, are used for pain relief associated with intubation. DEA also has a key regulatory role in the importation of controlled substances.

FDA's Role

FDA also plays a significant role in regulating the drug supply and addressing any drug shortages in the United States. FDA responds to potential shortages "by taking actions to address their underlying causes and to enhance product availability." See CRS In Focus IF11058, *Drug Shortages: Causes, FDA Authority, and Policy Options*.

DEA Accommodations for Registrant and Patient Needs Related to COVID-19

In response to questions and needs related to COVID-19, DEA issued public statements on how it is responding to the disease. DEA stated that it remains flexible in ensuring an uninterrupted drug supply, and supports "prescribing practices that limit exposure, enabling uninterrupted access to practitioners, and safeguarding a consistent and reliable drug supply."

Telemedicine

The CSA allows for several circumstances under which the practice of telemedicine can occur, one of which is a public health emergency declaration. DEA consulted with the Department of Health and Human Services to allow DEA-registered practitioners to begin issuing prescriptions for controlled substances to patients for whom they have *not* conducted an in-person evaluation. If certain conditions are met, including that the prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice, and that the practitioner complies with all applicable federal and state laws, a practitioner may prescribe a controlled substance without an in-person evaluation for as long as the COVID-19 public health emergency is in effect. Subject to specified conditions, a practitioner may issue a prescription using any of the methods of prescribing currently available, including issuing a prescription electronically or by calling in a prescription to a pharmacy.

Supply

Some of the drugs needed for intubation of COVID-19 patients are Schedule II controlled substances, such as fentanyl and hydromorphone. CSA regulatory requirements may limit the availability of

controlled substances in several ways. For example, security requirements may limit the amount of controlled substances a single facility may handle, while manufacturing quotas limit the national supply of controlled substances. Some hospital practitioners are concerned that their stock is insufficient to effectively respond to an anticipated surge in patients in need of intubation. While there is no CSA requirement or DEA rule regarding the *exact* amount of Schedule II controlled substances that a hospital can keep on hand, the quantity of controlled substances handled is one of 14 factors DEA may consider when evaluating a practitioner's controls and procedures to guard against theft and diversion. DEA has said that registrants who need to increase their supply should reach out to their local DEA field office to devise a customized path forward. Relevant state regulations also may need to be considered.

DEA has increased APQs for controlled substance medications that are in high demand due to the pandemic and stated it will approve increases in imports of medications necessary for patients on ventilators. It has also made an exception to the individual quotas that apply to bulk manufacturers. As of March 23, 2020, all DEA-registered bulk manufacturers are allowed to exceed the standard allowance in order to supply dosage from manufacturers with the active pharmaceutical ingredient(s), acknowledging this may be necessary to manufacture specific products to avoid shortages.

Other Actions

In addition to exceptions made for telemedicine and the supply of controlled substances, DEA has taken a number of other actions to respond to the COVID-19 emergency. For example, it has made allowances for registration of temporary emergency sites and provided exceptions to separate registration requirements across state lines. For a complete list of DEA responses and relevant guidance, see DEA's Office of Diversion Control, COVID-19 Information Page.