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Regulations Teed Up at the Drug Enforcement Administration

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In brief…

The Drug Enforcement Administration plans to release a flurry of proposed and final regulations this year, up significantly from previous years. Several of the regulations teed up at the Drug Enforcement Administration are long-awaited actions that seek to address the ongoing opioid epidemic.

As a law enforcement agency, the Drug Enforcement Administration (DEA) is not among the most active regulatory agencies. However, DEA's Diversion Control Division plans to release a flurry of regulatory actions this year. The Diversion Control Division has already released 5 proposed and final rules since the Spring 2020 Unified Agenda was published, and it plans to release 16 more by the end of the year. This is up significantly from previous years, and several of these rules seek to address the ongoing opioid epidemic.

Rulemakings at DEA

DEA's Diversion Control Division aims to control the "diversion" of controlled prescription drugs to illegitimate purposes while ensuring there is enough supply for legitimate needs. For example, prescribing a controlled substance to a patient with no medical necessity who is drug dependent is considered illegitimate. Under DEA's paradigm, pharmacies, hospitals, and practitioners who prescribe, dispense, or administer controlled substances must register with DEA, and they are closely monitored by the agency.

Although these regulations are intended to prevent controlled substances from being used for illegitimate purposes, they create barriers for some patients who use controlled substances legitimately. For example, the two drugs used to treat opioid use disorder – methadone and buprenorphine – are both DEA controlled substances, so they fall under the regulations. DEA regulations have made it challenging for patients with opioid use disorder to receive much needed treatment. In response, Congress directed DEA to reduce or remove certain regulatory barriers to medication-assisted treatment, and DEA plans to release several of the associated rules this year.

In its entry in the Spring 2020 Unified Agenda, DEA's Diversion Control Division signaled its intent to propose or finalize 21 rules this year. So far, DEA has released 5 of those actions. This is up significantly

over recent years; in its entry in the Spring 2019 Unified Agenda, DEA's Diversion Control Division only intended to release 13 rules in 2019. During the first year of President Trump's administration, DEA only planned to release one rule. During President Obama's second term, DEA never planned to release more than 10 rules in any given Unified Agenda.

The Unified Agenda only represents DEA's intentions for the year; it does not commit DEA to taking those actions. For example, only 2 of the 13 rules that DEA's Diversion Control Division planned to release in 2019 were actually released that year. Although there is no guarantee DEA will release the planned 21 rulemakings this year, there seems to an atypical burst in rulemaking occurring in DEA's Diversion Control Division. As mentioned, it already released 5 rulemakings this year, up well over the 2 rulemakings released last year.

There are many potential drivers of this uptick in DEA rulemakings. Congress seems to be behind the push for rules aimed at combatting the opioid epidemic. For example, DEA plans to release 5 rules that are clearly aimed at combatting the opioid epidemic. Of those, Congress directed DEA to release 4. Of course, it is certainly possible the administration also wants to combat the opioid epidemic through regulatory reform. It is not apparent what is driving the other regulatory changes. Is DEA's Diversion Control Division gearing up to release midnight regulations? Is there a policy shift occurring at DEA? Is DEA finally getting around to making programmatic adjustments? Regardless of what is driving the increase in activity at DEA, it is valuable for the public health community to follow these rulemakings.

DEA's Planned Rules for 2020

Many of the rules DEA plans to release this year intend to address the opioid epidemic. As mentioned, some of the rules will remove regulatory barriers to medication-assisted treatment. Other rules aim to reduce the volume of opioids available for diversion.

Other rules DEA plans to release are not directly related to the opioid epidemic. For example, some are programmatic, like the proposed rule to adjust fees for DEA registrations. Others seek to mitigate confusion surrounding long standing implementation problems, like how DEA regulations apply to Emergency Medical Services (EMS).

Special Registration for Telemedicine

Practitioners are generally prohibited from prescribing a controlled substance to a patient without first conducting an in-person medical evaluation. In the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Congress gave DEA the discretion to carve out a limited number of telemedicine exceptions that practitioners can use to bypass the initial in-person evaluation requirement. However, DEA failed to promulgate regulations implementing certain telemedicine exceptions. In response, Congress recently amended the statute to require DEA to set up a special registration program for telemedicine.

This rule will propose to allow practitioners to apply for special registrations to use telemedicine to prescribe controlled substances, including the drugs used to treat opioid use disorder. This will make it possible for patients with opioid use disorder to access medication-assisted treatment via telemedicine. A

practitioner who wants to use telemedicine will need to apply to DEA for a special registration and follow the requirements DEA puts in place.

DEA missed the statutory deadline of October 2019 to release the special registration regulations. DEA has yet to even release a proposed version of the rule. In the Unified Agenda, DEA signaled its intent to publish the proposed rule in August 2020, so it is possible it will release the proposed rule this year. OMB appears to have waived review of this rule, marking it as "nonsignificant" in the Unified Agenda.

Partial Filling of Prescriptions of Schedule II Controlled Substances

This rule will propose to allow a pharmacist to partially fill a schedule II controlled substance if requested by the patient or prescribing practitioner. Patients can return to the pharmacy to get the remainder of the prescription if needed. Existing DEA regulations only allow pharmacists to partially fill a prescription if the pharmacist cannot prescribe the full amount, but in the Comprehensive Addiction and Recovery Act of 2016, Congress directed DEA to allow for partial filling of schedule II controlled substances at the request of patients and practitioners.

The rule is expected to reduce the amount of unused opioids that end up being stockpiled in homes, where they run the risk of being misused. The Substance Abuse and Mental Health Services Administration reported that about half of the people who misuse prescription painkillers said they obtained them from friends and relatives. The rule may also reduce the large volume of pharmaceutical waste generated. Since the 2010 inception of DEA's National Prescription Drug Take Back Days, DEA has collected over 12 million pounds of prescription drugs that had to be properly managed and disposed.

OMB received this proposed rule for review on June 2, 2020 and has not concluded review. OMB's dashboard currently identifies the rule as "economically significant," meaning we can expect it to have an annual impact on the economy of at least $100 million or adversely affect the economy or a part of the economy.

Dispensing and Administering Controlled Substances for Medication-Assisted Treatment

DEA also plans to release an interim final rule this year implementing a portion of the SUPPORT Act that directs DEA to expand medication-assisted treatment. Among other actions, the SUPPORT Act directs DEA to allow pharmacies to dispense controlled substances to practitioners so they can then administer them directly to patients for detoxification treatment. Currently, pharmacies can only dispense a controlled substance to the person who will use the drug.

OMB received this rule for review on June 5, 2020 and has not concluded review. This rule is also identified as "economically significant" on OMB's dashboard, so we can also expect it to have an annual impact on the economy of at least $100 million or adversely affect the economy or a part of the economy.

Bringing Emergency Medical Services under DEA's Registration Paradigm

In this rule, DEA will propose to allow EMS registrants to transport controlled substances for the purpose of dispensing them under certain circumstances. The rule will include requirements EMS registrants must follow when handling controlled substances.

In 2017, the Protecting Patient Access to Emergency Medications Act was signed into law, which allows EMS to receive their own registration from DEA. Previously, EMS were not included in the Controlled Substances Act, causing confusion among EMS providers about whether they could carry and dispense controlled substances. States and DEA took a variety of regulatory and enforcement approaches. In 2014, DEA announced its intent to ban the use of "standing orders." Standing orders are what they sound like; medical directors give EMS providers permission to dispense controlled substances to patients exhibiting certain conditions without requiring them to get pre-approval for each patient. However, the 2017 Act specifically approved the use of standing orders, so we can expect this proposed rule not to include the ban.

OMB completed review of this proposed rulemaking over seven weeks ago on July 27, 2020, but it has yet to appear in the Federal Register.

Conclusion

DEA plans to release a flurry of proposed and final rulemakings this year. Many of the rulemakings are long-awaited reductions to regulatory barriers to medication-assisted treatment.

For a complete list of the rules DEA plans to release this year, see its entries in the Unified Agenda. To receive an alert when these proposed and final rules are released, and to learn when the comment periods for the proposed and interim final rules will open, sign up to receive email notifications for DEA publications from the Federal Register. You can also use the RIN number listed for a rulemaking in the Unified Agenda and search for its associated docket on Regulations.gov.