Rules of Substance
The DEA Enforces Prescription Drug Rules and Regulations
The practice of medicine is a complex activity that can involve many professional responsibilities. For physicians and other licensed medical practitioners, one major area of clinical practice involves medication prescription. The ability to prescribe medications, including controlled substances, is subject to an array of federal and state regulatory controls. The regulatory process includes federal oversight from the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, the Drug Enforcement Administration (DEA), and state agencies. The goal of this multifaceted regulatory system is to ensure prescription drugs that enter the market are safe, effective, and appropriately managed and dispensed.

In the United States, the DEA is primarily responsible for regulating the use of controlled substances. By definition, a controlled substance includes any drug, substance, or chemical for which legal access is restricted due to its potential to be abused or cause addiction. The DEA’s regulatory authority covers the manufacture, handling, storage, use, and distribution of all controlled substances. Notably, controlled substances can include both legal prescription drugs used for medical purposes (e.g., diazepam [Valium] and methylphenidate [Ritalin]) and illegal substances (e.g., heroin and LSD) with no known medical use.

Classifications
The DEA’s regulatory authority originates in the Controlled Substances Act, which took effect in 1971 as part of broader drug abuse, prevention, and control legislation. Under the Controlled Substances Act, the DEA classifies drugs, substances, and certain chemicals according to five main categories,
which are also called schedules. The schedule a drug, substance, or chemical falls into is determined by various qualifying factors including—and most importantly—its accepted medical uses and potential for abuse or dependency in humans.  

The classification system the DEA uses for controlled substances is summarized into five parts:

- **Schedule I.** These drugs, substances, or chemicals have no accepted medical use and the highest potential for abuse and psychological or physical dependence. Heroin, LSD, and methylenedioxymethamphetamine (ecstasy) are examples.

- **Schedule II.** These drugs, substances, or chemicals are dangerous with a high potential for abuse or severe psychological or physical dependence. This classification includes cocaine, oxycodone (OxyContin), methamphetamine (Desoxyn), fentanyl (Duragesic), amphetamine and dextroamphetamine (Adderall), and methylenedioxymethamphetamine (ecstasy) are examples.

- **Schedule III.** These drugs, substances, or chemicals pose a moderate-to-low potential for physical and psychological dependence. Examples include products that contain less than 90 milligrams of codeine per dosage unit, such as Tylenol with codeine, as well as anabolic steroids, ketamine, and testosterone.

- **Schedule IV.** These drugs, substances, or chemicals have a low potential for abuse or dependency. Examples include products used for anxiety or as sleep aids, such as alprazolam (Xanax), diazepam (Valium), and zolpidem (Ambien).

- **Schedule V.** These drugs, substances, or chemicals have the least potential for abuse. This classification includes antidiarrheal, antitussive, and analgesic products with limited quantities of narcotics in the preparations. For example, some cough preparations with less than 200 milligrams of codeine, such as Robitussin AC, are classified under Schedule V.

For the purposes of criminal prosecution, under DEA rules, a drug or substance does not have to be listed as a controlled substance to be classified as a Schedule I or Schedule II product. As such, a controlled substance analogue is a substance considered pharmacologically or structurally similar to a Schedule I or Schedule II product but is not approved for sale in the U.S. market.

**DEA Registration**

Controlled substances constitute about 10% of all prescriptions written in the United States. In 2017, 88% of physicians were reported to be prescribing controlled substances.

Under the Controlled Substances Act, a closed system of drug distribution is established for managing controlled substances by qualified medical practitioners. The federal statutory provisions are designed to create a legal distribution chain for controlled substances based on both the registration of licensed prescribers and documentation of prescribing and dispensing activity.

To prescribe controlled substances for medical uses, physicians, dentists, nurse practitioners, optometrists, veterinarians, physician assistants, and other licensed practitioners must apply for a DEA registration number. Such registration is granted by the DEA based on the applicant’s medical license and ability to meet various certification requirements.

With DEA registration, a physician or other practitioner is assigned a DEA number that allows them to write prescriptions for legal controlled substances. This registration system also provides the DEA with the means to track and monitor prescribing activities, including tracking who is prescribing the substances and the quantities prescribed. Notably, a DEA number follows a specific informational format comprised of two letters, six numbers, and one check digit. The format is designed to identify the prescriber and verify their registration status. Accordingly, pharmacies, health clinics, HMOs, and health insurers are required to use a provider’s DEA number to verify their eligibility to prescribe controlled substances.

To clarify, a physician or other qualified clinician requires a DEA number to prescribe controlled substances for medical use. But, of course, not all prescription medications are considered controlled substances. Antibiotics and blood pressure, cholesterol, and diabetes medications, for example, are categorized as noncontrolled substances. For this reason, a prescribing practitioner who does not prescribe controlled substances can legally practice without a DEA number. And yet, because most pharmacies and insurance companies use the DEA number to identify health care providers, working without one could be very difficult for a prescribing practitioner.

Furthermore, in some instances, state pharmacy regulations might be interpreted to require a DEA number for all prescriptions. Thus, while the use of the DEA number for identification purposes is not a DEA-approved practice, it has become a practical reality in the pharmacy corner of the health care system.

Additionally, individual health care providers use the National Provider Identifier as a unique health identifier. The National Provider Identifier is a standard identifier issued by the Centers for Medicare & Medicaid Services for transactions or services covered under the Health Insurance Portability and Accountability Act of 1996. When it comes to processing claims or fill-
Compliance Is Key
The management of prescription medications generally is a carefully regulated area of health care. With controlled substances especially, DEA rules combine with state requirements to create a rigorous regulatory tapestry that health care providers need to understand and comply with.

“In a medical practice, there can be both DEA rules and specific state rules for how to handle any kind of prescription controlled substance,” says David J. Zetter, lead consultant at Zetter HealthCare in Mechanicsburg, Pennsylvania. “If a physician is still using prescription pads, for example, there have always been rules on where those have to be kept or locked up, and not just left out on someone’s desk. Of course, it’s different today with electronic health records and so much being done electronically, via fax into a pharmacy, and so on. But if you’re dispensing any prescription products from within your organization, there are certain rules and requirements the practice should be complying with.”

Indeed, when health care providers violate DEA rules, however inadvertently, problems can ensue. A cautionary tale is offered by Zetter of the consequences when even what can be considered a minor rule is violated. “A medical practice I worked with got in trouble with the DEA for not maintaining the original copies of the DEA registration certificates for each provider with a DEA number,” he reports. “This was a [medical] practice with a large number of providers and multiple tax IDs. The practice paid the DEA registration fees for each of their providers.”

When a health care provider successfully applies for a DEA number, the certificate from the DEA is mailed to the provider, says Zetter, who is also a past president of the National Society of Certified Healthcare Business Consultants. “The original document from the DEA has to be maintained on-site at the practice,” he explains. “In this case, the practice wasn’t … They were unaware of the requirement. Instead, they had duplicate copies of the DEA certificates downloaded from the DEA website. As a result, they ended up coming under a memorandum from the DEA that they were now being monitored.”

Consequently, every time the practice applies for a new DEA certificate, it must first communicate in writing their intention to do so to the regional DEA office in their state. The practice then has to wait 10 days before formally submitting the application for a new DEA registration number. This requirement will be maintained until a date determined by the DEA, says Zetter.

Insight on On-Site Storage
For clinics such as urgent care or other facilities that store controlled substances on-site, ensuring drugs are kept secure is a top priority. For example, Zetter describes an urgent care practice he visited at a newly built Florida facility. “All the drugs they prescribe are kept in a locked room,” he reports. “Every bin [identifies] exactly which drug is in it. All the drugs are logged, with lot numbers and other identifying information so the practice can track every bottle or drug that enters the facility. This is important because they’re always rotating their supplies, making sure nothing is getting old or out of date, and tracking things of that nature. They are also monitoring access to the room, documenting who enters the room and at what time. No one can just go in and pull some drugs out. The practice is always making sure that the inventory is safe and secure.”

Practice procedures and protocols for managing on-site controlled medications should be formally documented in the procedure manual, advises Freda Miller, CMA (AAMA), a former administrator for an urgent care practice in Juneau, Alaska. “If and when things do change regarding any class of medication of drugs,” says Miller, “you can then change whatever you need to in your procedures manual to keep up with the compliance requirements.”

Miller describes the practice protocol she used to securely manage controlled substances: “We had a locked cabinet, and there were only two keys,” she says. “When the shift started in the morning, two people were assigned the keys to the locked cabinet where drugs were kept. It might be two different people the next day, but only two people ever had the keys so there was limited access. I also had a key because I would do a count of the drugs every week to make sure the counts I was receiving were accurate.”

As an experienced administrator, Miller emphasizes the importance of up-to-date record keeping. “Don’t ever let the paper-

DEA Office Inspection Tips
The Drug Enforcement Administration (DEA) is authorized to inspect any physicians who met the requirements of the Drug Addiction Treatment Act of 2000 (DATA) to obtain waivers.

The DEA will inspect a DATA-waivered physician every 15 years from when they are approved to prescribe buprenorphine, with the first inspection usually taking place within the first three years after they are initially waivered. If a physician applies for a higher patient limit, then that 15-year inspection period renews from the date their higher limit is approved, and they will likely be inspected again within the first three years after their patient increase.9

The DEA inspector may ask the DATA-waivered physician to provide the following details18:
- Current DEA registration denoting waivered status
- Patient prescription log
- Patient dispensing log (if dispensing)
- Safe and secure area where buprenorphine-naloxone combination and buprenorphine stock bottles are stored
- A list of patients receiving buprenorphine-naloxone or buprenorphine prescriptions (the list may identify patients by codes or numbers to protect patient privacy)
- Physician’s access to behavioral health professionals
work on the drugs you manage get behind or be inaccurate,” she says. “If the paperwork is behind or something doesn’t seem right, stop right then and go back and get it figured out before you let any time pass. You have to be able to show exactly what has happened to the drugs you manage for a two-year period. You don’t want to get into a situation where there might be a breach in your protocol that you didn’t discover right away just because you didn’t keep up with your end of the paperwork.”

Managing the Opioid Crisis

In recent decades, another area of concern for the DEA involves the rising incidence of opioid overdose deaths. From 1999 to 2019, nearly 500,000 people died from opioid overdoses. In 2019, more than 70% of the 70,630 drug overdose deaths that occurred in the United States involved an opioid drug.

This epidemic of opioid overdose deaths began in the 1990s with increased legal prescribing of opioid medications. In the past decade or more, however, there has been a shift toward an increase in deaths attributed to illegal heroin use. Since 2013, overdose deaths due to the use of fentanyl, an illicitly manufactured synthetic opioid, have significantly increased.

“The misuse of opioids is a public health crisis,” says Shawn A. Ryan, MD, MBA, a member of the American Society of Addiction Medicine (ASAM) board of directors. Recognizing the scope of the opioid crisis in society, ASAM works to support an improved understanding of opioid addiction and access to effective treatments for patients with opioid use disorder (OUD).

“Our organization is a physician and other clinician membership group of over 6,000 members that’s focused on increasing access to evidence-based addiction treatment and education around all facets of addiction medicine for medical staff and the public,” remarks Dr. Ryan. “We’re also involved in furthering improvement in the quality standards in addiction medicine, not just improving access to care.”

ASAM and other medical groups also advocate at the policy level for the medical needs of patients with OUD and substance use disorder. This includes addressing the impact of DEA rules and regulations on the management, availability, and dispensing of prescription medications used in treatment.

“The DEA and regulation of controlled substance prescribing and distribution is necessary,” says Dr. Ryan. “Of course, it’s not an exact science because humans and medicine and patient care are so complicated. It’s a little tough to write rules that address all patients at all times in all scenarios. That being said, part of the opioid crisis is present because of underregulation and limited oversight of opioid distribution from the 1980s to the 2000s. For this reason, regulation and oversight is a necessary component of controlled substance and prescribing distribution.”

Indeed, the regulatory role of the DEA in health care is a complex one—and not always without criticism or varying assessments of its effectiveness. For this reason, Dr. Ryan says health care providers should not overlook opportunities to share their input and perspectives with health care regulators involved in setting health care policy.

“It is important for health care providers to share their expertise and experiences working with drug addiction issues related to controlled substances with the DEA and other state boards,” says Dr. Ryan. “I’ve worked with them, and I have a lot of respect for the challenges in front of the DEA. Of course, some folks are very binary on the DEA—that it’s good or bad or whatever they may feel about it—but … its role is multidimensional. It’s complicated. I think what we need is to advocate for medical providers in every setting, including medical staff, to communicate as much as they can, within reason, the practice realities.”

As Dr. Ryan notes, invitations for public comment on regulatory rule changes are often part of the federal and state policymaking process. “Medical practitioners should not ignore notices or invitations from the DEA or a state board of pharmacy medicine for public comment on issues related to how controlled substances will be prescribed or regulated, including concerns with telehealth policies,” he says. “We need to take the time to comment and not let that email from the DEA fly by. Whether it’s a single practitioner, a practice group manager, or a health system administrator involved in the pharmacy supply chain with responsibilities related to controlled substances, they need to speak up and be heard.”

In its oversight capacity, the DEA—in collaboration with the FDA—establishes production quotas regulating the available supply of prescription opioid medications. In recent years, these production quotas have been steadily reduced for such medications. In fact, the production of widely used opioid pain medications such as oxycodone and hydrocodone has declined by more than half over the most recent five-year period. Concurrently, opioid prescriptions have also declined.

Notably, the American Medical Association (AMA) and other medical leaders have expressed concerns that DEA efforts to contain misuse of opioids unfairly stigmatize the legitimate use of prescription opioid medications. In turn, these concerns spill over into related criticisms regarding opioid prescribing guidelines adopted by the Centers for Disease Control and Prevention in 2016. The AMA fears that arbitrary limits and other restrictions on opioid prescribing hurt patients who have legitimate needs for opioid medications.

“The nation no longer has a prescription-opioid-driven epidemic,” writes James L. Madara, MD, executive vice president and CEO of the AMA, in a 2020 commentary on
the “CDC Guideline for Prescribing Opioids for Chronic Pain, 2016.” We are now facing an unprecedented, multifactorial and much more dangerous overdose and drug epidemic driven by heroin and illicitly manufactured fentanyl, fentanyl analogs, and stimulants. We can no longer afford to view increasing drug-related mortality through a prescription opioid-myoic lens.”

Regulating Medication Assistance
Health care leaders will continue to assess these complex issues. The AMA, ASAM, and other advocates for addiction medicine support a comprehensive public health approach to effectively address the harms caused by the misuse of opioids. The urgency of this advocacy is apparent in the social costs of controlled-substances misuse evident in the epidemic of opioid overdoses, emergency room visits, deaths, and untreated substance use disorders.

One important treatment tool in the campaign against opioid addiction involves prescription buprenorphine. Approved by the FDA in 2002, buprenorphine relieves withdrawal symptoms and pain while also helping patients who have OUD to normalize brain function. With methadone and naltrexone, buprenorphine is one of three FDA-approved medicines for treating opioid dependence.

The use of buprenorphine is considered a medication-assisted treatment and medication for opioid use disorder. As such, buprenorphine is prescribed as part of a comprehensive treatment plan that typically includes counseling or other behavioral health services.

Notably, buprenorphine is the first medication for patients with OUD that can be legally prescribed or dispensed in medical practices, outside of opioid treatment programs. Buprenorphine’s availability in medical practices has increased access to treatment for many patients.

Qualified practitioners who wish to administer, prescribe, and dispense buprenorphine in a practice setting are required to file an application for a
buprenorphine waiver certification with the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration. In turn, prescribing practitioners are subject to regulatory limits, depending on their level of training and how many patients they may treat with buprenorphine at any one time. Without a granted exemption, many practitioners are limited to treating no more than 30 patients at a time.\textsuperscript{15}

Unfortunately, 1 in 5 pharmacies refuse to dispense buprenorphine to patients.\textsuperscript{14} Some pharmacies reportedly are reluctant to dispense buprenorphine due to fears over the DEA’s reputation for what some consider overzealous enforcement of controlled substance rules. Unfortunately, despite buprenorphine’s reputation as a valued medication for OUD, many patients encounter barriers in accessing this medication.\textsuperscript{16}

“Regulation and oversight are necessary parts of the system for prescribing and dispensing controlled substances,” says Dr. Ryan. "But it is also important that we recognize the different controlled substances and how they need to be controlled and managed. For example buprenorphine—the most popular brand name is Suboxone—should not be as restricted as the rest of the opioid controlled-substance family. Yet what we see at the patient level are challenges for patients when they go to the pharmacy to get their medications for their opioid addiction. These are patients who need to stay on their medication-assisted treatment for OUD. This is because buprenorphine, which is a partial agonist opioid but an opioid nonetheless, gets caught up in the attempt to find the right regulatory framework in the management of opioids.”

**All-Out Outreach**

Obviously, opioid misuse constitutes a significant public health issue. As the AMA, ASAM, and other health leaders acknowledge, the goal of public health policy should be to ensure every patient in need has access to the full array of appropriate treatment options. In this context, the discussion of DEA rules and regulations for controlled substances invariably touches upon many larger public and community health issues.

Thanks to medical advocacy, for example, community access to the overdose-reversal drug naloxone (Narcan) has become an important component of the public health response to the opioid crisis. Medical and safety first responders, community health activists, and others are helping to bring this life-saving medication, which quickly and safely reverses an opioid overdose, into communities at risk for heroin and opioid addiction and misuse. Additionally, physicians are able to co-prescribe naloxone, along with their regular opioid prescriptions, to patients in treatment for OUD.

One individual with experience addressing the challenge of community drug addiction is Lee Rusch, director of the West Side Heroin/Opioid Task Force in Chicago. The task force works in partnership with community leaders, the Chicago Department of Public Health, area hospitals, and others to improve direct access to health care services for people who use addictive drugs. This work includes training volunteers and distributing naloxone in communities hard-hit by opioid overdose and opioid-related deaths.

“About 40% of all opioid overdose deaths in Chicago occur in a group of neighborhoods on the city’s west side,” says Rusch. “Our response to opioid overdoses
in these neighborhoods has been to get naloxone, or its [brand-name] nasal spray version, Narcan, out into the community. The goal is to make its use ubiquitous in the community—to make the presence of naloxone almost like having smoke detectors in homes.”

Community outreach initiatives such as this complement the work of health care providers who offer in-office clinical care for OUD and substance use disorder. As such, Rusch encourages health care providers, including staff who he notes often live in the same communities in which they work, to take the time to better understand the reality of drug addiction issues in their local community.

“I would encourage people working in health care to get out and see what’s happening in their community, meet the providers who are closest to the issue, and continually look at ways to improve care in the system,” he says. “It’s estimated that 60% of people who have OUD or substance use disorder have co-occurring disorders, and so it’s important to understand that we’re dealing with something much more complex than somebody who has a choice to ‘get high’ today. This is often part of a larger health challenge of trauma-informed care.”

While exploring the role of the DEA in the regulation of controlled substances, health care professionals should not lose sight of these larger medical and societal challenges. “In a sense, we are trying to tilt the system in a certain direction—to align community outreach more closely with those in health care who are already doing great work in harm reduction and destigmatizing addiction issues,” notes Rusch.

In the health care system, issues of regulatory responsibility for prescription controlled substances similarly intersect with the many patient care challenges involved in addiction medicine, pain management, and related clinical and treatment issues. In this sense, oversight of prescription medications classified as controlled substances requires an ongoing assessment of a complex balance of regulatory, policy, and medical concerns.

In the end, the management of prescription controlled substances in ways that are safe and benefit patients and society requires cooperation and engagement from everyone—regulators, clinicians, community leaders, and patients—to prevail in this vital part of health care. ✦

References


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**Drug Enforcement Administration**


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