

# Controlled Substances & Emergency Response

## Fact Sheet: Frequently Asked Questions

March 2019

The regulatory landscape around controlled substances is complex and evolving. A myriad of healthcare and public stakeholders are engaged in this field across the spectrum of care, including insurance providers, clinicians, pharmacists, mental health professionals, regulatory bodies such as the Drug Enforcement Agency, and more.

During disasters, complexity increases for patients and providers alike, with requirements of transporting, dispensing, refilling, and administering controlled substances frequently taking on a new sense of urgency or manifesting in new ways. These factors affect access to new or continued treatment for patients during a disaster.

This fact sheet is intended to:

- Outline current guidance that exists regarding the prescribing and dispensing of controlled substances during a disaster;
- Detail the challenges that patients, healthcare providers, and emergency managers experience related to the provision of controlled substances during disasters; and
- Highlight areas of opportunity for developing solutions and targeted planning.

This ASPR TRACIE fact sheet was developed to serve as an information resource for our stakeholders (e.g., regional ASPR staff, healthcare coalitions, healthcare entities, healthcare providers, emergency managers, and public health practitioners). It does **not** represent official agency policy, nor is it meant to be all encompassing. We welcome you to [reach out to us](#) if you have additional questions or recommended resources for inclusion.

### Q: What are controlled substances?

Controlled substances are a group of highly regulated drugs with a known potential for abuse, dependence, and related harm. The [U.S. Department of Justice Drug Enforcement Administration \(DEA\)](#) classifies controlled substances into five categories, according to the level of potential abuse by a user, in accordance with the [Controlled Substances Act](#) (Table 1).

The Controlled Substances Act—passed in 1970—directs the DEA in the development of rules and regulations that must be followed when prescribing, dispensing, administering, transporting, and storing controlled substances.<sup>1</sup> In order to work with controlled substances, any person or entity who

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<sup>1</sup> The DEA maintains a [complete list of controlled substances](#), which can be found in their list of resources related to [controlled substance schedules](#).

participates in these processes must [maintain current registration with DEA](#). This includes prescribers, pharmacies, drug manufacturers, and wholesaler distributors of controlled medications.

Table 1. Federal Schedule of Controlled Substances <sup>2</sup>			
Schedule	Description of Schedule	Examples	Prescription Refills
I	No current acceptable medical use, high potential for abuse	heroin, "LSD," "ecstasy"	N/A
II	High potential for abuse and dependence, considered dangerous	hydrocodone, methylphenidate (Adderall®), methadone	Schedule II prescriptions may not be refilled
III	Moderate to low potential for abuse	Codeine, ketamine, testosterone, buprenorphine	Refill as authorized on prescription; up to 5 refills over 6 months
IV	Low potential for abuse and dependence	Alprazolam (Xanax®), diazepam (Valium®), Zolpidem (Ambien®), Tramadol	Refill as authorized on prescription; up to 5 refills over 6 months
V	Lowest potential for abuse, containing limited quantities of narcotics	Pregabalin (Lyrica® <sup>2</sup> ), Robitussin AC®	Small quantities allowed without a prescription in some states, per state law, typically through the use of a logbook. Most states require a prescription, however.

**Q: How are controlled substances generally dispensed and administered in outpatient settings?**

There are two ways in which patients can receive controlled substances in outpatient settings. These distinctions are important, as they may be affected differently during emergencies.

1. A patient may be prescribed a controlled substance by a licensed provider to be filled by a DEA-registered pharmacy. Controlled substances are used to treat a range of physical and/or mental ailments, which can include the treatment of chronic or acute pain with narcotic analgesics or the use of amphetamines to treat disorders such as attention deficit hyperactivity disorder (ADHD) and narcolepsy.
2. A registered [opioid treatment program \(OTP\)](#) may administer or dispense controlled substances. OTPs exist to treat narcotic dependence disorders and are accredited by the U.S. Department of Health and Human Services' [Substance Abuse and Mental Health Services Administration \(SAMHSA\)](#). Examples of OTPs include methadone clinics and clinics with physicians certified to provide buprenorphine treatment. Through the treatment program, patients receive Medication-Assisted Treatment (MAT) for drug use disorders, including medications such as buprenorphine and methadone which are highly regulated and can only be dispensed through an OTP. A provider can be granted a waiver to prescribe short courses of buprenorphine, which is quite common. More detail on waivers is provided under the existing guidance for medical professionals on page 3.

<sup>2</sup> [Gabapentin](#), commonly used to treat nerve pain, epilepsy, and restless legs syndrome can be subject to abuse. Although it is not on the federal list of controlled substances, it is controlled in [some states](#).

## Q: Why does this matter in the field of emergency response?

Following a disaster, one of the most crucial patient care needs is to maintain regular treatment for acute and chronic disorders, including those that involve controlled substances. For prescriptions that are not categorized as controlled substances, this often involves obtaining an emergency prescription refill in advance of an impending natural disaster or replacing medications that are lost or damaged during the event. However, when patients are displaced out of state or otherwise unable to reach their home pharmacy and/or primary care physician, they may experience greater difficulty accessing necessary medications, especially controlled substances such as anti-anxiety and analgesic medications. For example, being unable to access their original prescribing doctor may complicate a patient's ability to obtain a new prescription to take to a new pharmacy while displaced.

**Financial stressors** can also have an effect on patients' ability to obtain or prioritize medication refills during disasters. Costs related to home repairs, replacing belongings, and even evacuation can impact financial resources typically put towards healthcare and medication costs. Locating in-network providers and considering out-of-pocket costs when evacuated or displaced are common stressors as well, even with insurance waivers in place.

In addition to the patients that need refills for their prescribed controlled substances, there is another set of patients that are impacted by the regulations of controlled substances. Briefly introduced earlier, these are patients that receive treatment for opioid use disorders at an OTP. These facilities can just as easily be affected by a disaster as other healthcare entities. If licensed OTP facilities become damaged during a disaster, patients are prevented from accessing their normal mode of treatment. While facilities are **required to have an emergency response plan** in place that includes a plan for patient treatment at another certified facility, these plans can be challenging for a myriad of reasons, such as a patient evacuating out of state.

### Challenges Patients Face Obtaining Controlled Substances During Emergencies

- Even during declared states of emergency, pharmacies cannot override "refill too soon" restrictions on controlled substances, as can be done in some cases with non-controlled prescriptions.
- Prescriptions are not as easily transferred, if transferrable at all, due to regulations on how controlled substances are dispensed at new pharmacies.
- Evacuated or displaced patients can encounter challenges in seeing a certified provider if they are unable to reach their home pharmacist or physician.
- The financial impacts of a disaster can add additional challenges, such as balancing home repair costs with replacing lost medications.

## Q: What guidance and/or resources exist regarding controlled substances and emergency response?

### *For Healthcare Professionals*

#### *Legislation, Regulation, and Policy*

- DEA regulations outline [requirements for a valid prescription](#) to be dispensed and refilled, and policies on the issuing, dispensing, and refilling of prescriptions for controlled substances as well as some specific cases, such as when prescriptions need to be transferred between pharmacies. Challenges that arise during the aftermath of a disaster are often complex, given the generally strict requirements of controlled substance prescriptions, including a pharmacist needing to receive the prescription from the original prescriber.
- [Pharmacist scope of practice](#) also varies by state, which has a direct impact on patients who are evacuated out of state or pharmacists involved in an event that affects multiple states. During disasters, scope of practice is often expanded to give pharmacists a greater ability to respond to the resulting medical needs. Because of these complexities, pharmacists are advised to use their professional judgment in accordance with any legal limits.
- The [Protecting Patient Access to Emergency Medications Act of 2017](#) amends the Controlled Substances Act in order to give emergency medical service providers the ability to register with DEA and handle controlled substances as such.
- The [Buprenorphine Waiver Management](#) process allows DEA-registered physicians and other DEA-registered medical professionals, such as nurse practitioners and physician assistants, to dispense or prescribe medications that are traditionally administered in the context of an OTP. The [Drug Addiction Treatment Act of 2000 \(DATA 2000\)](#) allows individual practitioners to administer FDA-approved narcotic controlled substances in schedules III – V, including buprenorphine, for the purpose of narcotic addiction treatment, outside of an OTP. Qualifying physicians may treat up to thirty or one hundred patients, as determined by their individual authorization from the [Center for Substance Abuse Treatment \(CSAT\)](#). The DEA can approve changes to a physician's allowed number of patients from 30 to 100 if the initial authorization was submitted a year prior to the change.

#### *Drug Enforcement Agency (DEA) Resources*

- The DEA provides [emergency assistance](#) to registered facilities responding to a disaster. This support includes:
  - Assistance relocating a DEA-registered address;
  - Reducing obstacles to resupplying a registrant after supplies are destroyed;
  - Providing guidance on the legal disposal of damaged supplies; and
  - Supporting other activities that can present a challenge to medical professionals in the wake of a disaster.
- Those requiring assistance may send requests to the disaster relief email account ([natural.disaster@usdoj.gov](mailto:natural.disaster@usdoj.gov)) that is monitored 24 hours a day, 7 days a week.

- DEA maintains [diversion control field offices](#) throughout the U.S. that can provide guidance when a practitioner has questions about DEA regulations and compliance. Information and local field office contacts can be found on their website.

*Additional Resources and Systems*

- Different state [Prescription Drug Monitoring Programs \(PDMPs\)](#) can serve as a potential resource for prescribers and pharmacists, allowing them to view patients’ controlled substance prescription dispensing histories. The PDMP is a statewide electronic database – updated in real time – that collects and stores data on controlled substances dispensed within the state and allows certified providers to view the electronic prescriptions of controlled substances in their state. [PDMPs are managed by a state agency](#), which can include health departments, pharmacy boards, or law enforcement. Each state controls who has access to the database, and for what purpose.

PDMPs are an important tool in supporting prevention planning and represent a potential resource for prescribers and pharmacists supporting local response efforts, local laws permitting. However, healthcare providers still experience challenges in viewing out-of-state PDMP dispensing records in light of limited interstate data sharing capabilities.

**For Patients**

Patients are generally advised to first consult with their home pharmacist, primary care physician, and/or psychiatrist, as appropriate, to get the guidance needed to sustain their supply of or access to their controlled substance medications during an emergency, particularly when an event can be anticipated (e.g., a natural disaster or other another notice event). In such a complex field, where the regulation of substances is tiered, facility types vary, and many different payors are involved, comprehensive guidance available for patients is limited. Direct consultation and planning with healthcare providers is a critical first step. Additional publicly available resources are highlighted below.

*Seeking Prescriptions*

- A patient’s provider is the best resource for patients needing prescriptions for controlled substances. Patients are advised to work with their pharmacist, physician, and other providers in advance of a disaster to develop a plan for treatment maintenance should a disaster occur.
- During and after the disaster, the patient’s best course of action when attempting to get new prescriptions is to contact their original prescriber to request a prescription be electronically transmitted (if possible) or telephoned to the pharmacy of the patient’s choice. Although schedule II medications are not eligible for a verbal telephone prescription,

**Sample State Legislation**

As codified in Virginia law, the state board of pharmacy may [issue a waiver during declared emergencies](#) waiving certain requirements of the Drug Control Act and the Board’s regulations governing the practice of pharmacy. However, the law also explicitly states that it does not authorize the “administering or dispensing of controlled substances by persons whose scope of practice does not include such authority.”

they are eligible to be prescribed via electronic prescription, which may be a viable strategy as long as the prescribing physician has access to their e-prescribing system during the disaster. If the displaced patient uses a chain pharmacy, the pharmacy should be able to pull records, like valid prescriptions, from other pharmacies within the chain, so long as the same computer system is used by all pharmacies within the chain. However, schedule II medications cannot be refilled or transferred in most instances.

- State and territory [Boards of Pharmacy](#) may issue waivers that are activated after an emergency declaration has been made. These may include blanket waivers allowing pharmacists to refill a prescription without the original prescription, assuming the pharmacist exercises reasonable judgment. These waivers do not override federal regulations, including those of the DEA. Pharmacists and prescribers are still held to federal regulations for controlled substances.

### *Uninsured Patients*

For uninsured patients trying to obtain prescriptions for controlled substances, support may be available through the [Emergency Prescription Assistance Program \(EPAP\)](#), provided the program is activated and the medications the patient requires are covered by the program. EPAP is a federal assistance program that can be activated as a portion of the [Stafford Disaster Relief and Emergency Assistance Act](#) at the request of a state following a public health emergency declaration, and provides prescription medications, durable medical equipment, vaccines, and certain medical supplies at no cost to uninsured patients affected by a disaster. This resource is only available to patients if and when it has been activated following a disaster, a decision that is made jointly by Federal and state governments.

As stated on the program's [website](#), EPAP covers most drugs listed in the Express Scripts database (patients and providers can search for covered drugs and products on the [Express Scripts website](#)).

EPAP runs a hotline (1-855-793-7470) during activations for patients and providers who have questions about the program, eligibility, and coverage. Pharmacy programs can enroll in EPAP with Express Scripts, by calling the [Network Contracting and Management line](#) (1-888-571-8182), during non-disaster or in an active disaster time in order to have ability to dispense during the EPAP activation. The program has covered thousands of claims for controlled substances, primarily narcotics-analgesics, in the last decade, evidenced by information from factsheets on the program's utilization during [Superstorm Sandy](#) and Hurricanes [Gustav](#), [Irma](#), and [Maria](#).

### *Patients of OTPs*

For patients seeking an OTP facility, the [SAMHSA Locator](#) map can be used to find mental health and substance abuse treatment facilities or to get in touch with a provider in a given area if needed. The map is intended and designed to serve as a routine source of contact information and is not a disaster-specific resource.

A "guest dose" may be an option for displaced patients that do not meet the criteria for take-home medications. Due to the highly regulated nature of treatment at OTPs, patients will often need to work with their home prescriber to receive a guest dose at a new facility. The [American Association for the Treatment of Opioid Dependence, Inc. \(AATOD\)](#) has a set of recommendations for patients and clinics

transferring patients given special circumstances such as an emergency event. In [this guide](#), the AATOD recommends that patients carry their information sheet from their home facility, learn the appropriate point of contact at the new facility, provide appropriate identification and fees, and avoid presenting themselves in an unsuitable manner that would warrant refusal of treatment by the OTP. SAMHSA's [Federal Guidelines for Opioid Treatment Programs](#) references this source as an example of policy that is consistent with their own regulations.

## **Q: What challenges do patients face during a disaster?**

### ***Patients Seeking Prescriptions and/or Refills for Controlled Substances***

As described in Table 1, refills of controlled substances can only be obtained if the drug is not a schedule II controlled substance. (Schedule II substances must be newly prescribed every time a patient needs another supply.) In addition, emergency refill laws vary by state and are instituted by each state's [Board of Pharmacy](#). There is a gap in publicly available information for patients who have issues getting their most highly-regulated medication. Sources like the Center for Medicare & Medicaid Services guide, [Getting Medical Care and Prescription Drugs in a Disaster or Emergency Area](#), and those from the [American Association for Retired Person \(AARP\)](#) do not include any specific information on how obtaining a controlled substance may be more challenging or may require additional steps.

### ***Challenges Associated with Transferring Prescriptions***

If a prescription is created through the [Electronic Prescriptions for Controlled Substances \(EPCS\)](#) system, it can be transferred according to Federal regulations. (However, at this time, there are likely to be challenges with transferring unfilled Schedule II electronic prescriptions; such challenges are currently being addressed and should be resolved in the coming years as this technology evolves.) This is helpful to patients who are displaced and unable to reach their home pharmacist. This issue becomes more complicated for prescriptions issued orally or on paper. The transfer of an unfilled original prescription received in these formats cannot take place. Insurance companies and pharmacies may have additional policies regarding the transferal process to help prevent abuse and diversion. Not every case is clear cut and may require additional research to decide the correct course of action.

### ***Challenges Associated with Verifying Prescriptions***

State law may require that patients present identification when refilling a controlled substance prescription at a new pharmacy, or have the pharmacist verify their identity through the original prescribing practitioner or a verification of their health plan eligibility. This can be a hurdle for patients who may have lost many of their belongings, including important documents, after their homes are damaged by a disaster, or for patients who may have forgotten non-essential items while quickly evacuating their homes in advance of a disaster. It is up to State Boards of Pharmacy to relax or amend prescription regulations if they so choose.

### ***Challenges Faced by Patients Receiving Treatment from OTP Facilities***

Opioid Treatment Program facilities (OTPs) may be damaged, destroyed, or impossible for a patient to reach due to damage cause by the disaster. According to SAMHSA's [Disaster Planning Handbook for](#)

**Behavioral Health Treatment Programs**, OTPs are required to complete disaster planning in order to become certified. This handbook provides a comprehensive guide to emergency planning for those who manage OTPs, and includes a set of tools to assist with the planning process. Stakeholders in the field indicate that some uncertainty exists regarding the coordination of treatment for patients being evacuated across state lines. This can impact patients who are trying to manage their substance use disorder while dealing with a disaster that displaces them to another state. SAMHSA recommends that OTPs connect with social service providers to prevent issues of misunderstanding that may lead to discrimination against patients with substance abuse disorders.

### **The Impact of Disasters on Patients Seeking Opioid Treatment Programs**

In their **Disaster Planning Handbook**, SAMHSA outlines a few cases following Hurricanes Katrina and Rita of possible discrimination faced by patients. Patients seeking OTPs were either required to have police escorts when traveling from hurricane shelters to methadone clinics or denied access to a clinic despite having letters from physicians confirming that they were patients at the clinic.

## **Q: What challenges do healthcare providers and facilities face during and after a disaster?**

### **Pharmacies**

#### *Maintaining Active DEA Registration*

If a pharmacy is damaged by the disaster, they may choose to go through the process of **transferring their registration from one location to another**. The new facility must meet the standard facility requirements of the DEA. It takes the DEA approximately one day to authorize a relocated facility once the facility has received state approval for the relocation.<sup>3</sup> In some cases, a pharmacy may want to take additional steps before considering relocation, particularly if associated with a chain. Pharmacies that have sustained damage to their actual supply of controlled substances should work with their chain headquarters or contact their local DEA field office for guidance.

**DEA registration renewals** are an important consideration during disasters due to timing. Registration occurs at a set time during each month; a disaster overlapping with this window can delay the registration process. In some cases, healthcare providers are not able to issue new prescriptions, and in some states, cannot refill previous prescriptions. The DEA works closely with registered healthcare providers during

### **Federal Responders and Controlled Substances**

While federal stockpiles of controlled substances exist, this supply cannot be locally deployed for disaster support to the general population. Pharmacists have to work with their distributors in advance of an emergency to ensure they have an adequate supply of necessary medications.

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<sup>3</sup> Information gathered during an interview with a DEA official, December 12, 2018.



disasters to overcome this obstacle to patient care.

### *Safety and Security*

Facilities that have controlled substances in supply often need [increased security](#) during a disaster to prevent theft or provide crowd control, which may not be available due to the competing response demands on security and law enforcement. DEA advises DEA registrants to reach out to law enforcement in order to make law enforcement aware of their situation and need for added security.<sup>4</sup> Pharmacies may also partner with local law enforcement or the local DEA field office to secure controlled substances.

### ***Opioid Treatment Program Facilities***

Facilities specializing in narcotic-based treatment programs may also be damaged and unable to carry on normal operations during an emergency event. When attempting to transfer capabilities and DEA registrations, these facilities must follow tight regulations. One solution for handling the complexities that arise during a potentially chaotic emergency response period is the process providers can take to become [DATA Waived Physicians \(DWP\)](#)s. As described earlier in the list of guidance and resources that exist for medical professionals, there is a process that allows physicians and other medical professionals to dispense or prescribe medications that are traditionally administered in the context of an OTP, like buprenorphine. DATA waived providers may treat up to 30 or 100 patients at any one time, dependent on their level of authorization from the [Center for Substance Abuse Treatment \(CSAT\)](#). Individual states have the final say in deciding who has these waiver allowances, which [may complicate the work that providers do to treat patients](#). The DEA provides specific guidance on what physicians can do to obtain these waivers at their site, which includes important references to the Controlled Substances Act for providers to consider. The [Comprehensive Addiction and Recovery Act \(CARA\)](#) signed into public law in 2016 extends buprenorphine waiver privileges to [qualifying nurse practitioners \(NPs\) and physician assistants \(PAs\)](#) until Oct. 1, 2021. By taking advantage of this waiver, healthcare providers can ensure that patients maintain access to their treatment for substance use disorders.

### **Q: What challenges do supply chain components face during and after a disaster?**

Controlled substances cannot be easily moved from a facility that is damaged to one that is operating. Medication transport requires increased security during a disaster, especially for controlled substances. This, in turn, requires a request be put into the county Emergency Operations Center (EOC) for an escort when entering the restricted area. This process is explained in the DEA's [Controlled Substances Security Manual](#). Moreover, local DEA field offices should be contacted when transferring controlled substances among facilities. DEA requires that a [222 form](#) in paper or electronic format (i.e., through the [Controlled Substances Ordering System](#) or CSOS) be submitted to transfer substances such as methadone. Physical access to a facility for delivery may be limited as well, due to access requirements, safety, or transport capabilities. Moreover, [requirements for secure storage and handling of narcotics](#) makes stocking them

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<sup>4</sup> Information gathered during an interview with a DEA official, December 12, 2018.

in any temporary facility difficult. Distributors of controlled substances may still face significant issues gaining access to new facilities after a disaster. There may be restricted areas in evacuation zones that require official re-entry certification for emergency personnel to access.

### **Practicing Preparedness: Emergency Planning for Patients and Facilities**

There are concrete steps that providers can take to help prepare their patients maintain access to their medicines, including controlled substances. The following questions may be used by stakeholders to assess and develop their own preparedness procedures which can in turn positively impact patients.

- How does your facility's emergency plan address your stock of controlled substances and the associated planning needs?
- Does your facility have an internal protocol for the implementation of waiver processes during a disaster? How do you track critical changes in the emergency refill regulations?
- Do your facility's evacuation and relocation processes account for required security measures involved in the movement of controlled substances?
- If electronic systems to track prescriptions and supply/needs are inaccessible, how is the dispensing and recording of controlled substance prescriptions handled?
- What pre-event guidance can you share with patients regarding controlled substances? How can you ensure that patients with prescriptions for controlled substances are empowered and informed before a disaster strikes?
- Do you know how and when to contact the public agencies that can support your facility's potential needs during a disaster? This may include your local DEA field office, your sheriff's department, your local police, and your county, city, and state EOCs.

#### ***Special OTP Considerations***

- If the patient cannot access their regular opioid treatment program (OTP) facility, are plans set in place to ensure that patients are aware of accessible back-up facilities?
- How are patients provided with the appropriate information sheets required upon transferal to a new facility for a guest dose?

#### **Additional Resources**

- [Mental Health and Substance Abuse Emergency Response Procedures \(US Code Title 42, Chapter 1, Subchapter D, Part 51d\) – US Law](#)
- [Pharmacy Topic Collection – ASPR TRACIE](#)
- [Emergency Prescription Assistance Program \(EPAP\): Overview Fact Sheet](#)

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