THE FENTANYL EPIDEMIC: STATE INITIATIVES TO REDUCE OVERDOSE DEATHS



DrugStrategies





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Fentanyl overdoses killed more than 28,000 Americans in 2017--- 40 percent of all drug overdose deaths reported nationwide.¹ The CDC's preliminary data for 2018, released in July 2019, reported a 14 percent increase in fentanyl related deaths during the past year (28,000/2017 to 32,000/2018)² even as all other drug overdose deaths have declined for the first time since 1990. Most of that decline can be attributed to reductions in overdose deaths from prescription opioids.³ Thus, fentanyl is now driving the most lethal opioid epidemic the U.S. has experienced in the past century.

Drug Strategies, a nonprofit organization created in 1993 with support from major foundations, convened several meetings in 2018 to identify promising strategies to address the fentanyl crisis. Philip Heymann, Chair of the Drug Strategies Board of Directors, and former U.S. Deputy Attorney General, along with Mathea Falco, President of Drug Strategies, brought together top officials from the U.S. Postal Service, the Department of Justice, FBI, Customs, DEA, FDA, as well as experts from Yale and Harvard Law Schools. After extensive discussions, participants concurred that while federal enforcement and interdiction efforts remain critically important, initiatives at the state level can have immediate impact in reducing fentanyl overdose deaths.

In 2017, just nine states were responsible for nearly 60 percent of all fentanyl related deaths in the U.S. In order to increase public awareness of both the scope of the problem and concrete steps that states have taken to reduce this death toll, Drug Strategies developed this report focused on those states that have been most seriously affected. The report offers seven recommendations that should encourage states to take effective action.

In developing this report, Drug Strategies collaborated closely with Shatterproof, a national organization committed to ending the devastation addiction causes families. Founded by Gary Mendell in 2012 after the death of his son, Brian, as a result of his addiction, Shatterproof aims to make the treatment industry more transparent and accessible. Their work is inspired by Mendell's vision that we can reduce the opioid epidemic by half with the information we have today. Their collaboration has been invaluable in creating this report and providing in-depth data on current limitations on treatment that prevent people from getting the help they need. Fentanyl, a synthetic opioid that is 50-100 times more potent than heroin, is fueling the most lethal drug epidemic America has experienced in the past century. As early as 2015, fentanyl related deaths were climbing rapidly in the industrial Midwest, in states including Ohio, Illinois and Michigan.⁴ By 2017, fentanyl accounted for over 28,000 of the 70,000 total reported drug overdose deaths in the country, targeting Appalachia, most of the Midwest, and the Northeast.⁵ By the time this report was developed in mid-2019, the fentanyl epidemic had reached the West Coast. Early reports in San Francisco indicate that fentanyl related deaths now surpass deaths from heroin or prescription painkillers, such as Vicodin and Oxycontin.⁶ In July 2019, CDC released preliminary data on drug overdose deaths for 2018, estimating an increase of more than 14 percent in fentanyl overdose deaths in 2018 (from 28,000 in 2017 to 32,000 in 2018).⁷ Although this epidemic has not spared any demographic group, CDC data for 2017 show that those most affected are whites (84.8%), males (72.1%) and people ages 25 to 54 (76%).8

Effective action is urgently needed, particularly at the state level where initiatives aimed at fentanyl overdoses can have immediate impact in reducing the death toll. This report reviews responses from nine states that suffered the highest number of fentanyl overdose deaths from 2011 through 2017 (Ohio, New York, Florida, Massachusetts, Pennsylvania, Maryland, Michigan, North Carolina, and Illinois). In 2017, these nine states were responsible for nearly 60% of all fentanyl deaths in the United States.⁹ In addition to the nine states, the report includes efforts by West Virginia and New Hampshire, because they reported the most disproportionate rates of fentanyl overdose deaths compared to their population size.¹⁰ This report highlights some of the most promising efforts to address the crisis taken by these seriously affected states, concluding with several state-level policy and practice improvement recommendations to reduce fentanyl overdoses and deaths. These recommendations include improved data collection, using specially designed software; standardized testing and death certificate reporting; promoting prevention strategies such as fentanyl test strips, naloxone distribution programs, reducing stigma, and public education campaigns.

The report also recommends expanded access to treatment, including eliminating Medicaid restrictions on access and reimbursement for medication for addiction treatment. While many states have taken some steps to address the fentanyl crisis, few, if any, have implemented all the recommendations in this report. It is imperative that states take a comprehensive approach to combating this epidemic, because they will be effective in reducing the rapidly increasing fentanyl death toll. Information was drawn from databases, peerreviewed literature, websites, press-releases and news articles. The Center for Disease Control and Prevention (CDC) Wonder Database and National Health Statistics Data Base provided a wealth of information on fentanyl related deaths, including complete data for 2017 and preliminary data for 2018. To query the database, the following codes were used: X40-44 (unintentional death), X60-64 (suicide), X85 (homicide), Y10-14 (undetermined intent) as the cause of death. The code T40.4 (Synthetic Opioid other than Methadone) was used as the contributing cause of death. Generally, data were divided by state and year.

We also analyzed utilization management restrictions applied by 11 state Medicaid programs to buprenorphine and naltrexone formulations used in the treatment of opioid dependence. We used data provided by MMIT, a data vendor with access to formulary coverage and restriction criteria for more than 98% of people covered by insurance. In the fee-for-service (FFS) market, we captured if the state plan imposed a prior authorization or step therapy requirement for each formulation, whereas, in the managed care market, we present the percentage of plans that impose these restrictions.

For daily buprenorphine and naltrexone formulations, we analyzed utilization management practices solely applied in the pharmacy benefit. Since injectable and implant buprenorphine and naltrexone formulations may be covered in either the medical or pharmacy benefits, we report the least restrictive practice applied between a plan's medical or pharmacy benefits. For some queries, race, gender, and age group were included as additional variables. The data retrieved from CDC was then used to create graphic visualizations using Tableau Software. Second, literature reviews were conducted of peer-reviewed sources. Finally, on-line searches using Google and other search engines were used to gather additional information from news articles, organization websites, press releases, and relevant state laws.

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THE FENTANYL EPIDEMIC

In 2017, fentanyl accounted for more than 28,000 drug overdose deaths, 40 percent of the total 70,000 drug overdose deaths reported in the United States.¹¹ Fentanyl related deaths continue to climb sharply, making this the most lethal drug epidemic America has experienced in the past century. Early reports from the CDC indicate more than a 14 percent increase in fentanyl overdose deaths from 2017 to 2018, 28,000 deaths to 32,000 deaths respectively.¹² As shown in Figure 1, as early as 2015, one can see a "fentanyl region" forming in the industrial Midwest. By 2017, that region covers the entire Appalachia, most of the

Midwest and the Northeast. Figure 1 also highlights how fentanyl deaths have increased in nearly every state each year. From 2015 to 2018 (preliminary data), fentanyl deaths nationwide have more than tripled.¹³

Across the United States, the demographics of fentanyl victims are roughly consistent. **Approximately 3 out of every 4 deaths are male (72.1%); 8 out of 10 are white (84.8%); and 3 out of 4 victims** (76%) are 25 to 54 years old.¹⁴

For this report, Drug Strategies researchers selected states that suffered the highest number of fentanyl related overdose deaths from

the beginning of 2011 through 2017 (Table 1), as well as states that experienced the most disproportionate rates of overdose deaths compared to their population size (deaths per 100,000)¹⁵ (Table 1 and Figure 2).

Ohio, New York, Florida, Massachusetts, Pennsylvania, Maryland, Michigan, North Carolina, and Illinois reported the highest total number of fentanyl related overdose deaths from 2011 through 2017. **In 2017 alone, these nine states were responsible for nearly 60% of all fentanyl deaths in the United States.**¹⁶ In addition to the nine states, this report includes West Virginia and New Hampshire, because they reported the highest numbers of fentanyl related overdose deaths compared to their population size. Ohio, Maryland, Massachusetts were also in this category (highest number of deaths per 100,000).¹⁷

Table 1: Number of Fentanyl-Related Deaths Reported by the CDC in 2016 and 2017¹⁸

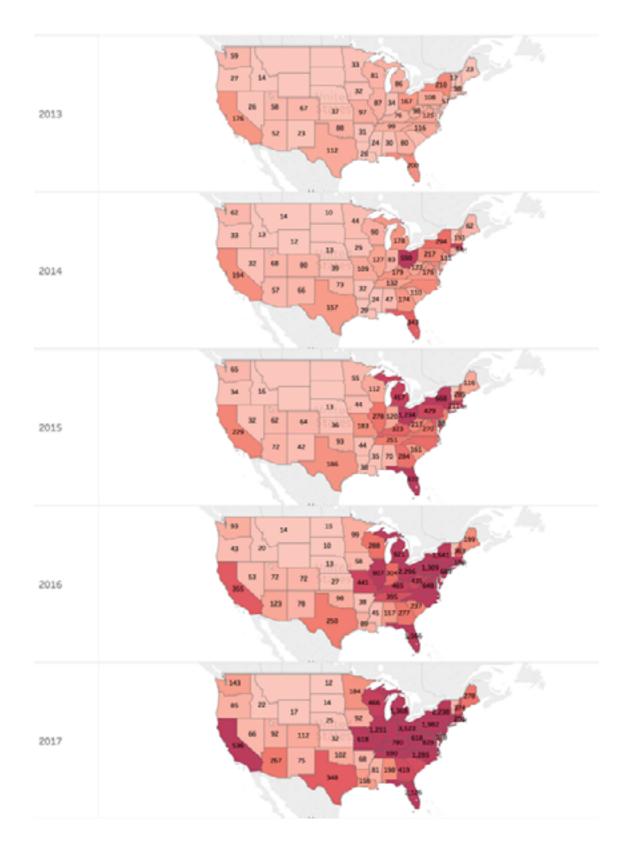
| State | 2016 Total # of deaths (CDC) | 2016 Deaths per 100,000 (CDC) | 2017 Total # of deaths (CDC) | 2017 Deaths per 100,000 |
|----------------|---------------------------------|----------------------------------|---------------------------------|----------------------------|
| Ohio | 2,296 | 19.75 | 3,523 | 30.22 |
| New York | 1,641 | 8.27 | 2,238 | 11.27 |
| Florida | 1,566 | 7.58 | 2,126 | 10.13 |
| Pennsylvania | 1,309 | 10.24 | 1,982 | 15.48 |
| Massachusetts | 1,550 | 22.71 | 1,649 | 24.04 |
| Maryland | 1,091 | 18.11 | 1,542 | 25.48 |
| Michigan | 921 | 9.27 | 1,368 | 13.73 |
| North Carolina | 601 | 5.98 | 1,285 | 12.51 |
| Illinois | 907 | 7.07 | 1,251 | 9.77 |
| West Virginia | 435 | 23.79 | 618 | 34.03 |
| New Hampshire | 363 | 27.19 | 374 | 27.85 |

THE DEMOGRAPHIC OF THE FENTANYL EPIDEMIC:

- About 3/4 deaths are male
- ➡ 8/10 are white
- 3 /4 victims are
 25 54 years old

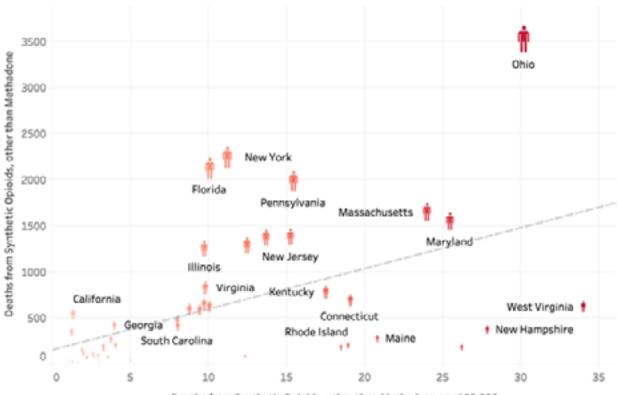
THE FENTANYL EPIDEMIC

Figure 1: Deaths from Synthetic Opioids Other Than Methadone by State and Year¹⁹



THE FENTANYL EPIDEMIC

Figure 2: 2017 Deaths from Synthetic Opioids Other Than Methadone by State²⁰ (Total Number v. Number per 100,000)



Deaths from Synthetic Opioids, other than Methadone per 100,000

Nearly every state in the U.S. has suffered from the fentanyl epidemic. This report highlights some of the most promising efforts to address the crisis taken by those states that have been most severely affected. In addition, the report recommends policy and practice improvements for states to consider in their battle to reduce fentanyl overdoses and deaths.

OVERDOSE DATA COLLECTION & INFORMATION SHARING

Data collection, analysis and sharing of information are critically important in federal and state efforts to reduce overdose deaths. Healthcare professionals, law enforcement agencies, policy makers and others involved must have timely, accurate data to respond effectively to the rapidly evolving fentanyl epidemic.

Death certificates

Death certificates are one of the most efficient ways to obtain data on drug overdose deaths. However, death certificates are often incomplete and do not always specify which drugs are involved in overdose deaths.²¹ This is often due to limited personnel resources and funding as well as the lack of standardized testing and reporting protocols.²²

Delays in obtaining and reporting data on non-fatal overdoses also inhibit timely response to emerging drug trends. Only two states included in this report have laws requiring health care professionals to report non-fatal drug overdoses to state health departments, and only one of the two states requires reporting of non-fatal overdoses within a short period of time (48 hours).²³

Complete death certificate information on drug overdose deaths, mandatory reporting of non-fatal overdoses to state health departments by health care professionals, and real-time data collection, analysis and mapping of overdoses are essential for developing timely strategies to reduce fentanyl overdoses and deaths. Complete death certificate information on drug overdose deaths, mandatory reporting of non-fatal overdoses, and real-time data collection, analysis and mapping of overdoses are essential for developing timely strategies to reduce fentanyl overdoses and deaths.

Overdose Monitoring and Mapping Systems

The Center for Disease Control (CDC) lags in timely reporting of overdose death data. For example, in October 2018, CDC released overdose death data from the previous year, 2017. The CDC continues to be the primary source for state drug overdose data. This is partly because most states lack a standardized methodology to track overdoses, both fatal and non-fatal, in real time across jurisdictions. Real time data and mapping of overdoses provide essential information for developing immediate, targeted responses as well as increasing the efficiency of limited resources.

The DEA's Washington/Baltimore High Intensity Drug Trafficking Areas (HIDTA) program has created a web app called ODMAP (Overdose Detection Mapping Application Program).²⁴ This app combines street level data entered by first responders with tools from a digital mapping company to provide real time alerts of overdose spikes. The first responder records whether the incident is fatal or non-fatal and how many

OVERDOSE DATA COLLECTION & INFORMATION SHARING

doses of Naloxone are administered at the scene. This information is submitted to a central database and mapped to an approximate location which gives public safety and public health officials immediate alerts to mobilize a response strategy. ODMAP is the first database and mapping system to have the capabilities of incorporating a nationwide map. ODMAP is currently used by more than 250 first responder agencies in 27 states. Agencies can join ODMAP and use it at no cost.

Although some agencies within Illinois and Michigan have access to ODMAP, they rely on their own systems for statewide data. Illinois currently uses Illinois Department of Public Health (IDPH) Syndromic Surveillance, which collects health related data.²⁵ Information is received as early as possible when an illness is identified in order to provide overall population-based awareness of the spread of disease in the state, including overdose cases. In Illinois, IDPH specifically focuses on visits to hospitals, so it may not accurately capture statistics of fatal and non-fatal overdoses if they are not treated in a hospital. Michigan has created the System for Opioid Overdose Surveillance (S.O.S.) to obtain and track non-fatal and fatal opioid overdose data in real time from emergency medical services (EMS), emergency departments (ED), and medical examiners (ME).²⁶

| State | Is there mandatory reporting of non-fatal overdose by health care professionals? | Type of real time overdose monitoring & mapping system used |
|----------------|--|---|
| Florida | No | ODMAP (since 2018) |
| Illinois | Yes, within 48 hours | IDPH real-time syndromic surveillance system and ODMAP (since 2018) |
| Maryland | No | ODMAP (since 2017) |
| Massachusetts | No | ODMAP (since 2017) |
| Michigan | No | System for Opioid Overdose Surveillance (S.O.S.) and ODMAP (since 2017) |
| New Hampshire | No | ODMAP (since 2018) |
| New York | No | ODMAP (since 2017) |
| North Carolina | No | ODMAP (since 2017) |
| Ohio | No | ODMAP (since 2017) |
| Pennsylvania | No | ODMAP (since 2017) |
| West Virginia | Yes, quarterly reports | ODMAP (since 2017) |

Table 2: Mandatory Reporting for Non-Fatal Overdoses & Use of Real Time Overdose Monitoring Systems

FENTANYL TESTING STRIPS

Drug users are often unaware that the drugs they are purchasing are laced with fentanyl. Dealers may add fentanyl to heroin, cocaine, and methamphetamine to increase potency as well as profits.²⁶ Drug users can monitor the presence of fentanyl in street drugs by using fentanyl test strips (FTS): they are fairly easy to use simply by dipping the test strips into drug residue mixed with water. The cost per test strip ranges between \$1.00 to \$2.00.²⁷

Studies conducted by Johns Hopkins University,²⁸ RTI international,²⁹ the San Francisco Harm Reduction Coalition,³⁰ and Brown University³¹ found that:

- 1. FTS are accurate.
- 2. There is a demand for FTS among people who use drug.
- 3. A positive FTS result may lead drug users not to use the drug, to use less of the drug, or to use the drug with people who have naloxone available to reverse possible overdose.

However, in almost all states it is illegal to sell and buy fentanyl test strips because of laws banning drug paraphernalia (including test strips). While those bans may not always be enforced, the technical illegality of fentanyl test strips reduces the potential for broader distribution of these life-saving devices.

Table 3: Legal Status of Fentanyl Test Strips

| State | Is possession of fentanyl test strips illegal under state drug paraphernalia laws? |
|----------------|--|
| Florida | Yes |
| Illinois | Yes |
| Maryland | No |
| Massachusetts | Yes |
| Michigan | Yes |
| New Hampshire | Yes |
| New York | No |
| North Carolina | Yes |
| Ohio | Yes |
| Pennsylvania | Yes |
| West Virginia | Yes |

In nearly every state, it is illegal to sell and buy fentanyl test strips, as they are considered drug paraphernalia.

NALOXONE

Naloxone, also known by the brand name Narcan[®], is a safe medication that is widely used by emergency medical personnel and other first responders to reverse opioid overdose. **From 1996-2014, at least 26,500 opioid overdoses in the United States were reversed by laypersons administering naloxone.**³² Expanding naloxone access and training drug users, their relatives, friends, and community members on

26,500 opioid overdoses were reversed by people administering naloxone in the past 18 years. how to administer it can significantly reduce fentanyl deaths. However, although naloxone sales are legal in all states, significant barriers to access remain. These include cost, Medicaid coverage, prescription requirements, as well as criminal and civil liabilities for prescribers, dispensers and laypersons. Consideration of the amount of Narcan carried by first responders is also crucial. **While 1 or 2 doses of Narcan may be required to reverse a heroin overdose, a fentanyl overdose,**

which is 50 to 100 times more potent, may require 5-10 doses of Narcan to reverse.³³

For individual consumers, Narcan kits, which include two doses of the overdose antidote, cost between \$130-\$150.³⁴ However, the cost may drop per kit for large scale orders. States with naloxone distribution programs have conducted large-scale purchases at varying costs. In 2017, West Virginia used a \$1,000,000 grant to purchase and distribute 8,000 naloxone kits.³⁵ In 2018, the District of Columbia announced a plan to purchase 76,000 naloxone kits for an estimated \$6,000,000.³⁶

Fentanyl overdose can require 5-10 doses of Narcan to reverse because it is 50-100x more potent than heroin.

| Table 4: Naloxone Medicaid Coverage, pharmacist dispensing, third party prescriptions, professional and |
|---|
| layperson immunity, naloxone distribution programs |

| | Does Medicaid cover the cost of take-home naloxone? Fee-for-Service Plan (FFS) Managed Care Plan (MC) | Can pharmacists dispense without prescription? ³⁷ | Are prescriptions authorized to third parties? (E.g. relatives, friends) ³⁸ | Do prescribers and dispensers have immunity from criminal & civil liabilities and professional sanctions?*39 | Do laypersons have immunity from civil and criminal liabili- ty for adminis- tering? ⁴⁰ | Does the state have a naloxone distribution program? How often** and widespread*** is distribution? |
|------------------|--|--|--|---|---|---|
| FL ⁴¹ | Yes (FFS plans) | Yes (since 2017) | Yes | Yes | No (criminal), Yes (civil) | No |
| 1L ⁴² | Yes (FFS plans) | Yes (since 2017) | Yes | No | Yes (criminal and civil) | Yes; recurrent; concentrated in certain counties |
| MA ⁴³ | Yes (FFS and MC plans) | Yes (since 2018) | Yes | No | Yes (criminal and civil) | Yes; recurrent; statewide |
| MD ⁴⁴ | Yes (FFS and MC plans) | Yes (since 2017) | Yes | No | No (criminal), Yes (civil) | Yes; recurrent; somewhat statewide |

NALOXONE

Table 4: Naloxone Medicaid Coverage, pharmacist dispensing, third party prescriptions, professional and
layperson immunity, naloxone distribution programs (continued)

| | Does Medicaid cover the cost of take-home naloxone? Fee-for-Service Plan (FFS) Managed Care Plan (MC) | Can pharmacists dispense without prescription? ³⁷ | Are prescriptions authorized to third parties? (E.g. relatives, friends) ³⁸ | Do prescribers and dispensers have immunity from criminal & civil liabilities and professional sanctions?*39 | Do laypersons have immunity from civil and criminal liabili- ty for adminis- tering? ⁴⁰ | Does the state have a naloxone distribution program? How often** and widespread*** is distribution? |
|-------------------------|--|--|--|---|---|---|
| MI ⁴⁵ | Yes (FFS and MC plans) | Yes (since 2017) | Yes | No | Yes (criminal and civil) | Yes; multiple pur- chases; concen- trated in certain counties |
| NC ⁴⁶ | Yes (FFS and MC plans) | Yes (since 2016) | Yes | No | Yes (criminal and civil) | Yes; recurrent; somewhat state- wide |
| NH ⁴⁷ | Yes (FFS and MC plans) | Yes (since 2015) | Yes | Yes | Yes (criminal and civil) | Yes; recurrent; statewide; house calls to at risk individuals |
| NY ^{48,} 49 | Yes (FFS and MC plans) + Nalox- one co-payment assistance pro- gram (NCAP) | Yes (since 2015) | Yes | No | Yes (criminal and civil) | Yes; recurrent; somewhat state- wide; naloxone distributed in prisons upon release |
| OH ⁵⁰ | Yes (FFS and MC plans) | Yes (since 2016) | Yes | Yes | Yes (criminal), No (civil) | Yes; recurrent; statewide |
| PA ⁵¹ | Yes (FFS and MC plans) | Yes (since 2015) | Yes | Yes | Yes (criminal and civil) | Yes; multiple pur- chases; concen- trated in certain counties |
| WV ⁵² | Yes (FFS plans) | Yes (since 2018) | Yes | No | Yes (criminal and civil) | Yes; multiple purchases; some- what statewide |

* NALOXONE IMMUNITIES ARE SIMPLIFIED IN THIS CHART, FULL DETAILS OF IMMUNITIES CAN BE FOUND AT http://pdaps.org/datasets/laws-regulating-administration-of-naloxone-1501695139

** Recurrent: organizations within the state constantly distribute naloxone; multiple purchases: the state has made multiple purchases and distributions of naloxone but is not constantly distributing it.

*** Statewide: the distribution program reaches virtually the entire state; somewhat statewide: the distribution program is widespread across the state, but not available everywhere: the program is not statewide and reaches only a number of counties (generally the most affected).

NALOXONE

MASSACHUSETTS TAKES STEPS TO EXPAND LIFESAVING NALOXONE ACCESS

Massachusetts has expanded naloxone access by passing the "Act for Prevention and Access to Appropriate Care and Treatment of Addiction" (the "CARE Act"), which was signed by Governor Charlie Baker in August 2018. The CARE Act directs the Massachusetts Department of Public Health to issue a statewide standing order authorizing all pharmacies to dispense naloxone without requiring a prescription and guarantees that practitioners who prescribe and pharmacists who dispense naloxone in good faith will be protected from criminal or civil liability.⁵³

The Massachusetts Department of Public Health has also implemented Overdose Education and Naloxone Distribution (OEND) programs in community-based settings. These programs train individuals likely to witness an overdose (bystanders) on how to reduce overdose risk, recognize signs of an overdose, access emergency medical services, and administer intranasal naloxone.⁵⁴

RHODE ISLAND'S ONLINE TOOLS TO PREVENT FENTANYL OVERDOSE DEATHS

Although Rhode Island is not one of the 11 states analyzed in this report, they have taken some progressive policy approaches in regard to opioid prevention and overdoses, thus we thought it would be important to highlight some of these initiatives.

Through an initiative led by Gov. Gina M. Raimondo, Rhode Island Overdose Prevention and Intervention Task Force launched the website preventoverdoseri.org. This website connects users to resources, such as treatment, education on fentanyl, and instructions on how to prevent overdoses. The site also provides statistics on the current opioid crisis in the state, along with information on where naloxone is sold and how much has been sold in the last several years.

All of the data are broken down by county, making it easy for local jurisdictions to understand how their communities are affected. In addition, the website has a map that shows where to find a NaloxBox. The NaloxBox, similar in concept to defibrillator stations, includes naloxone and a sanitary mask so that CPR can be performed until emergency personnel arrive.⁵⁷

OHIO'S PROJECT DAWN

Project DAWN (Deaths Avoided with Naloxone) is a statewide program in Ohio to reduce opioid deaths by distributing naloxone kits and training laypersons to administer naloxone.⁵⁵ Since its inception in 2015, Project DAWN has been responsible for reversing over 2,000 overdoses in Cuyahoga county alone. Over the past two years, the program has opened sites across the state.⁵⁶

FIRST RESPONDER CALLS IN NEW HAMPSHIRE

In New Hampshire, one of the states with the highest fentanyl-related death rates, first responders have started making phone calls to households with individuals known to have substance use disorders. Individuals, their relatives, and friends are offered CPR and naloxone administration lessons. First responders also provide free naloxone kits after lessons. The program is in its early stages and results are not yet available.⁵⁸

911 GOOD SAMARITAN LAWS

Increased Naloxone distribution and accessibility alone are not sufficient to reduce fentanyl related overdose deaths. It is also critical to call 911 in the case of drug overdose, as the high potency and duration of action of fentanyl may require multiple doses of naloxone to reverse – and to sustain reversal of a fentanyl overdose. However, people may not always call 911 in overdose situations due to fear of police involvement. 911 Good Samaritan Laws (GSLs) provide protection from prosecution for low-level drug offenses such as use of controlled substances or possession of paraphernalia for the person requesting medical assistance and the drug user who overdosed. Reducing barriers to calling 911 has the potential to save victims of overdose from serious injury and death.

Results from an evaluation of Washington State's Good Samaritan Law found that **88% of opioid users would be more likely to call 911 in the event of an overdose after learning about the law.**⁵⁹ Although 40 states and the District of Columbia have some type of 911 Good Samaritan Law, many states impose as a condition of immunity certain requirements that make it less likely that bystanders will call 911. For example, requirements may include having to cooperate with police (i.e., giving name, address, and remaining at the scene even after first responders have arrived). Further, few states have dedicated sufficient efforts to advertising to drug users and the public the protections offered by Good Samaritan Laws. As such, the laws and many of their provisions remain largely unknown to the intended beneficiaries.

| State | Protection from charge & prosecution? | Protection from arrest? | Protection against violation of parole or probation? |
|---|---------------------------------------|-------------------------|--|
| <u>Florida</u> | Yes | No | No |
| Illinois <u>Bill 1, Bill 2,</u> <u>Bill 3</u> | Yes | Yes | No |
| Maryland | Yes | Yes | Yes |
| Massachusetts | Yes | No | No |
| <u>Michigan</u> | Yes | Yes | No |
| New Hampshire | Yes | Yes | No |
| New York | Yes | Yes | No |
| North Carolina | Yes | No | Yes |
| <u>Ohio</u> | Yes | Yes | No |
| Pennsylvania | Yes | Yes | Yes |
| <u>West Virginia</u> | Yes | No | Yes |

Table 5: Levels of protection in reported states' Good Samaritan Laws

911 GOOD SAMARITAN LAWS

NEW YORK'S GOOD SAMARITAN LAW

New York State's GSL, adopted in 2011, provides protection from prosecution to bystanders and overdose victims who call 911 and are in possession of narcotics, marijuana, drug paraphernalia, and alcohol (for minors). To increase awareness of the law, New York City's Police Department launched a public campaign in June 2017, targeting the 30 precincts in the city where drug overdoses and deaths from overdoses were the highest.⁶⁰

The campaign included social media messaging and advertisements on public transit vehicles. The New York Health Department has also issued fact sheets that explain the details of the Good Samaritan Law, including its protections and exclusions from protection.

The state's efforts show promising results. A 2018 Pennsylvania State University study found that after New York's Good Samaritan Law was enacted in 2011, the number of heroin overdose patients taken to emergency rooms and hospitals increased more rapidly in New York than in neighboring New Jersey, which did not enact a GSL law until 2013.⁶¹

PUBLIC EDUCATION CAMPAIGNS

Despite fentanyl's deadly toll, public awareness of fentanyl's dangers is still limited. Targeted, culturally appropriate educational materials can inform the public about the risks of using fentanyl and provide information on preventing overdose and obtaining treatment. Awareness campaigns can be implemented through television, radio, posters, leaflets, magazines, social media, and newspapers. Although there is not yet research on the effectiveness of fentanyl education campaigns, prior research has shown that mass media campaigns can affect harmful behaviors, such as reducing smoking because of adverse health effects.

Studies of Public Awareness of Naloxone and Good Samaritan Laws

Unfortunately, public awareness of the dangers of fentanyl, available treatment options, and related public policies has not yet been widely studied. Table 6 below, which departs from the specific states in this report, looks more broadly across the U.S. at studies that have been conducted on public awareness of Naloxone and Good Samaritan Laws.

| State | Naloxone | 911 Good Samaritan Laws (GSL) |
|----------|--|---|
| Florida | | According to the Florida Youth Substance Abuse Survey in 2018, 30.5% of high school students across the state were aware of GSL. Manatee County reported having the highest awareness at 50.8%. The increased awareness is most likely due to coordinated efforts pro- moting the state GSL by community partners involved in <u>Drug Free Manatee</u> 's Addictions Crisis Task Force (ACT). ⁶² |
| Illinois | A 2018 study by Nikolaides et al. of 101 opi- oid users admitted to the ER in Cook County found that only 55% had heard of naloxone; and only 22% had access to it at some point. ⁶³ | |
| Indiana | | 2017-2018 survey by Watson et al. in the Harm Reduction Journal analyzed data from 217 lay responders from 20 counties. A separate analysis was conducted on the subsample of respondents who indicated they had called or not called 911 (n=75). Of those who reported witnessing an overdose, 20% of respondents did not call 911. Among those who did not call 911, the most common reason was that they worried about the police (33%). Those with knowledge of Good Samaritan protections were significantly more likely to have called 911 (84.7% vs. 15.3%). ⁶⁴ |

Table 6: Studies of Public Awareness of Naloxone and Good Samaritan Laws in the United States

PUBLIC EDUCATION CAMPAIGNS

Table 6: Studies of Public Awareness of Naloxone & Good Samaritan Laws in the US (continued)

| State | Naloxone | 911 Good Samaritan Laws (GSL) |
|-----------|---|-------------------------------|
| Wisconsin | In 2018, reporters from the Milwaukee Journal Sentinel and the USA TODAY NETWORK-Wis- consin surveyed 465 pharmacies from the Wisconsin Department of Health Services online naloxone directory, located across 15 counties. The survey found that 27% of phar- macies erroneously said that prescription for naloxone is needed although a prescription had not been necessary since 2016. ⁶⁵ | |

Shortage of Fentanyl-Specific Campaigns

Over the past decade, most states have conducted public education efforts related to overdose prevention and opioid addiction. Although many of these efforts include information about fentanyl, few states have launched fentanyl-specific awareness campaigns. While it is important that states continue to include fentanyl in their broader efforts, fentanyl-specific campaigns are needed because of the unique dangers posed by the extreme potency of fentanyl and its rapid proliferation.

Fentanyl-specific campaigns should educate the public on the lethal threat posed by the drug, its frequent presence in heroin, cocaine, and methamphetamines (often without the knowledge of the drug user), 911 Good Samaritan Laws, stigma associated with drug treatment, how to obtain and use naloxone, and how to find treatment for addiction.

Fentanyl-specific campaigns should educate the public on the lethal threat posed by the drug.

REGIONAL FAST FOOD CHAIN LAUNCHES EMPLOYEE TRAINING

After the death of a customer near Chicago, IL who injected herself with fentanyl-tainted heroin in the bathroom, White Castle, a regional fast food chain concentrated in the Midwest with a few locations in New York and Nevada, implemented training of waitstaff on how to handle overdose situations and added code-locks to their bathrooms so that staff know when the facilities are in use.

White Castle is not the only business engaged in overdose prevention. According to the Chicago Tribune, "in Boston, the public health commission has alerted business owners about the danger of overdoses. It has handed out posters that say, 'Check your restrooms: Your actions could help save a life,' and offered to train employees to administer naloxone."⁶⁶

PUBLIC EDUCATION CAMPAIGNS

Table 7: Reported state efforts to increase public awareness related to fentanyl, naloxone and Good Samaritan Laws

| State | Does this state have a statewide fentanyl-specific education program? | Does this state incorporate fentanyl education in a statewide opioid or overdose education program? | Does this state have a statewide naloxone public awareness program? | Does this state have a statewide 911 GSL awareness program? |
|----------------|---|---|---|---|
| Florida | No | Nothing Reported | No | No |
| Illinois | No | Yes | Yes | Nothing Reported |
| Maryland | Yes | Yes | Yes | Nothing Reported |
| Massachusetts | Yes | Yes | Yes | Nothing Reported |
| Michigan | No | Yes | Nothing Reported | Nothing Reported |
| New Hampshire | Yes | Yes | Yes | Nothing Reported |
| New York | Yes | Yes | Yes | Yes |
| North Carolina | No | Yes | Yes | Nothing Reported |
| Ohio | No | Yes | Yes | Nothing Reported |
| Pennsylvania | No | Yes | Yes | Nothing Reported |
| West Virginia | Yes | Yes | Yes | Nothing Reported |

The single most important benefit of seeking treatment for fentanyl and other opioid addiction is to prevent a fatal overdose. Anyone who tries to stop using fentanyl without treatment runs a serious risk of failure, relapse and risk of overdose. Fortunately, there are medications that can be prescribed to reduce craving, protect users from overdose and to promote recovery. The combination of these medications with counseling and supports is referred to as Medication for Addiction Treatment (MAT).

Three medications have been approved by the FDA to treat OUD's: methadone, buprenorphine, and naltrexone. While there are only three medications FDA has approved for treating OUD, each of these comes in various formulations (injectable, oral, sublingual) and several are available in long acting form (injections lasting 30 days). Moreover, most of these medications and formulations are available in generic formats under a variety of trade names. According to a 2018 SAMHSA report, Treatment Improvement Protocol (TIP) 63, research demonstrates that MAT is effective in reducing opioid use and in helping people remain in treatment, thus reducing the chances of overdose related deaths. The FDA has provided dosage guidelines for each of the medications used in OUD. However, the dosing guidelines for MAT were based predominantly on heroin and "prescribed" opioids. Since fentanyl is 50 to 100 times more potent than heroin and most opioids, dosing magnitudes and durations will have to be updated.67

However, accessing MAT can be a major hurdle for people with opioid use disorder seeking help. States that have expanded Medicaid coverage through the Affordable Care Act have the ability to provide access to early interventions and treatment options. Although Medicaid is not the major source of funding for OUD's, Medicaid covers nearly 4 out of 10 non-elderly adults with an opioid addiction.⁶⁸ Even with Medicaid expansion, prior authorization requirements (in which the doctor must obtain approval from an insurance company or Medicaid before prescribing medication), formulary restrictions (list of drugs and how they are covered under particular insurance plans), limits on medication dosage, and limitations on treatment levels and duration remain as potential barriers to accessing treatment.⁶⁹

Beyond these impediments to broader use of MAT, there are unique barriers to the prescribing of methadone and buprenorphine, described in detail below. Methadone can only be prescribed for addiction within federally licensed "methadone treatment programs" and prescribers of buprenorphine are required to take an 8-hour course in how to prescribe that medication and to receive a federal waiver enabling them to legally prescribe the medication. Less than five percent of US physicians have received that training and become "waivered."

3 medications have been approved by the FDA to treat opioid use disorder: methadone, buprenorphine, and naltrexone.

Diversion

Concerns about the misuse and diversion of medications used in OUD treatment are often front and center for policymakers and physicians alike. According to a 2017 survey, 26 percent of non-waivered physicians were concerned about diversion, compared with only 10 percent of waivered physicians.⁷⁰ To prescribe buprenorphine, physicians must obtain a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) that requires additional training which covers diversion issues. This suggests that education can play a key role in reducing physician concerns of misuse and diversion.

Furthermore, evidence indicates that the incidence of misuse and diversion drops as the availability of legally prescribed buprenorphine increases.⁷¹ In regards to methadone, the United States has seen a consistent decline in diversion rates by 13 percent each year since 2011.⁷² It is also important to note that **diversion rates of OUD medications are lower than diversion rates for other prescribed medications such as antibiotics and allergy medications.**⁷³

Methadone

Methadone, a synthetic opioid, is used primarily for detoxification and maintenance treatment of those addicted to opioids, including fentanyl. Methadone works by lessening opiate withdrawal symptoms, blocking the euphoric effects of opioids, and minimizing the cravings for opioids. Methadone is subject to an additional layer of regulation, which other medications used to treat opioid addiction are not. The regulations. issued by FDA in December 1972, were designed to create a special "closed system" of distribution and use of methadone, effectively restricting distribution to hospital pharmacies and to physicians registered with both FDA and DEA who could authorize dispensing of the medication in a treatment program only. Unlike buprenorphine, take-home prescriptions are not allowed.

Buprenorphine

Buprenorphine, like methadone, diminishes the effects of withdrawal and cravings in opiate users. However, unlike methadone treatment, which must be provided in a highly structured clinic or treatment program, buprenorphine can be prescribed or dispensed in physician offices, significantly increasing treatment access. The FDA has approved the following buprenorphine products:

- Bunavail[®] (buprenorphine and naloxone) citrus flavored strip that melts in the mouth
- Suboxone[®] (buprenorphine and naloxone) strip that melts in the mouth
- Zubsolv[®] (buprenorphine and naloxone) tablet that melts under the tongue
- Sublocade[®] (buprenorphine extended-release) injection
- Buprenorphine-containing transmucosal (enters through mucous membrane, such as mouth) products

Naltrexone

Naltrexone, is a longer acting form of the opioid antagonist Naloxone (24 – 36 hours) and is sold under the brand names ReVia[®], Depade[®], and Vivitrol[®], is used to treat opioid use disorders and alcohol use disorders. Naltrexone blocks the euphoric and sedative effects of opioids and alcohol. Naltrexone can be prescribed by any health care provider who is licensed to prescribe medications. It comes in a pill form or as an injectable.

Medicaid Coverage & Medication for Addiction Treatment (MAT)

Medicaid plays a central role in the effort to fight the fentanyl crisis by covering people who are addicted to opioids and increasing a state's capacity to provide access to early interventions and treatment. According to a report by Kaiser Family Foundation in 2018, **Medicaid covers nearly 4 out of 10 non-elderly adults** with an opioid addiction.⁷⁴ All state Medicaid programs cover at least one medication used in MAT and most cover all three medications. While each state has its own Medicaid eligibility criteria, qualification is typically determined by multiple factors such as: income, household size, disability, and family status.

The Affordable Care Act (ACA) allows states to expand Medicaid eligibility, often referred to as Medicaid Expansion, to uninsured children and adults based on income alone. The ACA's single criterion qualifies individuals for Medicaid whose incomes are at or below 138% of the federal poverty level, which in 2018 was \$16,753/year for an individual.⁷⁵ Expanding Medicaid eligibility across all states can help more people access treatment. Medicaid covers nearly 4 out of 10 non-elderly adults with opioid addiction.

Even with Medicaid Expansion, prior authorization (PA) requirements, formulary restrictions (list of drugs, including brand and generic formulations, and how they are covered under particular insurance plans), limits on medication dosage, and limitations on treatment duration remain as barriers to accessing treatment.^{76, 77}

| State | Medicaid coverage of MAT M = Methadone B = Buprenorphine N = Naltrexone | Does Medicaid require prior authorization (PA) for MAT? | State Imposed dosage limits? | Medcaid Expansion? |
|-------|---|--|---|--------------------|
| FL | M, B, N | No PA for oral naltrexone and naloxone vials PA required for all buprenor- phine formulations with re-authorization every 6 months. | Suboxone strips max 3 per day | No |
| IL | M, B, N | No PA for preferred medica- tions | 24 mg maximum dosage and quantity limits for metha- done | Yes (since 2014) |
| MA | M, B, N | No PA for Vivitrol, naltrexone tablets, oral methadone, and preferred buprenorphine formulations PA for non-preferred medi- cations (Zubsolv, Bunavail, Subutex) | PA required when buprenor- phine dosage exceeds 32 mg/ day, 24mg for >90 days, or 16 mg>180 days | Yes (since 2013) |

Table 8: Medicaid Coverage of MAT, prior authorization requirements, dosage limitsand Medicaid Expansion status

Table 8: Medicaid Coverage of MAT, prior authorization requirements, dosage limitsand Medicaid Expansion status (continued)

| State | Medicaid coverage of MAT M = Methadone B = Buprenorphine N = Naltrexone | Does Medicaid require prior authorization (PA) for MAT? | State Imposed dosage limits? | Medcaid Expansion? |
|-------|---|--|--|--------------------|
| MD | M, B, N | No PA for preferred bu- prenorphine/ naloxone combinations. PA and enrollment in com- prehensive management program required for Vivitrol injections | Bunavail subject to max limit of 16mg | Yes (since 2013) |
| MI | M, B, N | No PA for oral Vivitrol. PA required for buprenor- phine and Suboxone. | 24mg max for 1 year. After 1 year, renewal requests are reviewed on a case-by-case basis and need to include a treatment plan. Limits to quantity of methadone pre- scribed or available for filling prescription, i.e., minor with- out guardian consent limits quantity to no more than 72 hours' worth of methadone | Yes (since 2014) |

Table 8: Medicaid Coverage of MAT, prior authorization requirements, dosage limits and Medicaid Expansion status (continued)

| State | Medicaid coverage of MAT M = Methadone B = Buprenorphine N = Naltrexone | Does Medicaid require prior authorization (PA) for MAT? | State Imposed dosage limits? | Medcaid Expansion? |
|-------|---|---|--|--------------------|
| NC | M, B, N | No PA for Vivitrol, oral nal- trexone, and Suboxone. PA required for buprenor- phine | Suboxone film has a Maxi- mum daily dose of 16 mg/ day. * Sublocade has a maximum dose of two monthly initial doses of 300 mg followed by 100 mg monthly mainte- nance doses* Buprenorphine /nalox- one tablets, Zubsolv® and Bunavail® (requires trial and failure of Suboxone® Film or a medical reason the benefi- ciary cannot use Suboxone® Film) Maximum daily dose of 16 mg/day for (buprenorphine/ naloxone). * Maximum daily dose of 11.4 mg/day for Zubsolv®.* Maximum daily dose of 8.4 mg/day Bunavail®.* Buprenorphine (single ingre- dient products) Maximum daily dose of 16 mg/day* | No |
| NH | M, B, N | All MAT medications require PA | Quantity limits on all MAT medications (depending on various factors, this limits the amount that can be prescribed or filled at any given time; i.e. no more than a 3-day supply) | Yes (since 2014) |

Table 8: Medicaid Coverage of MAT, prior authorization requirements, dosage limits and Medicaid Expansion status (continued)

| State | Medicaid coverage of MAT M = Methadone B = Buprenorphine N = Naltrexone | Does Medicaid require prior authorization (PA) for MAT? | State Imposed dosage limits? | Medcaid Expansion? |
|-------|---|---|--|--------------------|
| NY | M, B, N | No PA for preferred or for- mulary buprenorphine or injectable naltrexone PA required for oral meth- adone, oral naltrexone and non-preferred medication list (Zubsolv and Bunavail) | Quantity limits on suboxone & buprenorphine | Yes (since 2013) |
| ОН | M, B, N | No PA for medications on preferred list for first 7 days PA for non-preferred drugs (methadone oral concen- trate, buprenorphine mono formula Sublingual (SL), Bunavail, buprenorphine/ naloxone SL tablets) No PA for Vivitrol PA for Suboxone and Zub- solv for 30 days following first week and then every 6 months after that | 16 mgs max for Suboxone, 11.4mgs max for Zubsolv | Yes (since 2013) |
| PA | M, B, N | No PA for Suboxone, bu- prenorphine, oral naltrexone, oral methadone, and Vivitrol PA for non-preferred drugs (Bunavail, Zubsolv) | 16 mgs/ day max dosage for Suboxone. | Yes (since 2015) |
| WV | M, B, N | No PA for Vivitrol and Subox- one film PA for buprenorphine with re-authorization every 6 months. | Buprenorphine: 24 mg maxi- mum dosage for first 60 days. 16 mg maximum mainte- nance dose | Yes (since 2014) |

Medicaid Utilization Management for Medication for Addiction Treatment In 2017, only 25 percent of individuals receiving treatment at a drug rehabilitation facility received one of the three FDA-approved drug treatment medications.⁷⁸ Several barriers contribute to the low percentage of individuals receiving medications in their treatment for OUD. For example, inadequate reimbursement rates may contribute to the suboptimal access for medications used to treat opioid dependence.⁷⁹ Utilization management involves a variety of practices insurance companies employ to control costs; and these practices are another significant barrier to accessing these medications.⁸⁰ Examples of utilization management practices include requirements for prior authorization (which can take 2-3 days), restrictions on medication dosage and/or treatment duration, as well as requirements for step therapy. Step therapy is the term used when insurance requires an individual to fail in an initial treatment that does not involve MAT, before they will be approved for medication for addiction treatment. Unfortunately, as has been repeatedly documented, these treatment "failures" can result in fatal overdoses.

Researchers from Shatterproof analyzed utilization management restrictions applied to buprenorphine and naltrexone formulations used in the treatment of OUD by the 11 state Medicaid programs covered in this report.* In the fee-for-service (FFS) market, the analysis captured if the state plan imposed a prior authorization or step therapy requirement for each formulation, whereas, in the managed care market, the analysis presents the percentage of plans that impose these restrictions. For daily buprenorphine and naltrexone formulations, researchers analyzed utilization management practices solely applied in the pharmacy benefit. Since injectable and implant buprenorphine and naltrexone formulations may be covered in either the medical or pharmacy benefits, the least restrictive practice applied between a plan's medical or pharmacy benefits are reported.

This report defines unrestricted access as no prior authorization or step therapy requirement applied, whereas restricted access indicates the application or a prior authorization and/ or a step therapy protocol. Unknown/not listed conveys that the formulation is not included in the formulary and not covered indicates that the formulation is explicitly excluded from the formulary. A health plans drug formulary contains a list of drugs and how they are covered for that particular plan. Table 9 and Figures 3 and 4, as well as Appendices 1 and 2, present these results.

Among Medicaid FFS programs, states vary in their application of utilization management techniques (see Table 9). For example, Illinois' state plan provides unrestricted access to eight of the ten medication formulations reviewed, as compared to Massachusetts' FFS program, which provides unrestricted access to only one buprenorphine and naltrexone formulations. Step therapy is the term used when insurance requires an individual fail at a treatment before approving an alternative treatment.

In 2017, only 25% of people receiving treatment at a rehab facility received any kind of FDA-approved drug treatment medication.

* We are unable to provide information on the application of prior authorization and step therapy requirements to methadone formulations due to data limitations associated with methadone used for the treatment of opioid dependence placement in the medical benefit. While it is possible that the Medicaid programs evaluated provide complete unrestricted access to methadone treatment, it is important that coverage to other MAT formulations are equally, if not more, accessible. A federal requirement mandating that methadone can only *be dispensed by licensed opioid treatment programs restricts* methadone access, especially in rural communities. Further, the different pharmacotherapy properties of methadone, *buprenorphine, and naltrexone suggest that some patients* may respond to one drug, while others will benefit from another. This patient dependent response indicates that comprehensive access to formulations of all three MAT drug types is necessary to address the opioid crisis.

Medicaid Utilization Management for Medication for Addiction Treatment

Similar to FFS programs, the application of utilization management restrictions on buprenorphine and naltrexone formulations varies greatly among Medicaid managed care plans within the same state, as well as across states. Figure 3 presents the application of these techniques to daily buprenorphine and naltrexone formulations in Medicaid managed care plans. Figure 4 presents the analyses for implant and injectable formulations.

Table 9: Restrictions (Prior Authorization/Step Therapy) Applied to Buprenorphine and Naltrexone Medication for Addiction Treatment Formulations in State Fee-for-Service Medicaid Programs, March 2019

| Location | Drug | Unrestricted | Restricted | Unknown | Not covered |
|---------------|---------------|--------------|------------|---------|-------------|
| United States | Probuphine | 28.3% | 30.2% | 41.5% | 0.0% |
| | Sublocade | 20.8% | 56.6% | 22.6% | 0.0% |
| | Vivitrol | 83.0% | 9.4% | 5.7% | 1.9% |
| | Bunavail | 18.2% | 80.0% | 1.8% | 0.0% |
| | Suboxone | 34.5% | 63.6% | 1.8% | 0.0% |
| | BupNalSubFilm | 1.8% | 1.8% | 96.4% | 0.0% |
| | Zubsolv | 16.4% | 80.0% | 3.6% | 0.0% |
| | BupNalSubTab | 16.4% | 61.8% | 21.8% | 0.0% |
| | BupHClSubTab | 20.0% | 60.0% | 20.0% | 0.0% |
| | Naltrexone | 65.5% | 14.5% | 20.0% | 0.0% |
| Florida | Probuphine | 0.0% | 0.0% | 100.0% | 0.0% |
| | Sublocade | 0.0% | 100.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubTab | 100.0% | 0.0% | 0.0% | 0.0% |
| | BupHClSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone | 100.0% | 0.0% | 0.0% | 0.0% |
| Illinois | Probuphine | 100.0% | 0.0% | 0.0% | 0.0% |
| | Sublocade | 100.0% | 0.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| | Bunavail | 100.0% | 0.0% | 0.0% | 0.0% |
| | Suboxone | 100.0% | 0.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 100.0% | 0.0% | 0.0% | 0.0% |
| | BupNalSubTab | 100.0% | 0.0% | 0.0% | 0.0% |
| | BupHClSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone | 100.0% | 0.0% | 0.0% | 0.0% |

Table 9: Restrictions (Prior Authorization/Step Therapy) Applied to Buprenorphine and Naltrexone Medication for Addiction Treatment Formulations in State Fee-for-Service Medicaid Programs, March 2019 (continued)

| Location | Drug | Unrestricted | Restricted | Unknown | Not covered |
|---------------|---------------|--------------|------------|---------|-------------|
| Maryland | Probuphine | 0.0% | 0.0% | 100.0% | 0.0% |
| | Sublocade | 0.0% | 100.0% | 0.0% | 0.0% |
| | Vivitrol | 0.0% | 0.0% | 100.0% | 0.0% |
| | Bunavail | 100.0% | 0.0% | 0.0% | 0.0% |
| | Suboxone | 100.0% | 0.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 100.0% | 0.0% | 0.0% | 0.0% |
| | BupNalSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupHClSubTab | 100.0% | 0.0% | 0.0% | 0.0% |
| | Naltrexone | 0.0% | 100.0% | 0.0% | 0.0% |
| Massachusetts | Probuphine | 0.0% | 100.0% | 0.0% | 0.0% |
| | Sublocade | 0.0% | 100.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupHClSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone | 0.0% | 100.0% | 0.0% | 0.0% |
| Michigan | Probuphine | 100.0% | 0.0% | 0.0% | 0.0% |
| - | Sublocade | 100.0% | 0.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupHClSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone | 0.0% | 100.0% | 0.0% | 0.0% |

Table 9: Restrictions (Prior Authorization/Step Therapy) Applied to Buprenorphine and Naltrexone Medication for Addiction Treatment Formulations in State Fee-for-Service Medicaid Programs, March 2019 (continued)

| Location | Drug | Unrestricted | Restricted | Unknown | Not covered |
|----------------|---------------|--------------|------------|---------|-------------|
| New Hampshire | Probuphine | 0.0% | 0.0% | 100.0% | 0.0% |
| | Sublocade | 0.0% | 0.0% | 100.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupHClSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone | 0.0% | 0.0% | 100.0% | 0.0% |
| New York | Probuphine | 100.0% | 0.0% | 0.0% | 0.0% |
| | Sublocade | 100.0% | 0.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupHClSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone | 100.0% | 0.0% | 0.0% | 0.0% |
| North Carolina | Probuphine | 0.0% | 100.0% | 0.0% | 0.0% |
| | Sublocade | 100.0% | 0.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupHClSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone | 100.0% | 0.0% | 0.0% | 0.0% |

Table 9: Restrictions (Prior Authorization/Step Therapy) Applied to Buprenorphine and Naltrexone Medication for Addiction Treatment Formulations in State Fee-for-Service Medicaid Programs, March 2019 (continued)

| Location | Drug | Unrestricted | Restricted | Unknown | Not covered |
|---------------|---------------|--------------|------------|---------|-------------|
| Ohio | Probuphine | 0.0% | 0.0% | 100.0% | 0.0% |
| | Sublocade | 0.0% | 100.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| | Bunavail | 100.0% | 0.0% | 0.0% | 0.0% |
| | Suboxone | 100.0% | 0.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 100.0% | 0.0% | 0.0% | 0.0% |
| | BupNalSubTab | 100.0% | 0.0% | 0.0% | 0.0% |
| | BupHClSubTab | 100.0% | 0.0% | 0.0% | 0.0% |
| | Naltrexone | 0.0% | 0.0% | 100.0% | 0.0% |
| Pennsylvania | Probuphine | 0.0% | 100.0% | 0.0% | 0.0% |
| | Sublocade | 0.0% | 100.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupHClSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone | 100.0% | 0.0% | 0.0% | 0.0% |
| West Virginia | Probuphine | 100.0% | 0.0% | 0.0% | 0.0% |
| | Sublocade | 0.0% | 100.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubFilm | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupNalSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | BupHClSubTab | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone | 0.0% | 0.0% | 100.0% | 0.0% |

Unrestricted implies no prior authorization or step therapy protocol applied. Restricted implies either or both a prior authorization or step therapy requirement is applied. Unknown implies that the formulation is not listed in the formulary. Not covered implies that the formulation is explicitly excluded in the formulary. Data current through March 2019 for Bunavail, Suboxone, buprenorphinenaloxone sublingual film, Zubsolv, buprenorphine-naloxone sublingual tablet, buprenorphine HCl sublingual tablet, and naltrexone. United States is defined as all 50 states and Washington, D.C.

Source: This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

Figure 3: Restrictions (Prior Authorization/Step Therapy) Applied to Daily Buprenorphine and Naltrexone Formulations Approved for the Treatment of OUD by Medicaid Managed Care Plans, March 2019 (% of plans)

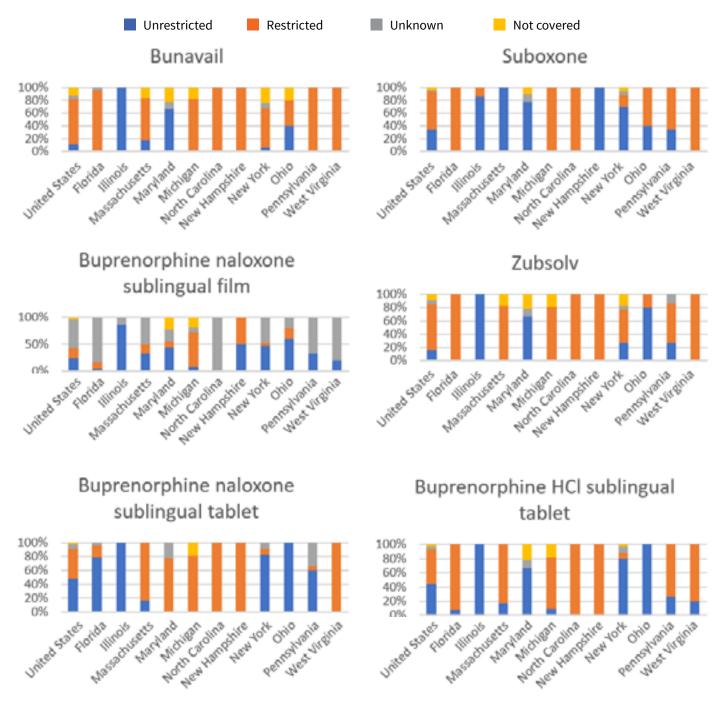
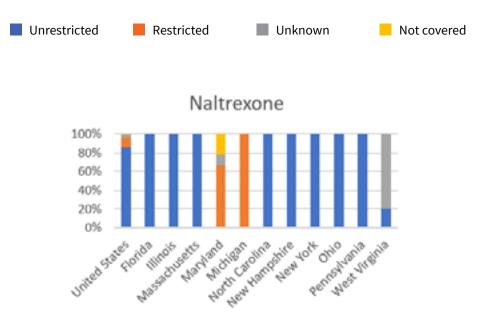


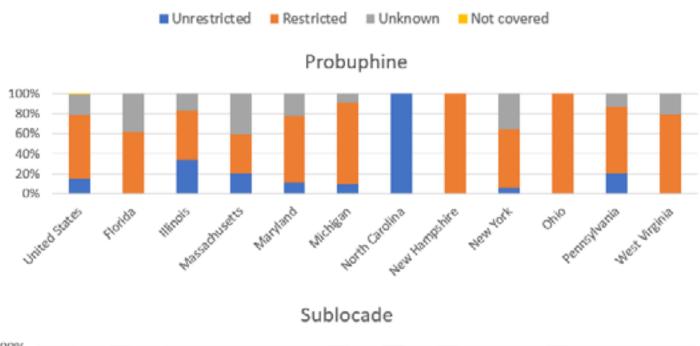
Figure 3: Restrictions (Prior Authorization/Step Therapy) Applied to Daily Buprenorphine and Naltrexone Formulations Approved for the Treatment of OUD by Medicaid Managed Care Plans, March 2019 (% of plans) (continued)



Note: See Appendix 1 for the quantitative estimates presented in Figure 3. Unrestricted implies no prior authorization or step therapy protocol applied. Restricted implies a prior authorization or step therapy requirement is applied. Unknown implies that the formulation is not listed in the formulary. Not covered implies that the formulation is explicitly excluded in the formulary. Data current through March 2019 for Bunavail, Suboxone, buprenorphine-naloxone sublingual film, Zubsolv, buprenorphine-naloxone sublingual tablet, buprenorphine HCl sublingual tablet, and naltrexone. United States is defined as all 50 states and Washington, D.C.

Source: This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

Figure 4: Restrictions (Prior Authorization/Step Therapy) Applied to Injectable and Implant Buprenorphine and Naltrexone Formulations Approved for the Treatment of OUD by Medicaid Managed Care Plans, May 2019 (% of plans)



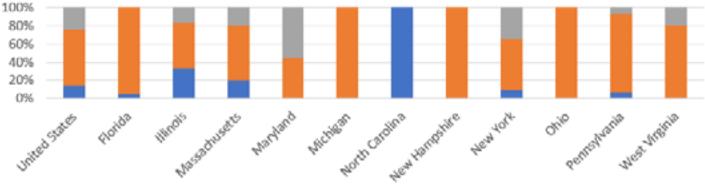
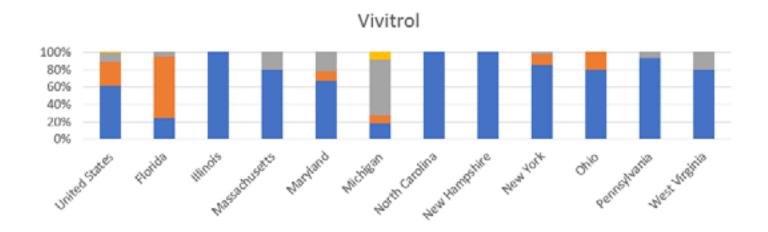


Figure 4: Restrictions (Prior Authorization/Step Therapy) Applied to Injectable and Implant Buprenorphine and Naltrexone Formulations Approved for the Treatment of OUD by Medicaid Managed Care Plans, May 2019 (% of plans) (continued)



Note: See Appendix 2 for quantitative estimates presented in Figure 4. Unrestricted implies no prior authorization or step therapy protocol applied. Restricted implies a prior authorization or step therapy requirement is applied. Unknown implies that the formulation is not listed in the formulary. Not covered implies that the formulation is explicitly excluded in the formulary. For Probuphine, Sublocade, and Vivitrol, the utilization management practice reported reflects the least restrictive practice applied between the medical and pharmacy benefit. Data current through May 2019 for Probuphine, Sublocade, and Vister and Vashington, D.C.

Source: This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

CORRECTIONAL FACILITIES & MEDICATION FOR ADDICTION TREATMENT

The war on drugs and mandatory sentencing laws have crowded our correctional facilities with inmates who often have a history of serious drug abuse problems. The Bureau of Justice Statistics estimates that at least two-thirds of incarcerated people suffer from substance abuse and only a small percentage of that group has access to treatment.⁸¹ While incarcerated, inmates typically stop using opioids and their tolerance for high opioid doses decreases, placing them at greater risk for overdose when they use opioids after release.

Drug overdose is the leading cause of death among recently incarcerated people.⁸² In North Carolina, a study of opioid overdose mortality among former North Carolina inmates from 2000-2015 found that they were 42 times more likely to die from an overdose than the general population. A 2017 study in Massachusetts found even more dramatic results: the opioid overdose death rate was 120 times higher for those recently released from incarceration compared to the rest of the adult population.⁸³ Offering treatment to incarcerated individuals can reduce the risk of overdose deaths. Although Rhode Island is not one of the 11 states analyzed in this report, they have taken pioneering, comprehensive approaches to dealing with the opioid crisis, with particular focus on providing treatment for their incarcerated population. They screen every individual entering the correctional system for opioid use disorder, and offer, along with drug counseling, all three medications approved by the FDA to treat addiction. When released from prison (or jail), former inmates are able to continue treatment without interruption with primary care providers or other MAT providers in the state.

In a study published by the Journal of the American Medical Association (JAMA), researchers found overdose deaths among people who had recently been imprisoned in Rhode Island dropped sharply in the first 6 months of 2017 compared to the same time period in 2016, indicating that the program has had a positive impact in reducing overdose deaths.⁸⁴ Intervening in the opioid epidemic at its most lethal and socially disrupting point--incarceration—by providing treatment to inmates gives hope and heals communities. Table 10 below shows which MAT treatment options are available for the states in this report.

CORRECTIONAL FACILITIES & MEDICATION FOR ADDICTION TREATMENT

| Table 10: MA | access in co | orrectional facilities. |
|--------------|--------------|-------------------------|
|--------------|--------------|-------------------------|

| | Do correctional facilities* offer MAT? |
|----|--|
| FL | Buprenorphine aided withdrawal program in Hillsborough County Jail, Tampa, Florida |
| IL | Naltrexone, methadone, and buprenorphine available in some correctional institutions. |
| MA | All 3 MATs available in state prisons Implementing a pilot program with all 3 MATs in the 5 Houses of Correction** by Sep 2019 **Massachusetts Department of Corrections defines a house of corrections as an institution where persons who have com- mitted minor offenses and who are considered capable of reformation are confined. |
| MD | Naltrexone and methadone available in some correctional institutions. |
| MI | Naltrexone offered in state prisons |
| NC | Program for Rutherford county jail inmates offers MAT & behavioral therapy. |
| NH | Naltrexone is offered in all state prisons |
| NY | Rikers Island Correctional facility offers 3 MAT medications and counseling |
| OH | Buprenorphine aided withdrawal program, Hamilton County Jail in Cincinnati. |
| PA | Naltrexone available at all state correctional institutions. |
| WV | MAT pilot programs authorized for people in custody of WV Division of Corrections in 2015. Pilot program expanded to include regional jails in 2016. Naltrexone is offered in all state prisons and some local jails. |

*Correctional facility refers to a jail, prison, or other place of incarceration.

RECOMMENDATIONS

Fentanyl overdose deaths are climbing rapidly, causing the most serious drug epidemic in the U.S. in the past hundred years. **Fentanyl overdose deaths are now more than twice the number of deaths from other prescription opioids, such as Vicodin and Oxycontin**, and account for approximately 32,000 deaths in 2018, according to preliminary CDC data. New initiatives are urgently needed: but several effective initiatives are already available. Based on the data collected from the states in this report, we arrived at seven recommendations that should provide a strong foundation for state actions to combat the fentanyl epidemic.

Fentanyl causes 2x more overdose deaths than all other prescription opioids.



Standardized data collection, analysis and information sharing must be implemented to allow for development of timely and accurate strategies.

Healthcare professionals, law enforcement agencies, policy makers and community organizations must have timely, accurate data to build effective responses to the rapidly evolving fentanyl epidemic.

- States should support complete, standardized reporting of fatal drug overdose information on death certificates.
- Centers for Medicare and Medicaid Services (CMS), CDC, and all relevant US government agencies should work to include a fentanyl-specific ICD-10 code in updating the medical coding system. Most statistical studies of fentanyl deaths rely on CDC's database, which uses ICD-10 codes to record causes of death. Unfortunately, fentanyl does not have a specific ICD-10 code. As a result, researchers and public health experts are forced to approximate when trying to determine the magnitude of the fentanyl crisis.
- States should require timely reporting of all non-fatal drug overdoses to state health departments.
- States should require all first responders (EMS, fire departments and law enforcement agencies) to use a real time overdose monitoring and mapping system, such as ODMAP. By utilizing a comprehensive system to track overdoses, both fatal and non-fatal, jurisdictions can take proactive steps to respond to overdose spikes.



Fentanyl test strips should be made legal.

Drug users are often unaware that drugs they buy from dealers may be laced with fentanyl. Providing fentanyl test strips (FTS) allows drug users to know if they are consuming fentanyl, which greatly decreases the chances of overdoses. In almost all states, it is illegal to sell and buy fentanyl test strips because of broad "drug paraphernalia" laws.

While those laws may not always be enforced for fentanyl test strips, the technical illegality of fentanyl test strips limits state efforts to broaden distribution of these life saving devices. States should follow the lead of Maryland and New York and specifically exempt fentanyl test strips from state paraphernalia laws.



Access to Naloxone (Narcan) should be expanded.

Naloxone, also known by the brand name Narcan, is a safe medication widely used by emergency medical personnel, other first responders and bystanders to counter an opioid overdose. From 1996-2014, at least 26,500 opioid overdoses in the United States were reversed by laypersons administering naloxone. Expanding naloxone access and training drug users, their relatives, friends, and community members on how to administer it can significantly reduce fentanyl deaths in the United States.

- Although all states in this report cover the cost of naloxone through their Fee-for-Service (FFS) Medicaid plans, only half of those states do so for their Managed Care (MC) plans. All Medicaid plans, including Managed Care plans, should cover naloxone.
- States should launch new, or expand existing, naloxone distribution programs.
- States should provide legal protections to medical professionals who prescribe naloxone and to medical professionals and laypeople who administer naloxone in overdose situations.
- Fentanyl, 50 to 100 times more potent than heroin, requires additional dosing of Narcan in the event of an overdose. First responders and Narcan distribution programs should adjust their training and supply levels to account for the increase in Narcan doses required to reverse a fentanyl related overdose.
- States should 1) study the geographical distribution of fentanyl-related overdoses in their states; 2) acquire sufficient naloxone doses to meet the expected needs; 3) distribute naloxone throughout the state with an emphasis on areas that are most affected; 4) install naloxone stations (NaloxBox) in any public areas known to be frequented by opioid users; 5) partner with local law enforcement, community organizations, and schools to distribute naloxone directly to at risk individuals and train drug users and bystanders on how to administer naloxone.



Encourage 911 calls to avert overdose deaths by adopting robust Good Samaritan Laws.

Calling 911 in the event of a fentanyl overdose saves lives. 911 Good Samaritan Laws (GSLs) provide protection from prosecution for low-level drug offenses such as use of controlled substances or possession of paraphernalia for the person requesting medical assistance and the person who overdosed. Reducing barriers to calling 911 can save victims of overdose from severe injury and death.

Although 40 states and the District of Columbia have some type of 911 Good Samaritan Law, many states impose requirements, such as having to cooperate with police (i.e., giving name and address, and remaining at the scene even after first responders have arrived) that make it less likely bystanders will call 911. Further, few states have adequate public education about the protections offered by Good Samaritan Laws.

- The GSLs of four of the states in this study only offer protection from charge and prosecution for drug use and possession, but they do not offer protection from arrest. Arrests may lead to subsequent charges for unrelated crimes and, thus, fear of arrest may deter bystanders from taking advantage of GSLs. States should broaden GSLs to include protection from arrest.
- States should extend GSL protections to callers and overdose victims who are in violation of their parole.
- 911 GSLs should offer protections for both bystanders and patients regardless of who calls 911.
- 911 GSLs do not always provide protections if the overdose victim dies. This may deter some bystanders from calling. States should remove this barrier to 911 GSL utilization.
- People who use drugs, police officers, and paramedics may be unaware of the protections offered under state GSLs, which may prevent people from seeking help. Education, training, and collaboration between the public and law enforcement is needed for effective utilization of 911 GSLs.
- Most GSLs require callers to cooperate with the police (including providing full name and other personal information and staying with the victim even after first responders have arrived). States should consider lowering those requirements in order to increase utilization of GSLs.

RECOMMENDATIONS



Launch and expand public educational campaigns targeting fentanyl.

Although the fentanyl epidemic has reached historic numbers, there is still a lack of awareness about the extreme threat posed by the drug. Over the past decade, most states have conducted public education efforts about overdose prevention and opioid addiction. While many of these efforts include fentanyl, few states have launched fentanyl-specific awareness campaigns.

- States should continue to monitor the level of awareness within their states of 1) potential fentanyl presence in other drugs, 2) the existence and proper use of fentanyl test strips, 3) protections offered by 911 Good Samaritan Laws, 4) what naloxone is, how to administer it, and how to obtain it.
- States should launch fentanyl-specific campaigns to educate the public about the lethal threat posed by the drug, the possible presence of fentanyl in other drugs, the protections offered by 911 Good Samaritan Laws, and how to obtain and administer naloxone.
- Fentanyl public awareness campaigns should engage the public in areas with high visibility to fentanyl users (e.g., public restrooms, convenience stores, bars and clubs).



Reduce stigma through education and policy change.

To reduce the numbers of overdose deaths it is imperative that the stigma associated with those addicted to opioids be significantly reduced. In a recent survey, 44% of Americans said that opioid addiction indicates a lack of willpower or discipline. Even worse, in that same survey less than 20% of Americans were willing to associate closely with someone who was addicted to opioids as a friend, colleague or neighbor.

The effects of stigma are tragic, notably causing countless Americans who are addicted to opioids to avoid going to treatment out of fear of discrimination and reducing capacity in the treatment system as many providers are unwilling to treat those addicted.

In this regard, states can significantly reduce the costs to society by making minor investments in public education and public policies. Details on these recommendations will be provided in a report published by Shatterproof later this year.

7

Increase access to treatment, especially Medication for Addiction Treatment.

The single most important benefit of obtaining treatment for fentanyl addiction is to prevent overdose. There are a wide variety of treatment options, but experts agree that for opioid addiction – particularly fentanyl addiction - Medication for Addiction Treatment (MAT) is the safest and most effective option. MAT is most effective in combination with counseling, social supports and other forms of therapy.

FDA has approved 3 medications to treat opioid dependence: methadone, buprenorphine, and naltrexone. The FDA has also imposed dosage limitations. Currently, all state Medicaid programs cover at least one medication used in MAT and most cover all three medications. Even with expanded Medicaid, policies such as prior authorization requirements, limits on medication dosage, restrictions for generic formulations and limitations on treatment duration remain as potential barriers to accessing treatment.

- All states should expand Medicaid eligibility to allow greater access to treatment, including evidence-based therapies and MAT.
- Despite lower costs of generic formulations compared to brand names, Medicaid programs continue to impose restrictions on generic formulations of buprenorphine and naltrexone. States should remove any generic formulation restriction to Medicaid plans.
- All 3 MAT medications and counseling should be offered in all correctional institutions.
- Expand access to buprenorphine by reducing barriers, such as waiver requirement, for doctors and nurses to prescribe it.
- Dose-capping—limiting the amount of methadone a patient can take on a daily basis was ruled "contrary to the current state of the medical literature and the principle of individualized treatment" in 2007 by the Substance Abuse and Mental Health Services Administration (SAMHSA) in the Federal Guidelines for Opioid Treatment. States should remove dosage caps on methadone.
- States with dosing-caps for buprenorphine below 24 mg per day should raise caps to meet the FDA's dosage limit of 24 mg per day.
- Since fentanyl is 50 to 100 times more potent than heroin, dosing magnitudes and durations for MAT should be updated accordingly to allow for effective treatment.
- Peer recovery coaches or social workers with specialized training should be available in hospital emergency rooms statewide to help connect overdose victims to treatment options and other resources.

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Philip Heymann, Harvard Law School professor emeritus and Chair of the Board of Drug Strategies, provided the inspiration for this report. His conviction that rapidly climbing fentanyl overdose deaths required immediate action led to our study of state fentanyl initiatives. Drug Strategies Board Member, Dr. A. Thomas McLellan provided invaluable advice.

Gary Mendell, founder and CEO of Shatterproof, shared our conviction that fentanyl overdose deaths can be greatly reduced by building on the knowledge we already have. He and his organization helped make this report widely available in order to encourage states to address the fentanyl epidemic effectively.

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Mathea Falco, President of Drug Strategies, developed this report, based on extensive research by Drug Strategies staff, Rebecca Stack-Martinez, William McConnell, and Sankari Ayyaluru, as well as Amanda Mauri from Shatterproof.

GLOSSARY

Buprenorphine: An opioid medication used in medication-assisted treatment (MAT) to help people reduce or quit their use of heroin or other opioids, such as fentanyl. Buprenorphine is sold both as a generic medicine and as name brands: Subutex[®] (buprenorphine), Bunavail[®] (buprenorphine and naloxone), Suboxone[®] (buprenorphine and naloxone), Zubsolv[®] (buprenorphine and naloxone), Sublocade[®] (buprenorphine).

CDC: Centers for Disease Control and Prevention is a federal agency that conducts and supports health promotion, prevention and preparedness activities in the United States, with the goal of improving overall public health.

DEA: The Drug Enforcement Administration is a federal agency that enforces the controlled substances laws and regulations of the United States.

Diversion: Diverting any legally prescribed controlled substance from the individual for whom it was prescribed to another person for any illicit use.

Dosage: Size or frequency of a dose of a medicine or drug.

Dosing-Cap: Local, state or federal regulation on maximum dosage of medicine or drug.

Drug Paraphernalia: Any equipment, product or accessory that is intended or modified for making, using, or concealing drugs, typically for non-medical purposes.

FDA: The Food and Drug Administration is a federal agency of the United States Department of Health and Human Services, responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed, and veterinary products.

Fentanyl: Fentanyl is a powerful synthetic opioid that is similar to morphine but is 50 to 100 times more potent. It is a prescription drug used for medical purposes. However, in recent years, illegal fentanyl, primarily from China and Mexico, has become widely abused in the U.S. In its prescription form, fentanyl is known by such names as Actiq[®], Duragesic[®], and Sublimaze[®]. Street names for illegally used fentanyl include Apache, China Girl, China White, Dance Fever, Friend, Goodfellas, Jackpot, Murder 8, and Tango & Cash.

Fentanyl Analogs: A compound that has a chemical structure similar to that of fentanyl, but differs from it in respect to a certain component. A search of scientific and patent literature will produce a list of more than 1,400 analogs from the fentanyl family.

Fentanyl Test Strips: Originally intended for urine drug tests, fentanyl test strips are used to test the presence or absence of fentanyl and fentanyl analogs in the illicit drug supply.

Good Samaritan Law: Provides basic legal protection for those who assist a person who is injured or in danger, such as a drug overdose. In essence, these laws protect the "Good Samaritan" from liability if unintended consequences result from this assistance.

Layperson/lay responder: Someone who responds to an emergency but has minimal training to do so.

Medication for Addiction Treatment (MAT): The use of medications, often in combination with behavioral therapy to treat opioid use disorders. Only three medications have been approved by the FDA to treat OUDs: methadone, buprenorphine, and naltrexone.

Medicaid: Medicaid provides health coverage to millions of Americans, including eligible low-income adults, children, pregnant women, elderly adults and people with disabilities. Medicaid is administered by states, according to federal requirements.

GLOSSARY

Medicaid Fee-for-Service (FFS): States may offer Medicaid benefits on a fee-for-service (FFS) basis, through managed care plans, or both. Under the FFS model, the state pays providers directly for each covered service received by a Medicaid beneficiary. Under managed care, the state pays a fee to a managed care plan for each person enrolled in the plan. In turn, the plan pays providers for all of the Medicaid services a beneficiary may require that are included in the plan's contract with the state.

Medicaid Managed Care (MC): Managed Care is a health care delivery system organized to manage cost, utilization, and quality. Medicaid managed care provides for the delivery of Medicaid health benefits and additional services through contracted arrangements between state Medicaid agencies and managed care organizations (MCOs) that accept a set per member per month (capitation) payment for these services.

Methadone: A synthetic opioid, approved by the FDA, is used primarily for detoxification and a medication for addiction treatment of those addicted to opioids, including fentanyl.

Naloxone: Also known by the brand name Narcan[®], naloxone is widely used by emergency medical personnel and other first responders to reverse opioid overdose.

Naltrexone: Sold under the brand names ReVia[®], Depade[®], and Vivitrol[®], this medication is primarily used to manage alcohol or opioid dependence and is approved by the FDA for use in medication for addiction treatment.

ODMAP (Overdose Detection Mapping Application

Program): An app that combines street level data of fatal and nonfatal overdoses entered by first responders with tools from a digital mapping company, to provide real time alerts of overdose spikes.

Opioid: A class of drugs that include the illegal drug heroin, synthetic opioids such as fentanyl, and pain relievers available legally by prescription, such as oxycodone (OxyContin[®]), hydrocodone (Vicodin[®]), codeine, morphine, and many others. **Opioid Use Disorder (OUD):** An opioid use disorder is defined as a problematic pattern of opioid use that leads to serious impairment or addiction.

Overdose (OD): Overdose occurs when a toxic amount of a drug, or combination of drugs overwhelms the body.

Prior Authorization (PA): Sometimes referred to as a "pre-authorization," is a requirement from the health insurance company or Medicaid that the doctor obtain approval from the plan before it will cover the costs of a specific medicine, medical device or procedure.

SAMHSA: The Substance Abuse and Mental Health Services Administration is the agency within the U.S. Department of Health and Human Services that aims to reduce substance abuse and mental illness in the U.S.

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Appendix 1: Restrictions (Prior Authorization/Step Therapy) Applied to Daily Buprenorphine and Naltrexone Medication for Addiction Treatment Formulations by Medicaid Managed Care Plans, March 2019 (% of plans)

| Location | Drug | Unrestricted | Restricted | Unknown | Not covered |
|---------------|--|--------------|------------|---------|-------------|
| United States | Bunavail | 11.7% | 70.2% | 4.5% | 13.6% |
| | Suboxone | 34.2% | 59.3% | 2.0% | 4.5% |
| | Buprenorphine naloxone sublin- gual film* | 25.1% | 18.9% | 52.1% | 4.0% |
| | Zubsolv | 16.1% | 70.0% | 5.0% | 8.9% |
| | Buprenorphine naloxone sublin- gual tablet* | 48.9% | 44.2% | 5.2% | 1.7% |
| | Buprenorphine HCl sublingual tablet * | 48.9% | 44.2% | 5.2% | 1.7% |
| | Naltrexone* | 87.3% | 9.9% | 2.2% | 0.5% |
| Florida | Bunavail | 0.0% | 95.8% | 4.2% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual film* | 4.2% | 12.5% | 83.3% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual tablet* | 79.2% | 16.7% | 4.2% | 0.0% |
| | Buprenorphine HCl sublingual tablet * | 79.2% | 16.7% | 4.2% | 0.0% |
| | Naltrexone* | 100.0% | 0.0% | 0.0% | 0.0% |
| Illinois | Bunavail | 100.0% | 0.0% | 0.0% | 0.0% |
| | Suboxone | 85.7% | 14.3% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual film* | 85.7% | 0.0% | 14.3% | 0.0% |
| | Zubsolv | 100.0% | 0.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual tablet* | 100.0% | 0.0% | 0.0% | 0.0% |
| | Buprenorphine HCl sublingual tablet * | 100.0% | 0.0% | 0.0% | 0.0% |
| | Naltrexone* | 100.0% | 0.0% | 0.0% | 0.0% |

Appendix 1: Restrictions (Prior Authorization/Step Therapy) Applied to Daily Buprenorphine and Naltrexone Medication for Addiction Treatment Formulations by Medicaid Managed Care Plans, March 2019 (% of plans) (continued)

| Location | Drug | Unrestricted | Restricted | Unknown | Not covered |
|---------------|--|--------------|------------|---------|-------------|
| Massachusetts | Bunavail | 16.7% | 66.7% | 0.0% | 16.7% |
| | Suboxone | 100.0% | 0.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual film* | 33.3% | 16.7% | 50.0% | 0.0% |
| | Zubsolv | 0.0% | 83.3% | 0.0% | 16.7% |
| | Buprenorphine naloxone sublin- gual tablet* | 16.7% | 83.3% | 0.0% | 0.0% |
| | Buprenorphine HCl sublingual tablet * | 16.7% | 83.3% | 0.0% | 0.0% |
| | Naltrexone* | 100.0% | 0.0% | 0.0% | 0.0% |
| Maryland | Bunavail | 66.7% | 0.0% | 11.1% | 22.2% |
| | Suboxone | 77.8% | 0.0% | 11.1% | 11.1% |
| | Buprenorphine naloxone sublin- gual film* | 44.4% | 11.1% | 22.2% | 22.2% |
| | Zubsolv | 66.7% | 0.0% | 11.1% | 22.2% |
| | Buprenorphine naloxone sublin- gual tablet* | 0.0% | 77.8% | 22.2% | 0.0% |
| | Buprenorphine HCl sublingual tablet * | 0.0% | 77.8% | 22.2% | 0.0% |
| | Naltrexone* | 0.0% | 66.7% | 11.1% | 22.2% |
| Michigan | Bunavail | 0.0% | 81.8% | 0.0% | 18.2% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual film* | 9.1% | 63.6% | 9.1% | 18.2% |
| | Zubsolv | 0.0% | 81.8% | 0.0% | 18.2% |
| | Buprenorphine naloxone sublin- gual tablet* | 0.0% | 81.8% | 0.0% | 18.2% |
| | Buprenorphine HCl sublingual tablet * | 0.0% | 81.8% | 0.0% | 18.2% |
| | Naltrexone* | 0.0% | 100.0% | 0.0% | 0.0% |

Appendix 1: Restrictions (Prior Authorization/Step Therapy) Applied to Daily Buprenorphine and Naltrexone Medication for Addiction Treatment Formulations by Medicaid Managed Care Plans, March 2019 (% of plans) (continued)

| Location | Drug | Unrestricted | Restricted | Unknown | Not covered |
|----------------|--|--------------|------------|---------|-------------|
| North Carolina | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual film* | 0.0% | 0.0% | 100.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual tablet* | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine HCl sublingual tablet * | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone* | 100.0% | 0.0% | 0.0% | 0.0% |
| New Hampshire | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 100.0% | 0.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual film* | 50.0% | 50.0% | 0.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual tablet* | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine HCl sublingual tablet * | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone* | 100.0% | 0.0% | 0.0% | 0.0% |
| New York | Bunavail | 5.9% | 61.8% | 8.8% | 23.5% |
| | Suboxone | 70.6% | 17.6% | 5.9% | 5.9% |
| | Buprenorphine naloxone sublin- gual film* | 47.1% | 5.9% | 47.1% | 0.0% |
| | Zubsolv | 26.5% | 50.0% | 5.9% | 17.6% |
| | Buprenorphine naloxone sublin- gual tablet* | 82.4% | 8.8% | 8.8% | 0.0% |
| | Buprenorphine HCl sublingual tablet * | 82.4% | 8.8% | 8.8% | 0.0% |
| | Naltrexone* | 100.0% | 0.0% | 0.0% | 0.0% |

Appendix 1: Restrictions (Prior Authorization/Step Therapy) Applied to Daily Buprenorphine and Naltrexone Medication for Addiction Treatment Formulations by Medicaid Managed Care Plans, March 2019 (% of plans) (continued)

| Location | Drug | Unrestricted | Restricted | Unknown | Not covered |
|---------------|--|--------------|------------|---------|-------------|
| Ohio | Bunavail | 40.0% | 40.0% | 0.0% | 20.0% |
| | Suboxone | 40.0% | 60.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual film* | 60.0% | 20.0% | 0.0% | 0.0% |
| | Zubsolv | 80.0% | 20.0% | 20.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual tablet* | 100.0% | 0.0% | 0.0% | 0.0% |
| | Buprenorphine HCl sublingual tablet * | 100.0% | 0.0% | 0.0% | 0.0% |
| | Naltrexone* | 100.0% | 0.0% | 0.0% | 0.0% |
| Pennsylvania | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 33.3% | 66.7% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual film* | 33.3% | 0.0% | 66.7% | 0.0% |
| | Zubsolv | 26.7% | 60.0% | 13.3% | 0.0% |
| | Buprenorphine naloxone sublin- gual tablet* | 60.0% | 6.7% | 33.3% | 0.0% |
| | Buprenorphine HCl sublingual tablet * | 60.0% | 6.7% | 33.3% | 0.0% |
| | Naltrexone* | 100.0% | 0.0% | 0.0% | 0.0% |
| West Virginia | Bunavail | 0.0% | 100.0% | 0.0% | 0.0% |
| | Suboxone | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual film* | 20.0% | 0.0% | 80.0% | 0.0% |
| | Zubsolv | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine naloxone sublin- gual tablet* | 0.0% | 100.0% | 0.0% | 0.0% |
| | Buprenorphine HCl sublingual tablet * | 0.0% | 100.0% | 0.0% | 0.0% |
| | Naltrexone* | 20.0% | 0.0% | 80.0% | 0.0% |

Note: Unrestricted implies no prior authorization or step therapy protocol applied. Restricted implies a prior authorization or step therapy requirement is applied. Unknown implies that the formulation is not listed in the formulary. Not covered implies that the formulation is explicitly excluded in the formulary. Data current through March 2019 for Bunavail, Suboxone, buprenorphine-naloxone sublingual film, Zubsolv, buprenorphine-naloxone sublingual tablet, buprenorphine HCl sublingual tablet, and naltrexone.

*Generic formulation.

Source: This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

Appendix 2: Restrictions (Prior Authorization/Step Therapy) Applied to Implant and Injectable Buprenorphine and Naltrexone Medication for Addiction Treatment Formulations by Medicaid Managed Care Plans, May 2019 (% of plans)

| Location | Drug | Unrestricted | Restricted | Unknown | Not covered |
|----------------|------------|--------------|------------|---------|-------------|
| United States | Probuphine | 14.6% | 64.0% | 21.2% | 0.3% |
| | Sublocade | 13.5% | 63.0% | 23.5% | 0.0% |
| | Vivitrol | 61.4% | 27.8% | 10.3% | 0.5% |
| Florida | Probuphine | 0.0% | 61.9% | 38.1% | 0.0% |
| | Sublocade | 4.8% | 95.2% | 0.0% | 0.0% |
| | Vivitrol | 23.8% | 71.4% | 4.8% | 0.0% |
| Illinois | Probuphine | 33.3% | 50.0% | 16.7% | 0.0% |
| | Sublocade | 33.3% | 50.0% | 16.7% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| Maryland | Probuphine | 11.1% | 66.7% | 22.2% | 0.0% |
| | Sublocade | 0.0% | 44.4% | 55.6% | 0.0% |
| | Vivitrol | 66.7% | 11.1% | 22.2% | 0.0% |
| Massachusetts | Probuphine | 20.0% | 40.0% | 40.0% | 0.0% |
| | Sublocade | 20.0% | 60.0% | 20.0% | 0.0% |
| | Vivitrol | 80.0% | 0.0% | 20.0% | 0.0% |
| Michigan | Probuphine | 9.1% | 81.8% | 9.1% | 0.0% |
| | Sublocade | 0.0% | 100.0% | 0.0% | 0.0% |
| | Vivitrol | 18.2% | 9.1% | 63.6% | 9.1% |
| New Hampshire | Probuphine | 0.0% | 100.0% | 0.0% | 0.0% |
| | Sublocade | 0.0% | 100.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| New York | Probuphine | 5.9% | 58.8% | 35.3% | 0.0% |
| | Sublocade | 8.8% | 55.9% | 35.3% | 0.0% |
| | Vivitrol | 85.3% | 11.8% | 2.9% | 0.0% |
| North Carolina | Probuphine | 100.0% | 0.0% | 0.0% | 0.0% |
| | Sublocade | 100.0% | 0.0% | 0.0% | 0.0% |
| | Vivitrol | 100.0% | 0.0% | 0.0% | 0.0% |
| Ohio | Probuphine | 0.0% | 100.0% | 0.0% | 0.0% |
| | Sublocade | 0.0% | 100.0% | 0.0% | 0.0% |
| | Vivitrol | 80.0% | 20.0% | 0.0% | 0.0% |

Appendix 2: Restrictions (Prior Authorization/Step Therapy) Applied to Implant and Injectable Buprenorphine and Naltrexone Medication for Addiction Treatment Formulations by Medicaid Managed Care Plans, May 2019 (% of plans) (continued)

| Location | Drug | Unrestricted | Restricted | Unknown | Not covered |
|---------------|------------|--------------|------------|---------|-------------|
| Pennsylvania | Probuphine | 20.0% | 66.7% | 13.3% | 0.0% |
| | Sublocade | 6.7% | 86.7% | 6.7% | 0.0% |
| | Vivitrol | 93.3% | 0.0% | 6.7% | 0.0% |
| West Virginia | Probuphine | 0.0% | 80.0% | 20.0% | 0.0% |
| | Sublocade | 0.0% | 80.0% | 20.0% | 0.0% |
| | Vivitrol | 80.0% | 0.0% | 20.0% | 0.0% |

Note: Unrestricted implies no prior authorization or step therapy protocol applied. Restricted implies a prior authorization or step therapy requirement is applied. Unknown implies that the formulation is not listed in the formulary. Not covered implies that the formulation is explicitly excluded in the formulary. For Probuphine, Sublocade, and Vivitrol, the utilization management practice reported reflects the least restrictive practice applied between the medical and pharmacy benefit. Data current through May 2019 for Probuphine, Sublocade, and Vivitrol.

Source: This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

THE FENTANYL EPIDEMIC: state initiatives to reduce overdose deaths

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