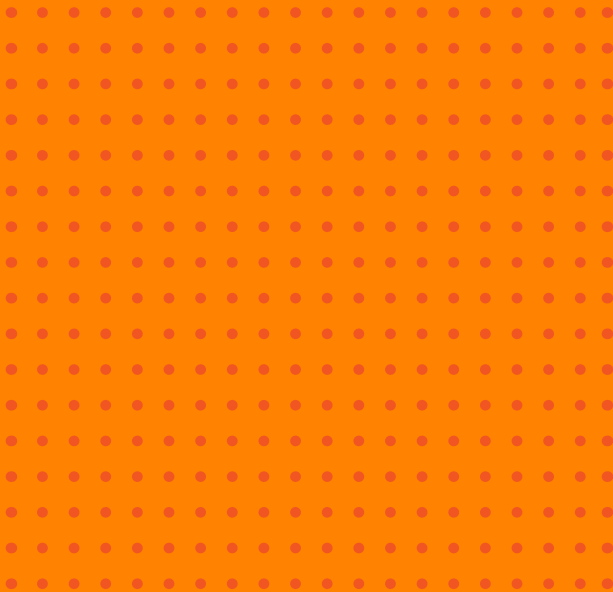




Evidence Based Strategies for Abatement of Harms





FROM THE OPIOID
EPIDEMIC

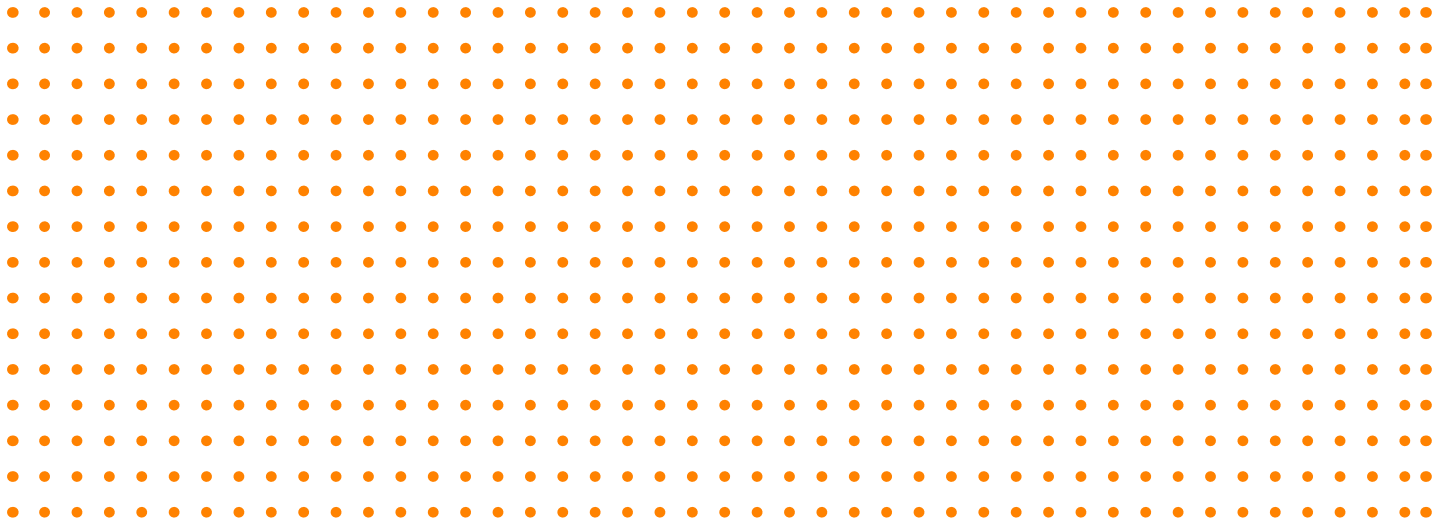


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FUNDER'S NOTE



The opioid epidemic has created tremendous loss across the country—in terms of lives lost, families impacted, increased strain on public services, and more. The ongoing opioid litigation represents an opportunity to begin to address those losses. Over the next several years, an estimated \$50 billion or more in damages is expected to be paid out to states, counties, cities, Indian tribes, hospitals, and other groups nationwide, to settle lawsuits brought against opioid manufacturers, distributors, and retail pharmacy chains, for their role in the opioid epidemic.

The question of how to allocate these funds to best serve the communities that have been affected by the opioid crisis remains a question for many jurisdictions. Policymakers, community leaders, and all those affected, want to avoid the outcomes of the tobacco litigation, in which only 2.6% of litigation payouts actually went to smoking prevention and cessation programs. State and local policymakers will, in many cases, have considerable discretion over how these lawsuit dollars will be spent in their communities—and they will need to weigh important trade-offs and make evidence-informed decisions to ensure the funds are well-spent.

Arnold Ventures is a nonpartisan philanthropy dedicated to tackling some of the most pressing problems in the United States, including criminal justice, education, health, and public finance issues. Our core mission is to invest in evidence-based solutions that maximize opportunity and minimize injustice. For years, we have sought to leverage data and evidence to save lives and reduce the social, economic, and criminal justice costs of the opioid epidemic. As part of that work, we chose to support the research and development of this guide to provide state and local governments with a resource that will serve the unique needs of their communities.

The team that developed this guide includes leading experts in a variety of fields and systems related to the opioid epidemic, including addiction medicine, primary care, specialty addiction systems, criminal justice, harm reduction, prevention, health policy and payment, and related outcome metrics. Collectively, these experts have deep familiarity with the relevant literature, cost-estimation methodologies, and management of the systems and interventions that jurisdictions may consider implementing in their communities.

By consolidating the research and providing concrete, practical recommendations to policymakers on how to pay for what works in an array of different systems, we hope this guide supports state and local officials in critical decisions ahead on how to spend dollars to reduce the harms of the opioid epidemic. The need to improve the lives of people living with opioid use disorder and their families is paramount, and the opportunity is now.

—

ARNOLD VENTURES

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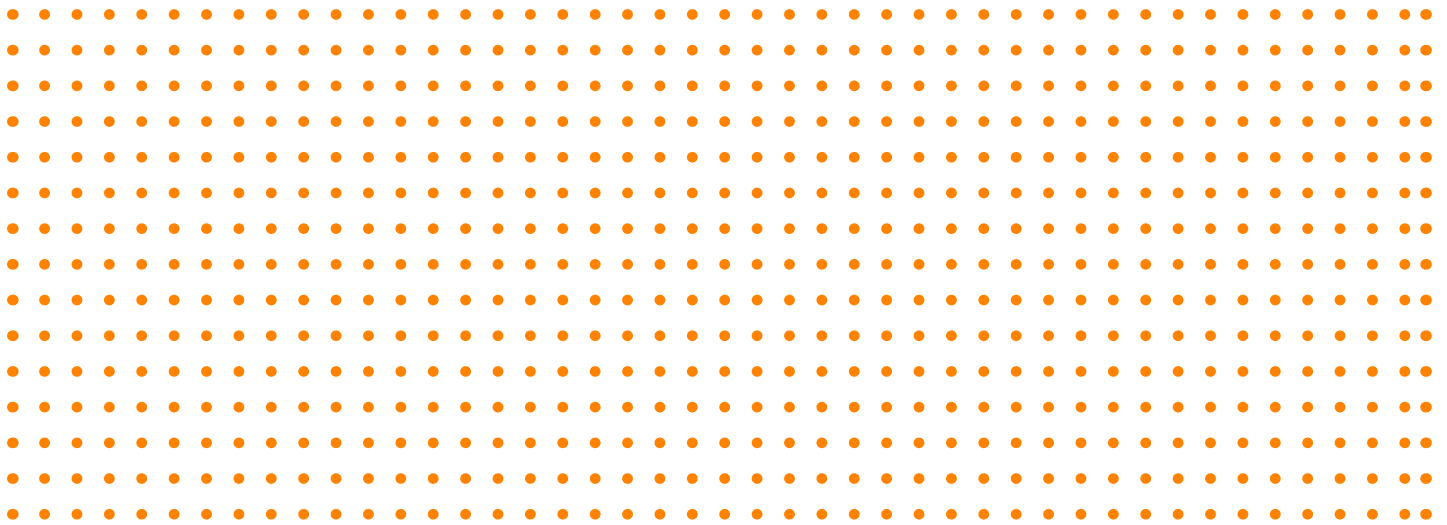
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CHAPTER 1: Introduction

Background on the Opioid Crisis and this Report

The current opioid epidemic has been raging for over 20 years in the United States. The number of deaths from drug overdoses in 2018 was estimated to be 67,367 (Hedegaard et al., 2020). From 1999-2018, more than 232,000 Americans died while taking prescription opioids. Many more Americans died while taking illicit opioids.

Until the 1990s, opioid-related overdoses resulted largely from use of illicit heroin. Beginning in the 1990s, however, the United States experienced the consequences of two dangerous trends: growing concerns about the under-treatment of acute and chronic pain in American medicine, and massive promotion of prescription opioids for the treatment of that pain. This confluence contributed to rapid growth in opioid use within the general population, illustrated by the more than 250 million prescriptions for opioids issued in 2011 alone. This alarming figure implies that medical professionals in the U.S. wrote enough prescriptions in 2011 to give 72 opioid pills to each American.

The growing supply of opioids, beginning in the 1990s, can be attributed directly to the activities of prescription drug manufacturers, physicians and dentists, and drug distributors, including wholesalers and pharmacies.

There are currently 42 states and 1,600 cities and counties suing manufacturers and distributors of prescription opioids and demanding billions of dollars in damages. Some of those claims have been consolidated into a legal case currently being heard in Cleveland, OH. Other claims are being adjudicated in courts around the country.

Some industry analysts are projecting a damages payout of \$50 billion or more to settle existing claims. In addition, a bankruptcy court in New York is considering how to distribute funds from the Purdue Pharma bankruptcy to aid in abatement of the harms stemming from Purdue's products. As the maker of OxyContin, Purdue is perhaps the most visible purveyor of prescription opioids.

According to the order consolidating the cases brought by cities and counties, there are two common allegations against drug manufacturers and distributors:

- Manufacturers of prescription opioid medications overstated the benefits and downplayed the risks associated with the use of their opioids, and aggressively marketed these drugs to physicians, either directly or through key opinion leaders.
- Distributors failed to monitor, detect, investigate, refuse, and report suspicious orders of prescription opioids.

DAMAGE CLASSES

The lawsuits currently in the courts involve two major classes of damages: backward-looking costs, or “compensatory damages,” incurred as a result of inappropriate prescribing and negligent distribution; and forward-looking, “abatement costs” that must be incurred in the future to remedy the opioid epidemic.

This report’s abatement analysis, therefore, has two functions:

1. To estimate the costs of evidence-based abatement actions.
2. To offer a strategy for how funds recovered from defendants would be spent.

ABATEMENT ESTIMATES

The abatement estimates made public to date are based on the estimated cost of implementing a large variety of programs that have been proposed by state officials, policy analysts, and federal commissions. These estimates include lists of nearly every abatement strategy that has been discussed or tried in the U.S. and elsewhere. Thus far, there has been a limited effort to distinguish among programs that have been shown to work, programs with uncertain effects, and programs that don’t work.

State and local governments distributing abatement funds will be forced to make hard choices about the abatement programs they will pursue, because:

- The financial outcomes of the litigation will surely result in payouts that are far lower than damage claims.
- Many of the proposed abatement actions are unlikely to contribute to reducing the harms created by the opioid epidemic.

About This Report

This report organizes what is known about public health-related services, programs, and strategies that are considered “best bets” for effectively putting abatement funds to work, based on current evidence about their impacts. The goal of this document is to inform the constrained choices state and local governments may soon be facing as they attempt to apply settlement funds to address the epidemic. This report sought to achieve this goal by:

1. Generating a list of evidence-based abatement options, describing the infrastructure and context required to successfully implement such efforts, and assembling existing evidence about the potential impact of abatement options.
2. Providing cost estimates for scaling the activities.
3. Considering how the political, financial, and infrastructure circumstances of states may make some packages of abatement programs more practical than others.

OVERVIEW OF ADDICTION TREATMENT

Historically, nearly all addiction treatment has been provided by specialty substance use disorder treatment “programs” that feature standardized durations, and regimens of counseling and behavioral therapies, for all patients. These programs have been variously sub-categorized by:

- Setting of care, including hospital, residential, outpatient, and office-based programs.
- Level of service intensity, such as those included in the American Society of Addiction Medicine’s Levels of Care (Mee-Lee, 2013).
- Modality or philosophy of care, including detoxification, methadone maintenance, and abstinence.

Realistic Outcomes for Addiction Treatment

Regardless of the particular setting, modality, or approach to addiction treatment, the goals of care are similar to treatment approaches for other serious, chronic medical illnesses:

- Reduce the major symptoms of the illness.
- Improve health and social function.
- Teach patients how to self-monitor.
- Manage threats to relapse.
- Achieving these goals in the treatment of other chronic illnesses is termed “disease control,” signifying that the illness is not cured, but is controlled through active management by the patient. In the treatment of opioid and other substance use disorders, the same result is termed “recovery.”

The 2016 Surgeon General’s Report, entitled *Facing Addiction in America*, concluded that recovery should be considered a realistic, even expected, result of comprehensive, continuing addiction treatment and management, just as disease control is considered a realistic outcome for most other chronic illnesses.

ORGANIZATION OF THE REPORT

This report begins by reviewing the core elements of treatment for opioid use disorder. It then considers the delivery of those treatments in specific contexts, including the specialty treatment system, primary care settings, harm reduction programs, and criminal justice settings.

The report then turns to issues of prevention, followed by a discussion of the data and policy infrastructures that are likely to maximize the impacts of spending that is guided by the evidence reviews contained in this report.

Finally, the report looks at the policy infrastructure governing the supply of treatment and the likelihood that those treatments yield the best possible outcomes.

NOTES ON RESEARCH REPORTING

This document reviews the results of research on medications, behavioral therapies, and recovery support services designed to bring about stable recovery from opioid addiction. The aim of these discussions is to identify components shown to result in better outcomes.

The document does not emphasize modalities, settings, or levels of addiction care because research on such comparisons is meager and provides little direction for future investment. Most of interventions discussed in this report can be used across modalities and settings. In a few instances, the report focuses on the application of the components of treatment in various settings, such as primary care or criminal justice.

Scientific Standards Used to Judge Effectiveness of Treatment Components

FIVE SOURCES OF RESEARCH FINDINGS

Research findings cited in this report come largely from reviews of five major scientific documents published on addiction treatment in recent years. These studies are listed below, followed by the reference that will be used to refer to each study throughout this report:

1. Medications for Opioid Use Disorder Save Lives, published by The National Academy of Sciences, Engineering, and Medicine in 2019. **(National Academies, 2019)**
2. Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health, published by the Office of the Surgeon General, U.S. Department of Health and Human Services, in 2016. **(Surgeon General, 2016)**
3. Facing Addiction in America: The Surgeon General's Spotlight on Opioids, published by the Office of the Surgeon General, U.S. Department of Health and Human Services, in 2018. This report focuses more specifically on opioids. **(Surgeon General, 2018)**
4. National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, published by The American Society of Addiction Medicine in 2015. **[ASAM (Kampman & Jarvis, 2015)]**
5. Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence, published by The World Health Organization (WHO) in 2009. **(WHO, 2009)**

Each of these documents was chosen because it was compiled separately and independently by teams of experienced and politically impartial researchers. Moreover, each of these separate reports has already been extensively reviewed and broadly accepted for their comprehensiveness and accuracy by other addiction professionals.

These reports relied on findings from systematic searches of electronic databases of research articles published in English. Within those searches—and reflected here—priority was given to systematic literature reviews and to replicated findings from multiple controlled trials and/or large scale, real-world population studies. The Food and Drug Administration uses the same standards for evidence of effectiveness.

CLASSIFICATION OF RESEARCH EVIDENCE

Many important issues in addiction treatment have not yet received rigorous scientific examination. This report includes information about potentially promising interventions that have not been rigorously evaluated. In summarizing the body of research for each treatment component, this report classifies the strength of evidence for specific interventions using the same system employed by the Centers for Disease Control and Prevention (Puddy & Wilkins, 2011):

- **Well supported:** Evidence derived from multiple controlled trials or large-scale population studies.
- **Supported:** Evidence derived from rigorous, but fewer or smaller, trials or restricted samples.
- **Promising:** Findings that do not derive from rigorously controlled studies but, nonetheless, make practical or clinical sense and are widely practiced.

One exception to this classification system appears in Chapter 5, which focuses on prevention. Chapter 5 uses the modified Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) approach to rating the strength of interventions for prevention.

Applying Scientific Standards to Patient Groups with Special Needs

This document prioritizes research findings that apply most broadly to the general population of individuals with opioid use disorder. With the exception of pregnant women and adolescents, the report offers less evidence on the many special-needs subgroups within the population of individuals with opioid use disorder, such as non-pregnant women, racial/ethnic minorities, individuals involved in the criminal justice system, veterans, persons with disabilities, and persons with an LGBTQ sexual orientation.

Issues associated with populations primarily served in specific contexts, such as the criminal justice system, are addressed in this document's review of how delivery of core services is best organized within specific contexts.

There are two reasons for prioritizing research findings most broadly:

Similar Processes Underlying Addiction

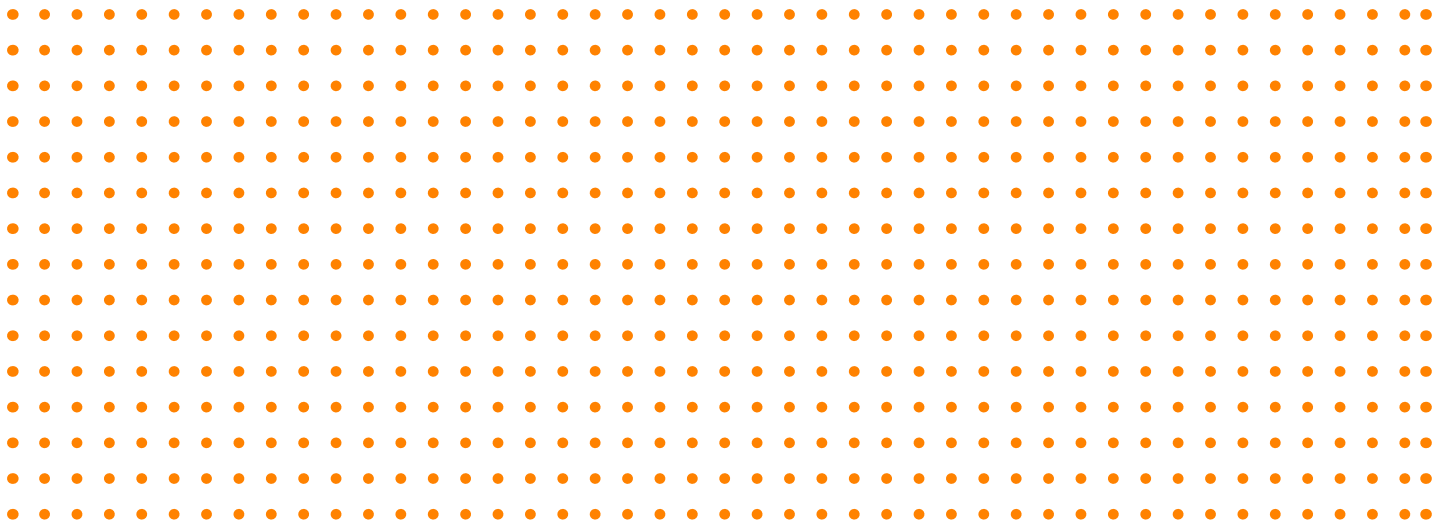
The genetic, neurochemical, and learned processes underlying the addiction process are largely similar across most subgroups. As a result, most research findings from the general population of individuals with opioid use disorder also apply to most special populations or subgroups.

Likewise, available research findings generally indicate that medications, therapies, and recovery supports shown to be effective in one subgroup generally are effective with other subgroups. These broad findings also apply to pregnant women and adolescents, whose needs are addressed separately in this report. However, the report also notes meaningful differences with respect to use of medications for opioid use disorder and behavioral therapies for these two groups.

In addition, it should be noted that individuals often vary in their response to standard treatment options, and that patients with special needs may require additional social supports, in addition to medication or behavioral interventions, to ensure treatment success.

A Dearth of Research on Subgroups

At this writing, available research only permits general population-level conclusions. Research on the specific effects of medications, therapies, or recovery supports for most important subgroups is limited.



CHAPTER 2: Treatment Components

Evidence-Based Components of Addiction Care in All Treatment Settings

Regardless of the setting, level, or approach to addiction care, all addiction treatments should offer a personalized set of evidence-based clinical practices shown by research to be effective in promoting recovery. These practices fall into three categories:

- 1. Medications for opioid use disorder.
- 2. Behavioral therapies.
- 3. Recovery support services.

Treatments or treatment programs that offer the greatest number of these evidence-based components tend to have the greatest likelihood of facilitating recovery.

The following sections offer recommendations for treatment in each of the categories listed above. These recommendations are based on a combination of evidence from the five scientific review documents cited in Chapter 1 and are listed in rank order based on the strength of the scientific evidence available to support each component.

Medications for Opioid Use Disorder

Several medications are among the most effective components of treatment for opioid use disorder (Wakeman et al., 2020). These medications include methadone, buprenorphine, and extended-release naltrexone. All three medications are approved by the U.S. Food and Drug Administration (FDA).

While the other essential treatment components discussed in Chapter 2 of this report, including behavioral therapies and recovery supports, have been determined to be effective for other substances, methadone and buprenorphine are only FDA-approved for the treatment of opioid use disorder. While extended-release naltrexone is approved for opioid use disorder, other formulations of naltrexone are also approved for the

treatment of alcohol use disorder. However, this discussion will be limited to research related to opioid use disorder.

Methadone, buprenorphine, and naltrexone are potentially effective in all treatment settings, as long as an appropriately trained workforce is available. Despite evidence on the effectiveness of these medications, however, fewer than half of facilities providing addiction treatment services offered any medications for opioid use disorder in 2019 and only four percent offered all three FDA-approved medications (amfAR, 2019).

METHADONE: WELL-SUPPORTED

Methadone has the strongest evidence supporting its effectiveness as a treatment for opioid use disorder, in part because it has been in use the longest. The Surgeon General (2016) and National Academies (2019) have determined that there is well-supported evidence demonstrating methadone's efficacy in treating opioid use disorder. The use of methadone

to treat opioid use disorder is also strongly recommended by the American Association of Addiction Medicine (Kampman & Jarvis, 2015) and World Health Organization (2009). Importantly, World Health Organization lists methadone as an essential medicine and considers it "optimal treatment" for opioid use disorder.

Methadone Studies

Methadone is an orally administered full opioid agonist, meaning it activates certain receptors in the brain over 24-36 hours to block opioid withdrawal and cravings. Methadone safely helps to manage addiction, withdrawal symptoms, and cravings. It also prevents overdose.

While methadone is an opioid, oral administration and a more complex metabolism produce slower onset at brain receptors and a much less intense euphoric rush than heroin or misused prescription opioids. Like other opioids, methadone can cause respiratory depression and, therefore, carries a risk for overdose. Methadone can be used for withdrawal management, but is more effective when used for long-term treatment, also referred to as "maintenance."

A number of large systematic reviews, large population studies, and randomized controlled trials demonstrate that, when compared to those who receive no treatment, patients with opioid use disorder who are maintained on methadone have:

- Fewer overdoses (Degenhardt et al., 2011; Wakeman et al., 2020).
- Reduced morbidity and mortality (Degenhardt et al., 2014; Larochelle et al., 2018; Sordo et al., 2017; Wakeman et al., 2020).
- Less injection drug use (Dolan et al., 2003; Gowing et al., 2011; Woody et al., 2014).
- Reduced risk for HIV/HCV transmission (Dolan et al., 2005; Marsch, 1998; Mattick et al., 2003; Sees et al., 2000).
- Improved social functioning (Mattick et al., 2003).
- Decreased criminality/criminal activity (Marsch, 1998; Mattick et al., 2003; Schwartz, et al., 2009, 2011).
- Lower rates of other opioid use (Mattick et al., 2009).
- Better retention in treatment (Mattick et al., 2009; Strain et al., 1993).
- Greater patient satisfaction than buprenorphine or naltrexone, the two other FDA-approved medications (Ali et al., 2017).

Prescribing Methadone

The effectiveness of methadone depends on proper dosing. Improved treatment retention and reduced illicit opioid use are associated with receiving higher doses of the medication (Bao et al., 2009; Strain et al., 1993, 1999).

There are instances in which methadone is diverted to illegal channels. However, research indicates that much of that diversion occurs among already-addicted individuals engaging in self-treatment, rather than among opioid-naïve individuals using methadone to get high (Mitchel, et al., 2009).

BUPRENORPHINE: WELL-SUPPORTED

There is well-supported evidence for the effectiveness of buprenorphine to treat opioid use disorder (Kampman & Jarvis, 2015; National Academies, 2019; Surgeon General, 2016). World Health Organization (2009, p. 31) has recommended buprenorphine as a "second-line therapy for patients in whom methadone is unwanted, inappropriate, or ineffective."

Buprenorphine Studies

Like methadone, buprenorphine acts on opioid receptors to block withdrawal and craving. Unlike methadone, buprenorphine is a partial opioid agonist, so there is a physiological limit on its ability to produce euphoria and the respiratory depression responsible for overdose.

In the U.S., buprenorphine is combined with naloxone in the product Suboxone to produce a misuse-deterrent formulation. Suboxone eliminates or markedly reduces the likelihood of illicit use of buprenorphine by an individual with an opioid use disorder. Buprenorphine is available in sublingual, subcutaneous, subdermal implant, and extended-release injectable formulations, allowing for greater flexibility than methadone in prescribing and dosing.

Because of its relatively safer risk profile, buprenorphine in all formulations can be prescribed in office-based settings by physicians and other prescribers who receive training and obtain a federal waiver to administer the medication. However, when buprenorphine use is combined with alcohol and/or sedatives, it can still result in overdose.

Like methadone, buprenorphine has been diverted, but research indicates that it is typically diverted to already-addicted individuals for self-treatment, rather than to opioid-naïve individuals for the purposes of misuse (Carroll et al., 2018; Cicero et al., 2018; Schuman-Olivier et al., 2010).

A number of large systematic reviews, large population studies, and randomized controlled trials demonstrate that, compared with placebo or no treatment, buprenorphine is associated with:

- Improved treatment outcomes (Thomas, et al., 2014).
- Fewer overdoses (Schwartz et al., 2013; Wakeman et al., 2020).
- Better treatment retention rates (Mattick et al., 2014).
- Less injection drug use (Woody et al., 2014).
- Reduced HIV/HCV transmission/risk (Mattick et al., 2003; Woody et al., 2014).
- Improved social functioning (Bart, 2012; Kakko et al, 2003; Mattick et al., 2003).
- Decreased criminal activity (Mattick et al., 2003).
- Lower rates of other opioid use (Fudala et al., 2003; Johnson et al., 1995; Thomas et al., 2014).

Some studies have found buprenorphine to be associated with reduced mortality (Laroche et al., 2018; Schwartz et al., 2013), but additional research is needed (Sordo et al., 2017).

As with methadone, higher doses of buprenorphine, such as 16-24 mg/day, are associated with better treatment retention (Ling et al., 1998) and reduction in heroin and cocaine use (Mattick et al., 2014). Compared to methadone, buprenorphine is slightly less effective in retaining patients in treatment (Mattick et al., 2014).

EXTENDED-RELEASE NALTREXONE: SUPPORTED

Research supports the effectiveness of naltrexone for the treatment of opioid use disorder. Naltrexone is different from methadone and buprenorphine because it is an opioid antagonist, meaning it blocks the opioid receptors completely, thereby preventing the intoxication and overdose effects of opioids.

About Naltrexone

Naltrexone comes in two forms: an oral, relatively short-acting formulation that lasts for 24-36 hours, and an extended-release injectable formulation that continues acting for 30 days. Vivitrol, the extended-release, injectable formulation of naltrexone is FDA-approved for the treatment of opioid use disorder. The oral formulation of vivitrol is not FDA-approved for this purpose.

Extended-release naltrexone has not been studied in the United States as extensively as methadone and buprenorphine. However, several European and Russian studies have found that naltrexone is associated with substantially lower rates of opioid use, reduced opioid cravings, and reduced polysubstance use, compared to a placebo (Lee et al., 2017; Tanum et al., 2017).

Naltrexone has the lowest initiation rates and the poorest adherence rates among patients, when compared to the other FDA-approved medications for opioid use disorder. However, several features may make naltrexone a more attractive treatment option for certain patients. First, because naltrexone is not an opioid, health care providers do not need special licensing to prescribe it. In addition, there is no risk that naltrexone will be diverted to the illicit drug marketplace. Abstinence for at least three days prior to administration of naltrexone is required to ensure the patient does not experience withdrawal symptoms.

Naltrexone is only recommended for patients who:

- Have withdrawn from opioids in prison, an abstinence-based inpatient rehabilitation facility, or other setting, and want to protect against relapse.
- Are highly motivated and would like to taper off opioids, including methadone or buprenorphine.
- Successfully completed methadone and buprenorphine treatment and want protection against overdose.
- Are adolescents and young adult patients with opioid use disorder.

TABLE 2.1: MEDICATIONS FOR OPIOID USE DISORDER TREATMENT¹

Component	Summary	Key Supporting Evidence	Level of Supporting Evidence
Methadone	• Full opioid agonist. • One of three medications approved by the FDA for opioid use disorder (OUD) treatment.	Patients maintained on methadone have: • Fewer overdoses. • Reduced morbidity and mortality. • Less injection drug use. • Reduced risk for HIV/HCV transmission. • Improved social functioning. • Decreased criminality/criminal activity. • Lower rates of other opioid use.	Well-supported ²
Buprenorphine	• Partial opioid agonist. • One of three medications approved by the FDA for the treatment of OUD	Buprenorphine is associated with: • Improved treatment outcomes. • Fewer overdoses. • Better treatment retention rates. • Less injection drug use. • Reduced HIV/HCV transmission/risk. • Improved social functioning. • Decreased criminal activity. • Lower rates of other opioid use.	Well-supported ³
Naltrexone	• Full opioid antagonist. • One of three medications approved by the FDA for the treatment of OUD.	Several European and Russian studies have found naltrexone is associated with: • Lower rates of opioid use. • Reduced opioid cravings. • Reduced polysubstance use.	Supported ⁴

1. Note: While all relevant references are listed, the level of supporting evidence indicated in the chart for each component reflects the authors' determination based on the balance of the cited evidence.

2. Ali et al., 2017; ASAM (Kampman & Jarvis, 2015; Bao et al., 2009; Degenhardt et al., 2011, 2014; Dolan et al., 2003, 2005; Gowing et al., 2011; Larochelle et al., 2018; Mattick et al., 2003, 2009; Marsch, 1998; Mitchell et al., 2009; National Academies, 2019; Sees et al., 2000; Sordo et al., 2017; Strain et al., 1993, 1999; Surgeon General, 2016; Wakeman et al., 2020; WHO, 2009; Woody et al., 2014.

3. ASAM (Kampman & Jarvis, 2015); Bart, 2012; Fudala et al., 2003; Johnson et al., 1995; Kakko et al., 2003; Larochelle et al., 2018; Ling et al., 1998; Mattick et al., 2003, 2014; National Academies, 2019; Schwartz et al., 2013; Sordo et al., 2017; Surgeon General, 2016; Thomas et al., 2014; Wakeman et al., 2020; WHO, 2009; Woody et al., 2014.

4. Lee et al., 2017; Tanum et al., 2017.

TREATMENT DURATION WITH MEDICATIONS

Continuity of care is essential for patients who wish to maintain treatment with medications.

The optimal duration of the treatment medications described here has not been—and is not likely to be—determined by randomized controlled trials. However, many observational studies conducted within and outside the United States over the past several decades found that patients who are maintained on any of the three FDA-approved medications for longer periods, such as six to 12 months, have significantly better clinical outcomes than those who discontinue medications earlier (Sees et al., 2000).

Tapering off these medications should not be considered until there is stable abstinence and improved health and social adjustment, which offer the best preparation for sustained recovery without medication assistance.

Even in the best of circumstances, medication tapering must be carried out with careful consideration and under medical supervision, given the high risk for relapse and overdose. Many field studies have shown elevated risks of relapse and overdose among previously maintained patients who discontinued their medication. The highest rates of overdose occurred in the weeks immediately following discontinuation (Williams et al., 2020). Reports from the Surgeon General (2016), National Academies (2019), ASAM (Kampman & Jarvis, 2015), World Health Organization (2009) and the U.S. Department of Health and Human Services (2019) recommend that only trained health care professionals should decide, together with the patient, whether and under what conditions medication should be discontinued.

MEDICATIONS AND SPECIAL POPULATIONS

There is little research examining the specific effectiveness or value of most medications for opioid use disorder within special populations. Thus, this report addresses only those research findings showing that a specific medication is contraindicated for a specific subgroup, or that special considerations are required when providing a medication for individuals in a subgroup.

Pregnancy

Naltrexone is not recommended for use during pregnancy (SAMHSA, 2018), but methadone and buprenorphine are safe medications to use in pregnancy. The risks and benefits of both methadone and buprenorphine are approximately the same for pregnant women as for the general population.

Methadone is associated with slightly higher treatment adherence and risk of overdose during medication initiation. Babies born to mothers on medication for opioid use disorder have lower rates of neonatal abstinence syndrome (NAS) than babies born to opioid-using mothers not engaged in medication treatment. NAS risk is similar with both methadone and buprenorphine, but its severity and duration are lower with buprenorphine than with methadone. There is no relationship between the maternal methadone dose and the likelihood of an infant developing NAS (SAMHSA, 2018).

Adolescents

Methadone and naltrexone are not FDA-approved for individuals younger than age 18. Nonetheless, limited data offer some support for the use of naltrexone with adolescents (National Academies, 2019).

Buprenorphine is safe and effective for treating adolescents with opioid use disorder, although treatment retention rates are lower for adolescents than for adults.

Federal guidelines require individuals under age 18 to have two failed attempts at short-term detoxification or abstinence-based treatment within a 12-month period before becoming eligible for methadone. The guidelines also require parental/guardian consent for administration of methadone. As a result, methadone has not been well studied in adolescents. However, limited data also offer some support for the use of methadone in this population (Camenga et al, 2019).

Treatment Cost Estimates for Expanding Access to Medications for Opioid Use Disorder

Estimating the costs of medications involves determining the cost of an individual's medications over a year's time period for each of the FDA-approved medications, in addition to that individual's treatment costs. Settlement fund managers for a state or local unit of government would then determine how many individuals it expects to serve over the year, and then multiply the cost per individual

by the number of individuals. This approach assumes a constant per-unit cost for each medication and treatment across the nation. However, discounts might be negotiated, depending on the volume of sales.

There are several complicating factors to consider when pricing medications for opioid use disorder, including initial set-up costs (including training, increased staffing and infrastructure), lack of adequate information about the demand for each of the three FDA-approved drugs, and the mix of medications that may be used, within a targeted program.

In calculating the price for each FDA-approved medication, this report relies on several data sources:

4. Budget data from CODAC Behavioral Healthcare, a nonprofit outpatient provider of treatment for opioid use disorder in Rhode Island. Using budget figures for the period covering Sept. 1, 2019 to June 30, 2020, CODAC estimated these costs for dispensing and delivering a daily dose of medication:
 - a. Methadone: \$20 per day, or \$608.33 per month.
 - b. Suboxone: \$19 per day, or \$577.92 per month. Buprenorphine is an active ingredient in suboxone, but it also includes naloxone.
 - c. Naltrexone: \$700 to \$1,100 per month in its injectable form.
2. A study of community-based treatment programs that introduced MOUD that used the Drug Abuse Treatment Cost Analysis Program (DATCAP.com) to estimate the total cost per participant for treatment (McCollister, et. al., 2018). For Suboxone (buprenorphine is an active ingredient in Suboxone, but it also includes naloxone), the range was \$503.82 to \$1,296.22 per patient per month, with a mean total cost of \$828.97 per patient per month. For extended-release (injectable) Naltrexone, the range was \$595.35 to \$1,791.24, with a mean total cost of \$1,082.38 per patient, per month. The total cost includes detoxification, provider costs, medications costs, and patient costs (such as travel). For purposes of our calculations, we inflated the costs to January 2020 dollars using the United States Bureau of Labor Statistics CPI Inflation Calculator.
3. A study seeking to validate cost-band estimates developed by the Center for Substance Abuse Treatment for the average cost of methadone treatment, which found a range of \$491.79 to \$633.10 per patient per month (French et. al., 2008). Costs were converted into January 2020 dollars using the United States Bureau of Labor Statistics CPI Inflation Calculator.

Combining the sources above provides the following range of costs for delivering MOUD:

- Methadone: \$491.79 to \$633.10 per patient / per month
- Suboxone (Buprenorphine + naloxone): \$503.82 to \$1,296.22 per patient / per month
- Naltrexone (injectable form): \$595.35 to \$1,791.24 per patient / per month

In addition, new programs must invest in start-up costs: one-time investments that include staff training (time spent attending in-person or web-based training) and the purchase of necessary equipment or supplies. Mean start-up costs were:

- \$1,182.19 per program for injectable Naltrexone, and
- \$860.98 per program for Suboxone (McCollister, et. al., 2018).

Start up costs for methadone programs were not available – but are likely much higher given that methadone can currently only be prescribed in stand-alone, dedicated programs that must pass stringent federal and state licensing requirements.

Third party payors, such as Medicaid, can and should be expected to help offset the ongoing cost of providing these three FDA-approved medications, though typically not the start up costs for new programs. The Affordable Care Act expanded Medicaid coverage for adults, and states are taking steps to address the opioid epidemic by covering the costs of medication.

All state Medicaid programs cover at least two of the FDA-approved medications, and most cover all three of these medications. Forty-one states cover methadone; all states and the District of Columbia cover buprenorphine; and all states cover naltrexone. This coverage spans across services ranging from inpatient detoxification, residential treatment, outpatient detoxification, and intensive outpatient treatment (KFF, 2019; Orgera & Tolbert, 2019).

Because states and localities are not equally burdened by the opioid epidemic, the local population demand for MOUD varies. Additionally, the existing treatment infrastructure for providing MOUD, and the financial investment needed to expand access to MOUD, varies as well. An equitable allocation of funds could be based on proportion of opioid related deaths, on existing opioid treatment capacity relative to demand, or a combination of the two approaches.

Behavioral Therapies for Opioid Use Disorder Treatment

ADDICTION COUNSELING AND BEHAVIORAL THERAPY

Addiction counseling, provided in group and/or individual sessions, offers sound advice, motivational support, and practical guidance to individuals seeking recovery from a substance use disorder. Counseling is often accompanied by assistance connecting patients to support services such as health care, legal assistance, childcare, housing, and employment (McGovern & Carroll, 2003; Woody et al., 1983).

Most states have few specific educational or training requirements for individuals who wish to become a licensed addiction counselor. Counseling can be performed by individuals with a wide range of training and background skills, including clergy, social workers, nurses, psychologists, and some of those with “lived experience.” (The National Center on Addiction and Substance Abuse, 2012.)

Behavioral therapies are interventions that involve structured conversation, and are usually provided by professionals and conducted in individual sessions. These therapies are designed to address deeper problems, such as developing coping skills, modifying problematic emotions or behaviors, improving relationships, and promoting self-efficacy (McGovern & Carroll, 2003). Administering behavioral therapies typically requires advanced education at the master’s, MD, or PhD level, and specialized training to demonstrate proficiency in a recognized type of therapy.

Both counseling and behavioral therapy should be made available in all addiction treatment settings that serve patients with opioid use disorder. However, patients’ receipt of medications should not be contingent on participation in counseling or therapy.

NOTES ABOUT THIS REVIEW OF BEHAVIORAL THERAPIES

Evidence Base

The evidence base for each type of behavioral therapy examined in this review is somewhat limited, given that most studies evaluate these interventions as a component of multimodal treatment interventions. This multifaceted approach makes it difficult to isolate the effects of any one behavioral intervention. Further, the effectiveness of the intervention is dependent, in large part, on the experience and expertise of the clinicians offering the intervention (Luborsky et al., 1985; Pilkonis et al., 1984).

Cost Considerations

The basic cost of addiction treatment programs will vary appreciably, depending on whether the program is situated in a hospital, residential, outpatient, or office-based setting. The discussions of cost considerations for behavior therapies that appear in the following sections focus on the costs of adding high-quality behavioral therapy to existing programs, not on the basic framework or costs of addiction treatment programs.

CONTINGENCY MANAGEMENT: WELL SUPPORTED

Major reports issued by the National Academies (2019), the Surgeon General (2016), ASAM (Kampman & Jarvis, 2015), and WHO (2009) have demonstrated that contingency management is effective, especially if offered as an adjunct to medication in treating opioid use disorder. Contingency management also can be combined effectively with other behavioral therapies, such as cognitive-behavioral therapy and family therapy.

Contingency management involves providing modest but tangible rewards for behaviors that are consistent with treatment goals. Rewards can include vouchers for community stores or for recreational activities. Treatment goals may include:

- Participation in program activities.
- Drug abstinence and medication adherence, as evidenced by toxicology screening.

Research shows that contingency management outcomes include longer periods of treatment retention and drug abstinence, and

greater improvement in social and personal functioning than either non-contingent counseling or no behavioral treatment (Higgins et al., 2013). These outcomes are particularly strong for reinforcement interventions offering take-home medication privileges (Carroll & Onken, 2005), or vouchers for community goods or services (Silverman, et al., 1996), in return for drug-free urine tests.

Randomized controlled trials have found less consistent results for contingency management as an effective adjunct to buprenorphine treatment (Carroll & Weiss, 2017; Ling et al., 2013; Schottenfeld et al., 2005). Studies found that an effective strategy for improving treatment retention featured a combination of injectable extended-release naltrexone and a contingency management intervention that rewarded patients with placement in a therapeutic workplace (DeFulio et al., 2012; Everly et al., 2011).

COST CONSIDERATIONS FOR CONTINGENCY MANAGEMENT

Contingency management is a relatively low-cost intervention that can be implemented effectively with relatively little staff training (Carroll et al., 2002; Higgins et al., 2013; Petry & Martin, 2002). Unlike the other behavioral therapies, contingency management interventions can be delivered by relatively easily trained addiction treatment counselors.

Contingency management should not be considered as a replacement for individual drug counseling sessions. Unlike other forms of behavioral therapy, contingency management interventions require adjunctive or supplemental services, including urine testing and vouchers, to be maximally effective.

Contingency management costs will be affected by several factors, which could differ among locales. Costs may vary, depending on:

- **The setting in which the intervention takes place**, which is usually lower cost outpatient or office-based settings, rather than residential settings.
- **The duration of the program**, which is usually 24 weeks.
- **Background and training of therapists**, which will affect compensation.

- **Expenses associated with the program**, including the costs of rewards, management of the rewards program, urine testing, and individual counseling sessions.

The cost of rewards in a contingency management program and the need for frequent drug screenings can present barriers to implementation in some treatment programs or settings (Carroll & Onken, 2005). Further, the effects of the intervention are not usually sustained once the incentive is stopped (Dunn et al., 2015).

Cognitive Behavioral Therapy: Well-Supported

Cognitive behavioral therapy (CBT) is a well-supported therapy focused on identifying and correcting negative thoughts and underlying assumptions about problematic feelings and behaviors, including depression, anxiety, or substance use. The therapy is designed to provide a means to improve those feelings and behaviors (Woody et al., 1983).

CBT is a sophisticated therapy provided in individual sessions, usually by a clinician with an advanced educational degree and substantial special clinical training (Carroll & Onken, 2005). Nonetheless, it is feasible to train advanced counselors to deliver CBT competently (Morgenstern et al., 2001).

CBT aims to prevent relapse among individuals with a substance use disorder. The therapy utilizes cognitive and behavior-modifying techniques to help patients identify and avoid emotional and situational triggers to use drugs. Patients are taught a set of skills, including coping, drug-refusal, problem-solving, stress management, and self-control (Kleber et al., 2006; McHugh et al., 2010).

A typical course of CBT is 12 weeks. Research examining CBT for treating opioid and cocaine use disorders shows that, in some cases, CBT's effects endure after a course of treatment (Carroll et al., 1994; Carroll et al., 2000; Epstein et al., 2003; Rawson et al., 2002).

There is well-supported evidence for the effectiveness of CBT in treating alcohol, cocaine, marijuana, and nicotine use disorders, either alone or in combination with other therapies (Carroll & Onken, 2005; Dutra et al., 2008; Hofmann et al., 2012; Magill & Ray, 2009; McHugh et al., 2010; National Institute on Drug Abuse, 1998). However, meta-analytic studies demonstrate that CBT has relatively less efficacy for the treatment of opioid use disorder (Hofmann et al., 2012). For example:

- The Surgeon General's (2016) report rated the effectiveness of CBT interventions for treating opioid use disorder as supported.

- The National Academies (2019) determined that CBT is “empirically supported” when used with medication for opioid use disorder.
- ASAM (Kampman & Jarvis, 2015) found “evidence of superiority” of CBT and contingency management over other behavioral therapies when used with medications for opioid use disorder.

CBT has not been shown to enhance medical management for patients receiving buprenorphine for the treatment of opioid use disorder. Two randomized controlled trials in office-based or primary care settings found that patients receiving buprenorphine for opioid use disorder did not have more positive treatment outcomes when CBT was added to a program of standard medical management (Fiellin et al., 2013; Ling et al., 2013).

Cost Considerations for Cognitive Behavioral Therapy

The cost of cognitive behavioral therapy will be affected by several factors, which could differ among locales. Costs may vary, depending on:

- The setting in which the intervention takes place, which will most likely to be lower cost outpatient or office-based settings, rather than residential settings, since CBT requires active patient participation and the practice of new skills in the patient’s normal living situation. To be maximally effective, CBT therapists should have a quiet, private office capable of holding both individual and family sessions.
- The duration of the therapy, which usually includes 12 weekly individual sessions. Many CBT therapists supplement their 12-session courses of therapy with six weekly or 12 bi-weekly telephone check-up sessions of 15-30 minutes each.
- Background and training of therapists who typically hold a master’s, MD or PhD in one of the clinical specialties and participate in six-to-nine months of intensive, individually supervised training by a senior CBT therapist.
- Associated or adjunctive services, which are minimal since most addiction treatment programs consider CBT a supplement to existing counseling, rather than a replacement for it.

FAMILY THERAPY: WELL-SUPPORTED

The effectiveness of family therapy in treating opioid use disorder is well-supported.

Engaging family and other social supports in the treatment of addiction promotes better treatment engagement, adherence, retention, and outcomes for adults and adolescents. More specifically, several forms of family therapy, including behavioral couples therapy, can improve communication and reduce interpersonal conflict and other relationship stressors that often contribute to or exacerbate a substance use disorder.

Family therapy appears to be effective in supporting treatment engagement and positive treatment outcomes, especially when it occurs in conjunction with medications for opioid use disorder (Brigham et al., 2014; Powers et al., 2008; Rowe, 2012).

The National Academies (2019), the Surgeon General (2016), ASAM (Kampman & Jarvis, 2015), and WHO (2009) all recommend the involvement of the family in treatment, whenever possible. However, it is difficult to discern which specific family therapy strategies and components are most likely to yield positive outcomes, given the many approaches to family therapy and the fact that this therapy usually is implemented in conjunction with other interventions, including contingency management (Carroll & Onken, 2005). Further, few studies present long-term results of family-based interventions, making it difficult to determine the extent to which these interventions promote sustained recovery from opioid use disorder (Rowe, 2012).

No fixed number of sessions are required to produce significant benefit from family or couples therapies. However, a 24-week course of treatment is typical.

Family Therapy for Adolescents

Most of the research on family-based therapy focuses on its use with families of adolescent patients. A variety of approaches have been developed to involve the family in addressing youth substance use disorders.

Some of these approaches target youth with specific co-occurring disorders, such as conduct problems, oppositional behavior, or criminal-justice involvement (Diamond & Josephson, 2005; Liddle et al., 2008; Rowe, 2012). However, few studies have examined the efficacy of these treatment approaches specifically for youth with opioid use disorder.

Cost Considerations for Family and Couples Therapy

- The cost of family and couples therapy will be affected by several factors, which could differ among locales. Costs may vary, depending on:
- **The setting in which the therapy takes place**, which is more likely to be lower cost outpatient or office-based settings, rather than residential settings. Family therapists should have a quiet, private office capable of holding both individual and family sessions.
 - **The duration of the therapy**. Research shows that 24 weeks of family therapy produces clinically significant benefits. Most family therapists supplement the 24-session course of therapy with 12 bi-weekly telephone sessions that usually last 15-30 minutes.
 - **Background and training of therapists** who are specially trained clinicians with a master’s, MD or PhD in a clinical specialty and receive between six and nine months of intensive, individually supervised training by a senior family therapist.
 - **Associated or adjunctive services**, which are minimal when family and couples therapy are viewed as a supplement to existing counseling instead of a replacement for it.

TABLE 2.2: BEHAVIORAL THERAPIES FOR OUD TREATMENT¹

Component	Summary	Key Supporting Evidence	Level of Supporting Evidence
Contingency Management	Seeks to: • Weaken reinforcement associated with substance use. • Strengthen reinforcements associated with healthier, alternative actions. • Provides rewards for behaviors associated with treatment goals, including: • Treatment participation. • Drug abstinence. • Adherence to medications for opioid use disorder (MOUD).	Effective in treating opioid use disorder (OUD), especially as an adjunct to methadone and buprenorphine treatment. • Longer periods of treatment retention and drug abstinence. • More improvements in social and personal functioning.	Well-supported ²
Cognitive Behavioral Therapy (CBT)	• Individual sessions focus on identifying and correcting negative thoughts and underlying assumptions about problematic feelings/ behaviors. • Uses cognitive and behavior-modifying techniques to provide patients with strategies to identify and avoid triggers to use drugs.	• Effective for treating OUD when used with MOUD. • Effects endure after treatment	Well-supported ³

Component	Summary	Key Supporting Evidence	Level of Supporting Evidence
Family Therapy	- Engages the family. - Works to improve communication and reduce interpersonal conflict and other family relationship stressors that contribute to substance use disorder. - Includes behavioral couples therapy. - Often used with families of adolescent patients.	- Effective, especially in conjunction with MOUD, in supporting treatment engagement and positive treatment outcomes for patients with OUD. - Involvement of family in treatment recommended whenever possible.	Well-supported ⁴

1. Note that while all relevant references are listed, the level of supporting evidence indicated in the chart for each component reflects the authors' determination based on the balance of the cited evidence.

2. ASAM (Kampman & Jarvis, 2015); Bickel et al., 2008; Carroll et al., 2001; Carroll & Onken, 2005; Carroll & Weiss, 2017; DeFulio et al., 2012; Dugosh et al., 2016; Everly et al., 2011; Higgins et al., 2013; Ling et al., 2013; National Academies, 2019; Prendergast et al., 2006; Schottenfeld et al., 2005; Silverman et al., 1996; Stanger & Budney, 2019; Surgeon General, 2016; WHO, 2009.

3. ASAM (Kampman & Jarvis, 2015); Carroll et al., 1994, 2000; Carroll & Onken, 2005; Dutra et al., 2008; Epstein et al., 2003; Fiellin et al., 2013; Hofmann et al., 2012; Kleber et al., 2006; Ling et al., 2013; Magill & Ray, 2009; McHugh et al., 2010; Morgenstern et al., 2001; National Academies, 2019; National Institute on Drug Abuse, 1998; Rawson et al., 2002; Surgeon General, 2016; Woody et al., 1983.

4. ASAM (Kampman & Jarvis, 2015); Brigham et al., 2014; Carroll & Onken, 2005; Diamond & Josephson, 2005; Liddle et al., 2008; National Academies, 2019; Powers et al., 2008; Rowe, 2012; Surgeon General, 2016; WHO, 2009.

BEHAVIORAL THERAPIES AND SPECIAL POPULATIONS

Limited research has been conducted to determine the effectiveness or value of behavioral treatment components with special populations. Thus, this report discusses only those research findings showing that an evidence-based component is contraindicated for a subgroup, or that special considerations are required when implementing the intervention with a subgroup.

Pregnancy

In general, behavioral therapies show little efficacy in pregnancy. When interventions such as contingency management are used during pregnancy, they tend to show less efficacy, compared with their use in non-pregnant women (Terplan et al., 2015). These findings are due, in part, to the fact that many people reduce their substance use during pregnancy, making it more difficult to assess the intervention's additional effect.

Adolescents

Adolescent Community Reinforcement Approach is a contingency management intervention specifically designed for treating adolescents with substance use disorder. This approach promotes treatment goals through family, social, and educational/vocational incentives and reinforcements. Efficacy for this approach has been shown for adolescent alcohol use disorders and marijuana use disorders (Davis et al., 2019; Godley et al., 2017; Stanger & Budney, 2019). However, rigorous studies focusing on the effectiveness of this approach in the treatment of adolescent opioid use disorder are lacking.

Cognitive behavioral therapy is effective for adolescents with a variety of substance-use disorders (Becker & Curry, 2008; Waldron & Kaminer, 2004; Waldron & Turner, 2008), but few methodologically rigorous studies are available on its effectiveness in treating adolescents with opioid use disorder.

Clinical Monitoring

Clinical monitoring involves both regularly scheduled and periodic, unannounced biological testing of urine, saliva, and blood during treatment for patients taking any type of medication for opioid use disorder (American Society of Addiction Medicine, 2017). Biological testing/monitoring is not a form of treatment. However, it has clinical value as part of a treatment protocol.

In criminal justice settings, biological testing/monitoring has been used routinely, particularly with individuals on probation or parole. Such testing detects and then punishes drug use with incarceration.

In clinical settings, biological testing/monitoring has much different uses. Clinical monitoring carried out as part of addiction treatment is designed to help patients manage their opioid use disorder in much the same way blood pressure or hemoglobin A1c measurements are used to manage hypertension and diabetes, respectively (Dennis & Scott, 2011; Dennis et al., 2003).

Clinical monitoring has five purposes:

1. Assure adherence with the prescribed medication.
2. Deter diversion of medications to the illicit drug marketplace.
3. Guard against risk of overdose from drug-drug interactions.
4. Serve as an indicator of patient progress during the course of treatment.
5. Promote full patient disclosure and honest discussion of behavioral problems in counseling and behavioral therapy (Alford et al., 2011; American Society of Addiction Medicine, 2017; Barthwell et al., 2018; Dennis & Scott, 2011; Dennis et al., 2003; Jarvis et al., 2017; Lagisetty et al., 2017).

Recovery Support Services in Opioid Use Disorder Treatment

DRUG-FREE HOUSING: WELL SUPPORTED

The effectiveness of drug-free housing for Opioid Use is well-supported by the evidence.

The Surgeon General (2016) cites well-supported evidence for the effectiveness of drug-free housing in the treatment of most substance use disorders. For example, an 18-month descriptive study showed decreased drug and alcohol use and increased employment among 245 adults with substance use disorders who were actively engaged in sober-living homes (Polcin et al., 2010).

A randomized controlled trial by Milby and colleagues (2005) offers evidence of the effectiveness of providing drug-free housing as an incentive for achieving abstinence that is sustained over six months and verified by toxicology screening. Based on this evidence, Milby and colleagues rate the effectiveness of drug-free housing used in the context of outpatient treatment for opioid use disorder as “supported.”

Numerous barriers exist for implementing effective drug-free housing, including quality, fraud, zoning laws, and licensing. Because drug-free housing is not a traditional level of care, it is not regulated as treatment by any state. This lack of regulation precludes states from enforcing standards of quality for drug-free housing. Ensuring that drug-free housing is, in fact, drug-free, is a key concern. Without proper oversight, drugs are often introduced into drug-free housing. This drug presence undermines recovery and negates the benefits of this service.

SELF-HELP/MUTUAL-SUPPORT GROUPS: WELL-SUPPORTED

Self-help and/or mutual-support groups like Alcoholics Anonymous (AA) or Narcotics Anonymous (NA) are free, easily accessible, and widely available sources of peer support for recovery. This report rates the effectiveness of self-help/mutual-support groups, especially AA, as well-supported when used in the context of treatment for opioid use disorder. Other types of self-help/mutual-support groups, such as NA, Smart Recovery, and Women for Sobriety, are similar in concept, but often different in approach. These groups have not been thoroughly evaluated.

AA and other peer-support groups are free and not regulated by any governmental or commercial insurance agency. Therefore, these groups are technically not a “paid service” that could be purchased using opioid settlement funds. Nonetheless, these groups are recommended by the ASAM (Kampman & Jarvis, 2015), based on a few large field studies (Kelly et al., 2020).

Tracy and Wallace (2016), cited in the National Academies (2019) report, state that the use of peer-support groups is promising, but needs more rigorous evaluation. Humphreys and colleagues (2004) found strong support for the ability of peer-support groups to promote abstinence among study participants, although the dropout rate for these types of groups—90 percent—is high. In a Cochrane review, Kelly and colleagues (2020) concluded there was enough evidence from randomized controlled trials to support the use of AA for positive long-term outcomes such as abstinence. In contrast, the Surgeon General’s (2016) report stated that the use of Narcotics Anonymous has not been studied extensively. Still, the report calls NA a “promising practice.”

It is important to note that self-help/mutual-support groups like AA and NA do not constitute treatment. States should not make participation in such groups a requirement for receiving medication for opioid use disorder.

CHILDCARE: PROMISING

Childcare is a promising recovery support that has high face validity because it could reduce barriers to sustained participation in outpatient treatment, especially among women. However, there is currently little empirical evidence supporting the inclusion of childcare in treatment of opioid use disorder.

Only one quasi-experimental study, featuring a non-equivalent control group, found evidence that childcare services, bundled with other social services, was an effective component of opioid use disorder treatment (Marsh et al., 2000). Based on this evidence, the study rates as “promising” the effectiveness of adjunctive childcare provided in the context of outpatient treatment for opioid use disorder.

CASE MANAGEMENT: PROMISING

This report rates the effectiveness of case management in the context of treatment for opioid use disorder to be promising.

Case management was recommended in the National Academies report (2019), but was not supported by accompanying evidence. Assertive Community Treatment, which offers the individual highly specialized and personal care every day of the year, at home or in community settings, was recommended by ASAM (Kampman & Jarvis, 2015), but there was poor evidence supporting its use. The supporting studies were conducted with subpopulations, including individuals who were homeless and those with severe mental illness, rather than with a broader population experiencing substance use disorder.

PEER SUPPORT/PEER PROVIDERS: PROMISING

The use of peer support services in the context of treatment for opioid use disorder is promising, based on the limited evidence available to date.

In a typical peer support program, recovering individuals are asked to develop a peer-to-peer relationship with patients. Peer providers help engage and motivate people with opioid use disorder to enter some form of continuing treatment. Peer providers also assist with resolving common barriers to continued care, such as providing transportation or an active referral to treatment programs. Increasingly, paid peer providers are playing a role in emergency department settings, detoxification programs, and as adjuncts to residential treatment programs.

The National Academies (2019) cites Chapman and colleagues (2018), who conclude there is no randomized controlled trial data on the effectiveness of peer providers. The Surgeon General (2016) cites the Substance Abuse and Mental Health Services Administration (Park-Lee et al., 2015), which states that peer providers can be important for maintaining recovery but does not cite evidence to support this conclusion.

Use of peer providers is widespread and has received many favorable reviews from treatment programs and healthcare delivery organizations. However, the practice of peer support is not well standardized, and no studies currently attest to its effectiveness.

TABLE 2.3: RECOVERY SUPPORT SERVICES IN OPIOID USE DISORDER (OUD) TREATMENT¹

Component	Summary	Key Supporting Evidence	Level of Supporting Evidence
Drug-Free Housing	Offers substance-free environments and support from fellow recovering residents.	- Decreases substance use and increases employment. - Supports sustained abstinence over six months. - Reduces illegal activity.	Well-supported ²
Self-Help/ Mutual Support Groups	- Free, widely accessible sources of peer support for recovery and abstinence. - Alcoholics Anonymous is the most researched and supported program. - Other programs may have similar positive outcomes, but require more research.	- Not a “paid service” that could be purchased with settlement funds. - Recommended, but more rigorous evaluation is needed.	Well-supported ³
Childcare	Enables patient engagement and treatment retention.	- Little evidence to support including childcare in OUD treatment. - One study found bundling childcare and social services is effective.	Promising ⁴
Employment Counseling and Support	Non-clinical wrap-around service that supports recovery.	- Logical adjunct to treatment services. - Few studies address employment counseling and support. - Receiving treatment should not depend on being employed.	Promising ⁵
Case Management	Helps individuals access services like: - Physical and mental health care. - Substance use disorder treatment. - Other social services.	- Case management recommended, but not supported by evidence. - Assertive Community Treatment recommended.	Promising ⁶
Peer Support/ Peer Providers	Recovering peers develop supportive relationships with individuals who have substance use disorders, to increase likelihood of their sustained recovery	- Peer providers can be important for maintaining recovery. - Widespread practice. - Not supported by evidence.	Promising ⁷

1. Note that while all relevant references are listed, the level of supporting evidence indicated in the chart for each component reflects the authors' determination, based on the balance of the cited evidence.

2. Lo Sasso et al., 2012; Milby et al., 2005; Polcin et al., 2010; Surgeon General (2016).
3. ASAM (Kampman & Jarvis, 2015); Kelly et al., 2020; National Academies, 2019; Tracy & Wallace, 2016.
4. Marsh et al., 2000; Surgeon General (2016);
5. Surgeon General (2016).
6. ASAM (Kampman & Jarvis, 2015); National Academies (2019); Surgeon General (2016).
7. SAMHSA, 2015.

Treatment in Primary Care Settings

Primary care plays a fundamental role in treating OUD. Primary care providers (PCP) are the largest group of potential buprenorphine prescribers in the U.S. These providers, who include physicians and advanced practice providers like nurse practitioners and physician assistants, are well-positioned to improve treatment access and capacity for OUD (Barnett et al., 2019; Wakeman & Barnett, 2018). There are several reasons for this.

First, primary care can be more convenient for patients than specialty care options, such as a psychiatrist, an opioid treatment program, or an inpatient treatment facility. This is particularly true in rural areas where distance to specialty care and access to transportation can present a barrier (Joudrey et al., 2019).

Second, seeing a PCP often carries less stigma than seeking specialty treatment. This reduced stigma could increase the number of patients who are open to initiating and remaining in treatment.

Third, PCPs can motivate individuals with OUD to address other comorbid medical issues and can provide routine preventive care.

Five primary care-centered interventions described in the following pages have a demonstrated track record or show strong promise for improving access to treatment and quality of care for OUD. They are:

1. Team-based modules in primary care.
2. Hospital-to-primary care linkages.
3. Expanding nurse scope of practice and reducing administrative barriers to prescribing.
4. Primary-to-specialty care linkages.
5. Physician-to-physician support systems.

TEAM-BASED MODELS IN PRIMARY CARE FOR OUD TREATMENT

Team-based models are extremely well-established in primary care. This model is best exemplified by the patient-centered medical home (PCMH) concept (Jabbarpour et al., 2017). PCMH is a care-delivery model through which treatment by a team of healthcare professionals is coordinated through the patient's primary care physician to ensure the patient receives the necessary care when and where the patient needs it, in a manner the patient can understand.

The evidence supporting team-based primary care models for behavioral health treatment is well supported in OUD and extremely well-established for mental health conditions outside of OUD.

Integrating team-based behavioral health into primary care has been a core theme in the PCMH movement since its inception. One common example for behavioral health integration is the

"Collaborative Care Model," which engages non-physician staff members, including care managers, non-physician behavioral health providers (BHP) like social workers or psychologists, or other behavioral health consultants (American Psychiatric Association Academy of Psychosomatic Medicine, 2016).

Team-based models distribute the many tasks necessary for high-quality mental health care among professionals with different expertise. For example, these models may rely on:

- A nurse care manager to provide coordination.
- A behavioral health provider for therapy.
- A physician for clinical management.

A full review of the Collaborative Care Model is outside the scope of this report. However, a comprehensive summary from the Substance Abuse and Mental Health

Services Administration (SAMHSA) provides significant detail (American Psychiatric Association Academy of Psychosomatic Medicine, 2016). The Massachusetts Nurse Care Manager Model, which teams nurse care managers with

PCPs, provides one example of the collaborative care model that has been implemented widely and shows promise in uncontrolled observational studies.

TABLE 2.4: MODELS OF TEAM-BASED PRIMARY CARE FOR OUD TREATMENT

Team-Based Model	Summary	Key Components	Level of Supporting Evidence
Collaborative Care Model	Integrates non-physician care coordinators and behavioral health providers like social workers into standardized workflow of primary care for OUD management.	• Screening identifies at-risk patients. • Care coordinator-behavioral health provider team up with primary care provider (PCP). • Patients are tracked through a registry. • Team meets regularly.	Well-supported ¹
Massachusetts Nurse Care Manager Model	• Based on Federally Qualified Health Center. • Focuses on teaming up nurse care managers with PCPs.	• Nurse care manager performs initial screening, intake, and education, often with assistance from a medical assistant. • Nurse care manager provides ongoing management of OUD and other medical issues. • Prescribing physician and nurse care manager co-manage patients. • Psychological services are integrated on-site or nearby, though specific services vary from site to site.	Promising ³

1. Watkins et al., 2017

2. Alford et al., 2011

Scaling and Implementation Considerations

Adapting team-based OUD models into existing PCMH clinics may be significantly easier than incorporating team-based models into traditional, physician-centered clinics, considering the current state of team-based care in regional primary care clinics.

Team-based models require motivated, well-trained team members, including social workers, psychologists, registered nurses, and other staff. Finding and training qualified health care workers to support these models can be a significant challenge, even if practices have adequate funding to hire new staff.

Cost Estimates

Primary care clinics adapting new models of care require increased reimbursement for additional staff, training, and other services. The Medicaid Health Homes program established under the Affordable Care Act provides one benchmark to estimate the potential costs of promoting team-based models of primary care. For example, Maryland Health Homes paid \$98.87 per member per month, plus a one-time payment of \$98.87 for the initial intake.

Hospital-to-Primary Care Linkages

When a patient presents in the emergency department (ED) with an opioid-related overdose, that patient is stabilized medically and discharged with a referral to addiction treatment. This standard operating procedure leaves the patient with the sole responsibility for setting up and waiting for an appointment at a time when the patient is in the midst of withdrawal symptoms. Given this lack of longitudinal coordination, it is not surprising that few individuals with OUD are connected to treatment (Alinsky et al., 2020; Larochelle et al., 2018).

In hospital-to-primary care linkage models, OUD patients in the ED are administered buprenorphine, and discharged with a primary care appointment and enough take-home buprenorphine to last until the appointment takes place. Directly linking a patient to primary care, especially when initiating buprenorphine, increases the likelihood that the patient will engage in treatment.

Linkage can also extend to patients being discharged from an acute-care inpatient hospital. The typical standard of care for these discharged patients is similar to discharges from ED settings. Patients are offered referrals to follow-up addiction providers in the hope that they will continue to engage in treatment after discharge.

In the hospital-to-primary care linkage model, however, patients admitted for short-term inpatient stays for medically managed withdrawals are linked directly to primary care before discharge. Patients are also maintained on buprenorphine, rather than tapered off before discharge. Maintaining buprenorphine treatment increases engagement in treatment and reduces illicit opioid use up to six months later.

TABLE 2.5: EXAMPLE OF HOSPITAL-TO-PRIMARY CARE LINKAGES

Hospital Coordination Model	Summary	Key Components	Level of Supporting Evidence
Emergency Department (ED) Linkage to Primary Care	• Administer buprenorphine to patients presenting with opioid use disorder (OUD) in the ED. • Arrange follow-up appointment with primary care physician.	• Screening and brief intervention. • Appointment made with primary care center within three days of ED discharge. • Buprenorphine initiated in the ED and continued at home until primary care appointment.	Supported ¹
Short-term Inpatient Linkage to Primary Care	Inpatient initiation of medications for opioid use disorder (MOUD), and MOUD maintenance at home until linkage to primary care.	• PCP is contacted before patient is discharged and an appointment is scheduled within a week of discharge. • Patient receiving inpatient medically managed withdrawal continues on buprenorphine, rather than being fully tapering off the medication before discharge.	Well-supported ²

1. D’Onofrio et al., 2015; 2017

2. Liebschutz et al., 2014; Stein et al., 2020

Scaling and Implementation Considerations

The foundation of hospital-to-primary care linkage models is a workforce of prescribers who are equipped with buprenorphine waivers and comfortable initiating patients on treatment. In addition, the linkage models will work best in communities that have resources to which patients can be linked. Communities without an opioid treatment program or a base of primary care practices with buprenorphine treatment capacity may not be able to take advantage of linkage models until a more robust community-based treatment infrastructure is established.

Cost Estimates

There is no consensus on exactly how linkage models should be built or what their typical cost structure should be. The process of linking ED and inpatient OUD patients with primary care is not traditionally reimbursed as a separate service by payers. Recent trials (D’Onofrio et al., 2015, 2017; Liebschutz et al., 2014) identified several resources that are needed to implement hospital-to-primary care linkages in addition to clinical trial staff:

- Buprenorphine-waivered ED or inpatient prescribers.
- Additional nurse coordinator or social worker time to provide brief counseling.
- Referral services for linkage to primary care.

Resources would also be needed to provide the training necessary for implementation of a linkage model. For many hospitals, these resources might include funds to cover the salary of one clinical coordinator full-time equivalent, plus additional funds for training and a project manager.

MODELS TO EXPAND THE OUD TREATMENT WORKFORCE

Buprenorphine, the mainstay of outpatient OUD treatment, can only be prescribed by a clinician with a federal waiver. Obtaining that waiver requires hours of training. The waiver system represents a fundamental barrier to improving access to OUD treatment in primary care.

There has been a significant increase in buprenorphine waivers over the past decade. The number of waived prescribers in the U.S. grew from 3.8 per 100,000 persons to 17.3 per 100,000 persons from 2007 to 2017 (McBain et al., 2020). This growth is impressive. However, only a small fraction of PCPs has obtained waivers, and an even smaller fraction use them.

Fortunately, nurse practitioners (NP) and physician assistants (PA) appear to be filling the gap (Xue et al., 2019). In 2016, the Comprehensive Addiction and Recovery Act (CARA) enabled NPs and PAs to apply for waivers after 24 hours of training, compared to eight training hours for physicians. The expansion of waivers to NPs and PAs grew rapidly, with 12,706 waivers

acquired by these advanced practice providers by 2019 (Barnett, et al., 2019). States with a fully independent scope-of-practice regulation for NPs had twice as many waived NPs than states with limited scope-of-practice policies.

Vermont offers the most relevant example of state efforts to incentivize waiver acquisition and expand OUD treatment. Through its Medicaid 1115 waiver, Vermont offered a \$500 incentive payment to physicians who completed the waiver training, and enhanced reimbursement for physicians prescribing buprenorphine to 10 or more patients (ASPE, 2018; Van Donsel et al., 2019). There is no evidence regarding how buprenorphine waiver adoption in Vermont would have progressed in the absence of such an incentive, but a one-time incentive payment, potentially combined with non-financial peer pressure, could be a promising practice for other states to consider.

TABLE 2.6: EXAMPLE MODELS TO EXPAND THE OUD-TREATMENT WORKFORCE

Model	Summary	Key Components	Level of Supporting Evidence
Incentives for buprenorphine waiver acquisition	Create financial incentives for primary care providers to become a buprenorphine prescriber under the Drug Addiction Treatment Act (Extends CARA provisions).	• Reimburse for the provider’s time to do DATA-waiver training. • Increase reimbursement for prescribing to more than 10 patients. • Pay capitated rates for induction, stabilization, and maintenance.	Promising ¹

Model	Summary	Key Components	Level of Supporting Evidence
Promote Use of Nonphysician Providers	- Encourage DATA-waivers and hiring of nurse practitioners (NP) and physician assistants for buprenorphine prescribing. - Expand scope-of-practice laws to enable independent prescribing.	Not yet demonstrated but expanding scope of practice laws for NPs appears likely to be effective.	Promising ²

1. Van Donsel et al., 2020

2. Barnett et al., 2019; Spetz et al., 2019

Scaling and Implementation Considerations

Achieving wide-scale implementation of a waiver-related incentive program is not necessarily a major challenge since such a program could be implemented through state-level policy or regulation changes, or wide-scale incentive programs. However, there may be political or cultural barriers to implementing the necessary policy changes, such as gaining support from stakeholders for expanding scope-of-practice policies for NPs or PAs, and accepting a “harm reduction” framework of strategies and ideas for reducing negative consequences associated with drug use.

Cost Estimates

The cost of implementing incentives for waiver acquisition or expanding waivers for NPs/PAs will depend on the approach taken. The cost of a simple monetary incentive to encourage physicians, NPs, and PAs to take waiver training would likely be in the range of \$500-\$1,000, multiplied by the number of clinicians targeted for program participation.

Expanding scope-of-practice policies is a legislative and regulatory change that cannot be purchased using abatement funds. However, NPs and PAs usually make 50 percent or less of the standard salary for physicians. Allowing NPs and PAs to prescribe buprenorphine could be very cost-effective for government-run facilities like community health centers.

PRIMARY-TO-SPECIALTY CARE COORDINATION

The need for better integration of addiction specialty care within primary care has been documented in multiple surveys. These surveys report that a key barrier to the participation of PCPs in OUD treatment is their lack of comfort with addiction treatment, and their need for specialty support (ASPE, 2018; Louie et al., 2019). Many PCPs also attribute their lack of participation in OUD treatment with their lack of knowledge of this treatment, and their lack of institutional support and peer support from colleagues who treat OUD (Haffajee et al., 2018).

A popular and much-discussed strategy for providing coordination between addiction specialists and PCPs is the “Hub and Spoke” model, a Health Home initiative created under Section 2703 of the Affordable Care Act for Vermont Medicaid beneficiaries (Brooklyn & Sigmon, 2017). In the Vermont Hub and Spoke model, primary care and other “spoke” practices collaborate closely on OUD treatment with a regional “hub,” which is typically a formal Opioid Treatment Program (OTP) staffed with addiction specialists.

Patients typically receive intake and buprenorphine induction at the hub, and then receive OUD treatment centered at either the hub or at spoke clinics, depending on the patient’s needs and acuity. The Baltimore Collaboration Opioid Prescribing (Co-OP) model implements the Hub and Spoke model in an urban setting (Chou et al., 2016; Stoller, 2015). The evidence supporting the hub and spoke model is still limited.

TABLE 2.7: MODELS OF PRIMARY-TO-SPECIALTY CARE COORDINATION

Model	Summary	Key Components	Level of Supporting Evidence
Project Extension for Community Healthcare Outcomes (ECHO)	Uses an internet-based audiovisual network for provider mentoring and education from off-site experts.	- Providers in primary care can access education and mentorship remotely. - Mentors do not see the patients. - HIPAA-level communication costs and infrastructure are not needed.	Promising ¹
Physician-to-Physician Warmlines	Physician-led, phone-based service for PCPs to call and discuss addiction treatment.	Specialists staff consultation phone lines for non-emergent questions about addiction treatment from PCPs.	None existing

1. Arora et al, 2011

Scaling and Implementation Considerations

Even with unclear outcomes, the Hub and Spoke model has been an operational success in rural Vermont. This success may be due, in part, to the fact that Vermont has a network of OTPs that can serve as hubs. It appears that at least one or more strong OTP hubs are needed to build a successful program. The Hub and Spoke model may be the most natural fit for rural areas with an anchor OTP or addiction specialty practice that has the capacity to centralize OUD care for a region.

Cost Estimates

Detailed cost estimates from a 2013 overview of the Hub and Spoke model estimated the cost of Health Home staffing enhancements to Hub OTP programs as \$1,776 per patient per year. For each Spoke clinic, estimated cost is \$164 per member per month, based on one full-time equivalent (FTE) RN and one FTE licensed clinician case manager for every 100 patients across multiple providers within a Health Service Area.

PHYSICIAN-TO-PHYSICIAN SUPPORT SYSTEMS

In general, primary care physicians have little training and clinical support to provide high-quality addiction treatment. In a 2016 survey of more than 1,000 rural physicians with a buprenorphine waiver, three of the top-four barriers endorsed by respondents were related to constraints on their ability to provide addiction care (Andrilla et al., 2017).

Physician-to-physician support with specialists, which takes place by phone or video conference, is one approach to providing support for PCPs who lack comfort with addiction treatment or need guidance for complex cases. Project Extension for Community Healthcare Outcomes (ECHO) is the best-known example of this model of care. The ECHO model uses an internet-based audiovisual network to link primary care clinics, typically in rural areas, with university-based specialists for mentoring and education. ECHO has been implemented for dozens of different disease models, including opioid use disorder and other substance use disorders.

Another less time-intensive physician-to-physician model is the specialty “warmline.” This is a physician-led phone service staffed by addiction specialists. The specialists take calls confidentially from other physicians, typically PCPs, on addiction-related care questions. Hours of availability and scope of services vary widely. Examples of warm lines include the Massachusetts Consultation Service for the Treatment of Addiction and Pain (MCSTAP) and the University of California San Francisco Clinician Consultation Center (California Substance Use Line, n.d.; MCSTAP, n.d.).

TABLE 2.8: MODELS ENHANCING PHYSICIAN-TO-PHYSICIAN SUPPORT

Model	Summary	Key Components	Level of Supporting Evidence
Project Extension for Community Healthcare Outcomes (ECHO)	Uses an internet-based audiovisual network for provider mentoring and education from off-site experts.	• Providers in primary care can access education and mentorship remotely. • Mentors do not see the patients. • HIPAA-level communication costs and infrastructure are not needed.	Promising ¹
Physician-to-Physician Warmlines	Physician-led, phone-based service for PCPs to call and discuss addiction treatment.	• Specialists staff consultation phone lines for non-emergent questions about addiction treatment from PCPs.	None existing

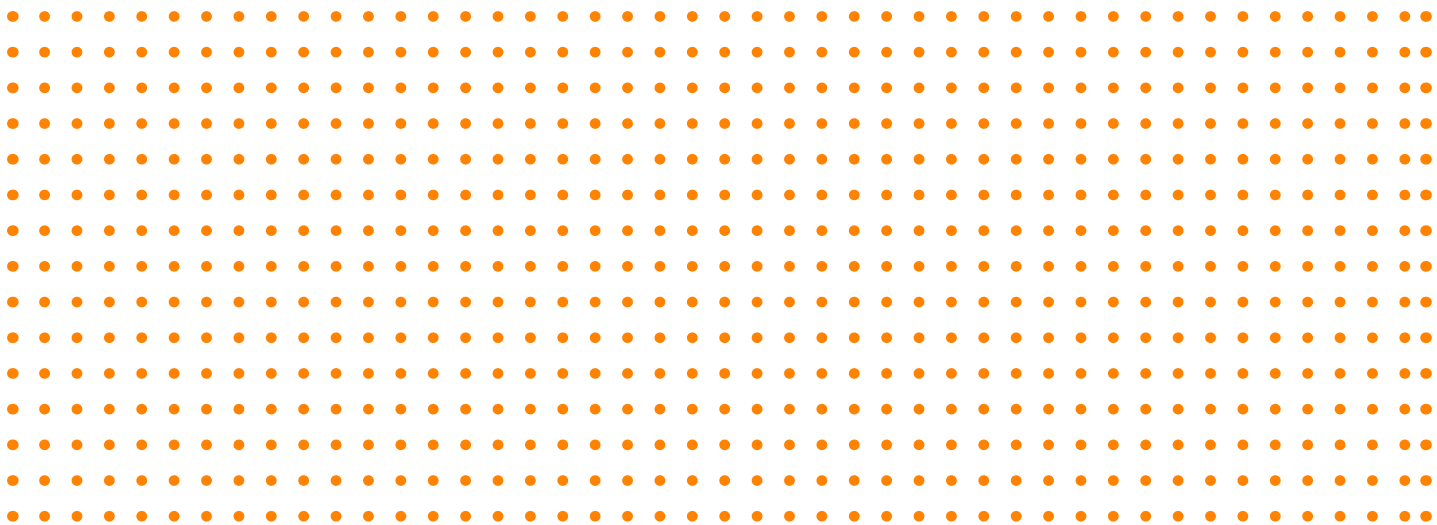
1. Arora et al, 2011

Scaling and Implementation Considerations

Though their evidence base is limited, Project ECHO and physician-to-physician warmlines are well suited to provide additional addiction specialty resources in remote areas through a relatively low-cost, scalable mechanism. Both interventions use centralized resources and a specialist or specialist team that can connect to a geographic area of any size by phone or videoconference.

Cost Estimates

Project ECHO estimates that the cost of establishing one ECHO Hub program is approximately \$200,000 a year. Project ECHO has published a detailed budget that describes the costs of establishing a new model and its necessary components.



CHAPTER 3: Harm Reduction

Harm reduction approaches enable people who do not wish to, or are unable to stop using opioids to make positive changes in behavior that can improve their health and minimize the risks of opioid use. Harm reduction is increasingly recognized as an essential part of a comprehensive strategy to combat the opioid epidemic. While the strongest research evidence supports the role of two harm reduction interventions—syringe services and naloxone distribution programs—it should be noted that the interventions discussed in this chapter are not supported by randomized trials.

TABLE 3.1: HARM REDUCTION INTERVENTIONS

Intervention	Summary	Key Components	Level of Supporting Evidence
Syringe services programs	Provides sterile syringes to people who inject drugs, to reduce infectious disease transmission.	- Needs-based distribution, as opposed to restricted distribution or one-to-one exchange of syringes. - Comprehensive harm reduction and health care services, including testing, counseling, treatment referrals, social and legal services, and other injection equipment.	Well-supported ¹
Naloxone distribution and access	Distributes naloxone for use in event of an opioid overdose.	- Access and broadening distribution to people who use drugs or are close to individuals who use drugs. - Access and broadening distribution to first responders and emergency personnel.	Well-supported ²

Intervention	Summary	Key Components	Level of Supporting Evidence
Hepatitis C and HIV education and prevention	Education on strategies to minimize risk of hepatitis C and HIV infection for people who inject drugs.	- Strategies include multiple sessions of counseling, group education, and peer training. - Specific components uncertain, given heterogeneity of effective models.	Supported ³
Supervised Drug Consumption Sites	Provides safe environment for consumption	- Reduces risk of overdose - Creates opportunities for engagement in treatment	Promising ⁴

1. Platt et al., 2017; UNAIDS, 2016; Wodak & Cooney, 2004.

2. Abouk et al., 2019; McClellan et al., 2018; Rees et al., 2017; Walley et al., 2013

3. Garfein et al., 2007; Gilchrist et al., 2017; Meader et al., 2010; Sacks-Davis et al., 2012

4. Caulkins et al., 2019.

Syringe Services: Well-Supported

Syringe services programs provide sterile equipment to individuals who inject drugs. These programs are sometimes referred to as “syringe exchanges” or “needle exchanges.” Available data indicates that there are close to 400 syringe services programs operating in the U.S., with locations primarily in urban areas, on the West Coast, and in the Northeast (North American Syringe Exchange Network, 2020; Teshale et al., 2019). Many people who could benefit from a syringe services program do not live close enough to obtain services from a program (Canary et al., 2017).

SUMMARY OF EVIDENCE

A large, robust observational literature, including reviews by the World Health Organization (Wodak & Cooney, 2004) and the United Nations (UNAIDS, 2016), supports the effectiveness of syringe services programs in:

- Reducing blood-borne infections, particularly transmission of HIV (Aspinall et al., 2014; Fernandes et al., 2017; Hurley et al., 1997; Platt et al., 2017; Strathdee & Vlahov, 2001; Wodak & Cooney, 2006).
- Reducing injection risk behaviors, such as syringe borrowing and lending (Des Jarlais et al., 1995; Donoghoe et al., 1989; Vlahov et al., 1997).

While randomized controlled trials of syringe services programs have not been conducted, this assessment of the strength of the evidence is based on a large number of observational studies showing findings that have remained consistent as better quality data have become available and as programs have been replicated. This assessment relies on a set of criteria developed by Bradford Hill (1965) that has been used extensively to assess public health interventions.

Studies also indicate that syringe services programs are associated with:

- Reduced frequency of injection, and increased drug treatment entry and retention (Hagan et al., 2000; Platt et al., 2017).
- Non-clinical benefits, including averted treatment costs (Cabase & Sanchez, 2003; Gold et al., 1997; Jones et al., 2008; Kwon et al., 2012; Laufer, 2001; Nguyen et al., 2014; Sweeney et al., 2019; Wodak & Cooney, 2004).
- Studies of syringe services programs showed:
- No evidence of increased injection frequency or recruitment of new users (Hartgers et al., 1992; Watters et al., 1994).
- No evidence of increased drug debris in the surrounding environment (Broadhead et al., 1999; Doherty et al., 2002; Oliver et al., 1992).

Research indicates that the largest benefits of syringe services come from locating these programs in areas with a higher density of injection drug use (Harris, 2006).

SCALING AND IMPLEMENTATION

High-quality syringe services programs share a few characteristics that are important to consider when establishing new programs.

Needs-Based Distribution

The most effective syringe services programs do not require one-for-one syringe exchanges, through which a single sterile syringe is distributed for each returned, used syringe. Syringe services programs with unrestricted or loosely restricted syringe distribution—called “needs-based distribution”—are associated with higher rates of sterile syringes per injection, lower HIV incidence, and safer injection practices.

Because needs-based distribution decouples syringe distribution from syringe collection, it enables individuals to access as many syringes as needed. Needs-based distribution is associated with reduced syringe borrowing and lending, and decreased incidence of HIV (Kerr et al., 2010).

Comprehensive Harm Reduction and Health Care Services

The highest quality syringe services programs offer a comprehensive package of harm reduction and health care services (Centers for Disease Control and Prevention, 2010; Fernandes et al., 2017). These packages include:

- Education on preventing transmission of hepatitis C and HIV.
- Anonymous hepatitis C and HIV testing.
- Counseling and medical care.
- On-site drug treatment or referrals to that treatment.
- Social and legal services.
- Distribution of other injecting equipment like swabs, cookers, filters, and water ampoules to prevent the risk of blood-borne infection.
- Distribution of naloxone and condoms.

In light of surges in overdose deaths due to fentanyl, newer evidence suggests the efficacy of incorporating anonymous fentanyl-testing technologies into the comprehensive package of services offered by syringe services programs. Limited available research indicates that the distribution of fentanyl test strips or other testing technologies to people who inject drugs may influence injection decisions, and possibly reduce the risk of fatal overdose (Sherman et al., 2019). However, since the majority of the heroin supply in many or most regions in the U.S. has been penetrated by fentanyl over time, the tests may offer little extra information to potential users. However, these tests may offer value to users of other drugs, including cocaine.

Complementary Distribution Approaches

Most evidence on the effects of syringe services programs comes from studies of distribution taking place at fixed distribution sites. However, complementary distribution approaches should also be considered for abatement funding, even though less evidence for this distribution approach is available.

The World Health Organization reported on evidence supporting the effectiveness of syringe distribution through pharmacy sales and vending machines (Wodak & Cooney, 2004). These complementary distribution sites tend to attract a population of injection drug users that is different from those using fixed-location syringe services programs and may help to broaden access to an effective intervention. Similarly, outreach syringe distribution strategies, such as mobile vans and home visits, are increasingly becoming part of a comprehensive syringe services program approach.

BASIC FINDINGS ON COST

The cost findings for syringe services programs included in this report are based on a comprehensive syringe services program using a traditional “store-front” facility structure. Research by Teshale and colleagues (2019) offers the most current evidence on the estimated cost of establishing and operating a comprehensive syringe services program. These estimates include one-time start-up costs and annual costs associated with personnel, operations, and prevention and medical care services. Estimates are based on the number of clients served each year and whether the service is categorized as rural, suburban, or urban.

Cost Estimates

Total cost for a syringe services program ranged from:

- \$0.4 million for a small, rural syringe services programs serving 250 clients, to
- \$1.9 million for a large, urban syringe services program serving 2,500 clients.

The initial start-up costs represent:

- 1.6 percent of the total cost for small, rural program.
- 0.8 percent for a large, urban syringe services program.

Cost per-syringe distributed varied from:

- \$3 for a small urban program, to
- \$1 for a large rural program.

Other available estimates of the costs per syringe are as low \$0.13 (Harris, 2006), suggesting that these estimates may represent the higher end of the cost scale.

Cost per client per year varied from:

- \$2,000 for small, urban programs, to
- \$700 for large, rural programs.

Cost Savings

Nguyen and colleagues (2014) estimated that a new investment of \$10 million in syringe services would avert an estimated 194 HIV infections and avoid \$75.8 million in lifetime HIV treatment costs.

A larger new investment of \$50 million would avert approximately 816 HIV infections and avoid \$319 million in lifetime HIV treatment costs (Nguyen et al., 2014).

Naloxone Distribution: Well-Supported

Naloxone is a competitive opioid-receptor antagonist that reverses the effects of an opioid overdose when administered promptly and in an appropriate dose. By blocking opioids from binding to opioid receptors, naloxone reverses the opioid-induced suppressed respiration, which can cause death (Boyer, 2012).

First approved as an opioid overdose reversal drug by the Food and Drug Administration (FDA) in 1971, naloxone initially was used exclusively by medical professionals in health care settings (Campbell, 2019). In the 1990s, laypersons began using naloxone in the community (Campbell, 2019; McDonald et al., 2017). All of the currently available FDA-approved formulations of naloxone can be used by laypersons outside health care settings (Sharpless, 2019). These formulations include:

- Branded (Narcan) and generic injectable naloxone products, which can be administered intravenously, intramuscularly, or subcutaneously. These products can also be administered intra-nasally with a mucosal atomizer device.
- An auto-injector product called Evzio.
- A nasal spray naloxone, including the branded Narcan Nasal Spray (Jiang, 2018).

Naloxone may need to be administered more quickly, and may require multiple doses, to reverse an overdose involving fentanyl. Fentanyl is a particularly strong opioid that is prevalent in the street drug supply in many regions of the country (Frank & Pollack, 2017).

SUMMARY OF EVIDENCE

Quasi-experimental studies have evaluated the impact of state naloxone access laws and community-based naloxone distribution programs. These studies suggest that broadening access to naloxone among laypersons in the community is effective in reducing opioid overdose mortality (Abouk et al., 2019; McClellan et al., 2018; Rees et al., 2017; Walley et al., 2013).

ISSUES OF SCALING AND IMPLEMENTATION

There are a number of mechanisms by which states can scale up the availability of naloxone, including:

- Facilitating community-based distribution directly to persons at risk for opioid overdose.
- Requiring first responders to carry and use naloxone. This requirement would apply to law enforcement, fire and rescue, and emergency medical services.
- Passing laws to ease restrictions on prescribing, dispensing, and possessing naloxone. These laws would facilitate naloxone's availability among persons at risk for opioid overdose and their family members and friends.

Community-Based Distribution Programs

States could use abatement funds to provide supplies of naloxone, purchased in bulk at a reduced per-kit cost, to organizations like syringe services programs. These organizations may be best suited to distribute naloxone to people who use opioids because they have high contact and established trust with persons at high risk for opioid overdose.

Descriptive data found that community-based distribution programs in 30 states and the District of Columbia distributed 152,283 naloxone kits and reported 26,463 overdose reversals among kit recipients between 1996 and 2014 (Wheeler et al., 2015). The majority of reversals were carried out by other individuals who use opioids and were present with the person overdosing (Wheeler et al., 2015). Coffin and colleagues (Coffin & Sullivan, 2013) have estimated that one overdose death can be averted for every 227 naloxone kits distributed directly to persons using heroin.

Requiring First Responders to Carry Naloxone

States could use abatement funds to provide bulk supplies of naloxone to first responders. Distribution of bulk supplies to these groups may depend on a jurisdiction's current authorizations for administration of naloxone. Legal analyses conducted in 2013 suggest significant national variation in legal authorization for different types of first responders to administer naloxone (Davis et al., 2015; Davis et al., 2014). Jurisdictions vary in whether they authorize all types of first responders to administer naloxone and whether they order responders to carry naloxone.

BASIC FINDINGS ON COST

Three FDA-approved formulations of naloxone are available for medical and community use. These formulations vary substantially in terms of price, which has increased over time (Gupta et al., 2016; Rosenberg et al., 2018). The FDA has clarified that all formulations, including the least expensive injectable formulation of naloxone, are approved for community distribution and for use by non-medical professionals (Sharpless, 2019).

TABLE 3.2: MEDICATION COSTS

Product	Approximate Cost (February 2020)
Injectable naloxone	\$20-\$40 for two units
Narcan Nasal Spray*	\$140 for two units
Enzio auto-injector	\$5,000 for two units

**The FDA approved a generic version of a naloxone nasal spray in April 2019, but the manufacturer has not yet announced its cost or availability timeline (Food and Drug Administration, 2019).*

Table 3.2 supporting references: (Centers for Medicare and Medicaid Services, 2019; GoodRx, 2020; Gupta et al., 2016; Jiang, 2018)

Additional costs associated with scaling up naloxone distribution include:

- Overdose prevention training for first responders and laypersons. Training covers such topics as identifying an opioid overdose and administering naloxone.
- Storage and inventory.
- Building an infrastructure for distributing naloxone to the people and places most likely to experience opioid overdoses.

Other Harm Reduction Approaches

Abatement funds could be used to scale other harm reduction approaches, such as HIV and hepatitis C education, harm reduction-oriented policing, and overdose prevention sites or “safe consumption sites.”

HIV AND HEPATITIS C EDUCATION: SUPPORTED

Data from randomized controlled trials conducted in the U.S. and in international settings indicate that hepatitis C and HIV educational and psychosocial interventions can reduce risky injection practices, like sharing injection equipment, which facilitate hepatitis C virus and HIV transmission (Garfein et al., 2007; Gilchrist et al., 2017; Latka et al., 2008; MacKesy-Amiti et al., 2013; Meader et al., 2010; Sacks-Davis et al., 2012). The literature includes a variety of interventions, such as multiple sessions of counseling, group education, and peer training.

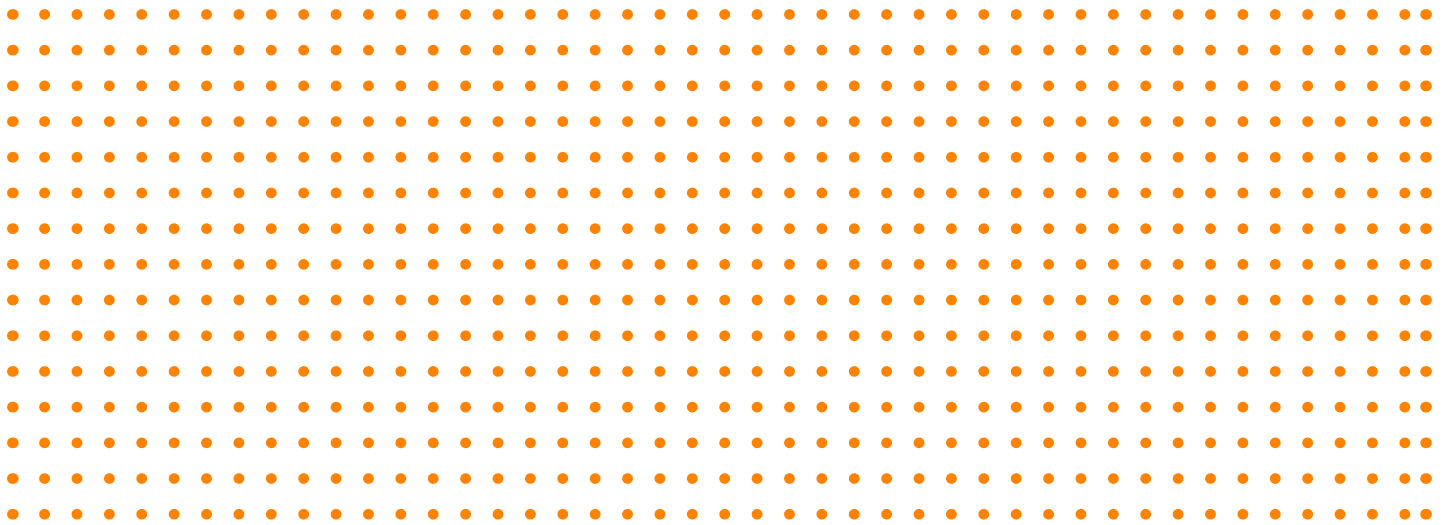
The diversity of models that have been evaluated make it challenging to discern which elements and delivery methods would produce the largest reductions in risky injection practices (Gilchrist et al., 2017; Meader et al., 2010; Sacks-Davis et al., 2012). Nevertheless, the literature suggests that education on hepatitis C and HIV, and methods for reducing risk of transmission, can have a positive impact on risky injection practices (Gilchrist et al., 2017; Meader et al., 2010; Sacks-Davis et al., 2012).

SUPERVISED DRUG CONSUMPTION SITES

A less developed research evidence base exists for supervised drug consumption sites, also known as overdose prevention sites. A recent systematic review catalogued at least nine quasi-experimental studies evaluating supervised drug consumption sites in three cities outside the U.S. That review found positive or no effects of safe consumption sites on most outcomes examined, including fatal overdose (Caulkins et al., 2019; Kilmer et al., 2019). Although this literature is limited, it provides no indication that these sites cause harm and, rather, suggests promise for their health benefits.

The only available evidence on supervised drug consumption sites in the U.S. come from qualitative and survey-based research focused on one unauthorized site. However, the study assessed the experiences of individuals using this site and not the site’s impact on outcomes (Davidson et al., 2018; Kral & Davidson, 2017). If abatement funds are directed to piloting supervised drug consumption sites, this funding allocation should require a rigorous evaluation to build an evidence base for this approach.

Like syringe services programs, supervised drug consumption sites offer the opportunity to make comprehensive services available to individuals who are disconnected from the traditional health and social service delivery system. These comprehensive services would include medical and mental health care services; naloxone, sterile syringes, and other harm reduction services; and other support programs.



CHAPTER 4: Care for Opioid Use Disorder in the Criminal Justice System

Need for Opioid Use Disorder Care in the Criminal Justice System

The phrase “criminal justice system” refers to the full continuum of programming provided in the community by law enforcement at four distinct intercepts:

- Law enforcement.
- Courts and probation, including drug and other specialty courts.
- Jails, prisons, and re-entry from incarceration.
- Community supervision including parole and probation.

Nearly seven million people are currently under the supervision of the U.S. criminal justice system: 2.3 million people are incarcerated in jails and prisons; 840,000 people are on parole; and 3.6 million people are on probation (Prison Policy Institute, 2019).

Most people involved in the criminal justice system have a history of a substance use disorder (SUD) or problematic substance use. Sixty-five percent of all currently incarcerated individuals meet the criteria for a substance use disorder (The National Center on Addiction and Substance Abuse at Columbia University, 2010). Substance-use rates among people on parole and probation are two to three times substance-use rates among the general population (The Pew Charitable Trusts, 2018).

A significant portion of justice-involved people with SUD histories have or have had opioid use disorders (OUD). People with an OUD are much more likely than the general population to become involved in the criminal justice system. Those with no opioid use in the past year have a 16-percent chance of becoming involved in the criminal justice system, while people with an OUD have a 50-percent chance of criminal justice system involvement (Winkelman et al., 2018).

The Substance Abuse and Mental Health Services Administration (SAMHSA) reports that approximately 17 percent of people incarcerated in state prisons and 19 percent of people incarcerated in jails report regular opioid use. Over 30 percent of incarcerated individuals report suffering from serious withdrawal symptoms or an inability to control their opioid use. Each year, over 200,000 people with a heroin use disorder are incarcerated, a figure constituting 24 to 36 percent of the incarcerated population (Boutwell et al., 2007; Bronson et al., 2017; Legal Action Center, 2011).

OUD CARE IN CRIMINAL JUSTICE SETTINGS

The final report of the President's Commission on Combating Drug Addiction and the Opioid Crisis (2017) recommended increased access to SUD treatment, particularly medication for opioid use disorder (MOUD), for incarcerated people with OUD, including those detained while awaiting trial.

Treatment using OUD medications is correlated with reduced risk of mortality following release from incarceration. Studies have shown that:

- People with OUD who were receiving MOUD were 75 percent less likely to die, and 85 percent less likely to die due to drug overdose, in the first month after release (Marsden et al., 2017).
- People who receive treatment using methadone and buprenorphine have lower rates of re-arrest and reincarceration (Evans et al., 2019; Farrell-Macdonald et al., 2014; Westerberg et al., 2016).
- Injectable naltrexone is effective in preventing opioid use relapse in justice-involved individuals (Lee et al., 2016; Evans et al., 2019; Farrell-Macdonald et al., 2014; Westerberg et al., 2016).

Access to OUD Care in the Criminal Justice System

Despite clear scientific evidence demonstrating the health, social, and public-safety benefits of OUD treatment, most people in the criminal justice system who need OUD care, including MOUD, do not receive it (National Academies, 2019; SAMHSA, 2019; Surgeon General, 2016; The President's Commission on Combating Drug Addiction and the Opioid Crisis, 2017).

Racism in the health care system has been a significant barrier for people of color who need clinically appropriate SUD care that helps them achieve and maintain long-term recovery. Despite the coverage expansions and consumer protection provisions of the Affordable Care Act and the Mental Health Parity and Addiction Equity Act, persistent financing barriers have precluded millions of Americans from receiving the care they need to become and remain well.

What Jurisdictions Can Do

The criminal justice system offers many opportunities, at every intercept, to engage with people with OUD and provide them the evidence-based care they need.

Jurisdictions seeking to improve policies and practices that strengthen access to opioid and other SUD care for the criminal justice population should first assess the landscape of resources and challenges in their states, and then identify opportunities and challenges associated with expanding OUD care in each intercept of the criminal justice system. This review will help decision makers:

- Map out the most urgent areas of need.
- Identify policy and practice changes that would require a financing strategy.
- Identify appropriate partners.
- Determine short-term and long-term action steps.

Principles of Drug Abuse Treatment for Criminal Justice Populations, published by The National Institute on Drug Abuse (NIDA, 2014), offers important evidence-based guidance for determining how to build a system of evidence-based SUD care throughout the criminal justice system. Several of the principles identified in NIDA's research-based guide explicitly support the provision of evidence-based OUD care throughout the criminal justice system. Those principles include:

- Assessment is the first step in treatment.
- Treatment must last long enough to produce stable behavioral changes.
- Tailor services to fit the needs of the individual.
- Continuity of care is essential as people with drug use histories re-enter the community.
- Medications are an important part of treatment for many justice-involved people who use drugs.

Findings on Effective Strategies

A 2017 study found that less than five percent of people referred through the criminal justice system to specialty OUD care received either methadone or buprenorphine (Krawczyk et al., 2017). The final report of the President's Commission on Combating Drug Addiction and the Opioid Crisis (2017) acknowledged significant barriers to providing MOUD to people with OUD in the criminal justice system. Citing research, which included a national survey of corrections staff in 14 states, the commission noted that most MOUD provided behind prison walls is limited to detoxification or to maintenance treatment for pregnant women (Belenko et al., 2013; Friedmann et al., 2012).

Research has also shown that an extremely low percentage (2%-10%) of people with an OUD receive MOUD while on probation or parole (Clark et al., 2014; Friedmann et al., 2012; Mumola & Bonczar, 1998; Nordstrom & Marlowe, 2016). Most drug courts fail to offer all three forms of MOUD for OUD, despite considerable efforts to improve access to evidence-based OUD care for people participating in drug court (National Academies, 2019).

HIGH NEED, LOW CARE

Several factors have led to the disproportionately high number of people who need but are not receiving effective OUD care in the criminal justice system.

1. The community-based health system has failed to effectively address the health needs of people with SUD.
2. Lack of resources for SUD and other health care services and medications has resulted in less effective health care throughout the criminal justice system.
3. Lack of coordination between health and criminal justice decision makers has made it difficult to achieve cross-system collaboration, data sharing, and innovation.
4. Policy failures, combined with racially discriminatory drug policies, have criminalized a health problem and resulted in the arrest and incarceration of many people with SUD for reasons unrelated to drug crimes.
5. Criminal justice professionals charged with making health care-related decisions often lack training on SUD, evidence-based services, medications, and supports (McMillan & Lapham, 2005).

INTERVENTION AND CONNECTION

Each criminal justice intercept presents important opportunities for intervention and connection to evidence-based opioid and other SUD care.

Training

At each intercept, states and localities should require and fund the training of law enforcement, court, corrections, and community corrections staff on opioid and other SUD, effective treatment services, and medications, and recovery supports.

Access to Treatment

Improving the strikingly low rates of treatment in the criminal justice system should start with these steps:

- Screen for opioid and other SUDs. This screening works best when it is a routine part of the individual evaluation process and incorporated at every intercept of the criminal justice system.
- Expand access to treatment. Studies show that when FDA-approved MOUD are made available, people treated in the criminal justice system experience better outcomes. The state of Rhode Island has successfully expanded access to opioid and other SUD care in the corrections system resulting in reduced rates of overdose (Green et al., 2018).
- Make treatment available at every intercept. The likelihood of improvement increases when people have access to all FDA-approved MOUDs and all evidence-based elements of care at every point of the criminal justice system.

As jurisdictions take steps to expand access to evidence-based elements of care, they should pay attention to special considerations at each intercept:

Law Enforcement

Jurisdictions should support the development of new and expanded police-based programs that divert people into evidence-based opioid and other SUD care. Pre-arrest SUD care and other early diversion strategies have been found to be effective in reducing recidivism, as measured by lower arrest and felony charge rates (Clifasefi et al., 2017). Jurisdictions should prioritize programs that mobilize mental health and SUD treatment experts through mobile and other crisis services.

Courts and Probation

Drug treatment and other specialty court programs should adopt policies clarifying that individuals engaged in MOUD treatment will not be precluded from entering into, remaining in, or completing specialty court programming. Probation office policies should ensure that people receiving MOUD can continue treatment and that people who need MOUD treatment can receive it.

Jails, Prisons, and Reentry

States and localities can learn from the successes of other jurisdictions like the state of Rhode Island, which saw positive outcomes after it expanded access to opioid and other SUD care in the corrections system (Green et al., 2018).

Evidence and experience show that as states and localities provide MOUD and other evidence-based OUD care inside prisons and jails, it is equally important that they arrange for in-reach services provided by community-based SUD treatment providers. These arrangements ensure seamless continuation of care as individuals leave jails and prisons and re-enter their communities (Guyer et al., 2019).

Jurisdictions may benefit from examining the experiences of states, including New York and Ohio, which have sought to improve health outcomes for incarcerated individuals by:

- Introducing addiction medications and the provision of other core evidence-based care prior to release.
- Coordinating and linking to community-based OUD services upon release (Gardner et al., 2018; Jannetta et al., 2017).
- Activating Medicaid and other benefits before release so that reimbursement for needed care is in place as soon as individuals leave incarceration.

Parole

Parole agents should ensure people can receive or continue receiving clinically appropriate SUD care, including MOUD.

COSTS FOR IMPLEMENTING EVIDENCE-BASED PROGRAMS IN THE CRIMINAL JUSTICE SYSTEM

Every jurisdiction will find it challenging to estimate the costs of interventions that expand access to improved OUD health services throughout the criminal justice system.

The biggest challenge to cost estimating is that criminal justice systems differ greatly across jurisdictions. For example, some states like Rhode Island have one, integrated state-level prison and jail system, while other states separate their jails from their prison systems. Local sheriffs manage the jails and a commissioner reporting to the governor's office manages the prison system. In some cases, cities may share jail systems. To complicate matters further, many states contract with private-sector providers to manage some aspects of incarceration.

Because of this complexity, each program intervention will require the appropriate jurisdiction's own effort to estimate cost. Individuals knowledgeable about a targeted program intervention and its cost components must participate in any cost-estimating exercise.

Cost-Estimating Example

This example illustrates how a cost estimating methodology might be applied to an opioid treatment program (OTP). Using the following cost-estimating methodology, a state would:

Establish a clear goal or goals for the OTP. Assume the OTP's goal is to reduce the number of overdose deaths among inmates released into the community. First ask, "How does the state introduce the OTP program with fidelity to the research and with cost effectiveness in mind?" The answer might be,

"Look at research and examples of other states that have successfully introduced similar programs."

This example looks at a Rhode Island program designed to expand OTPs in correctional facilities with populations of not more than 3,000 inmates. The program was implemented by CODAC Behavioral Healthcare. All three medications approved by the FDA for the treatment of OUD—methadone, buprenorphine, and naltrexone—are included in the program. Rhode Island does not have a unified prison system.

Identify inputs. Give thought to inputs that produce immediate outputs, generate processes, and lead to outcomes linked directly to the goal. In this example, your outcome is to “Introduce the OPT within the prison.” One process that would need to occur is: “Screen all existing and new entrants for OUD.” This screening would require clinical staff.

To help identify inputs, make three assumptions:

1. Staffing limitations would make it unfeasible to train existing prison staff to conduct screening.
2. Some existing prison space capacity would be dedicated to the program, along with an area for separating inmates in the treatment program from the general population.
3. The treatment program would need:
 - a. Counselors.
 - b. Clinicians who can administer medications.
 - c. A part-time pharmacist to manage those medications in a secure location.
 - d. Staff to manage the community outreach process and track inmates after they leave the facility.
 - e. A part-time physician.
 - f. An outside evaluator to track program progress in achieving results.

In this example, then, the inputs would be:

- Dedicated space.
- Counselors (assume 4 positions).
- Dispensing nurses (6 positions).
- Program director (1 position).
- Medications.
- An evaluator (1 position/consultant).
- Insurance and licenses.
- A training program to help prison staff associated with the program better serve inmates who are being treated.

Identify results or outputs. The inputs identified above produce immediate results, or outputs. For example:

- A separate area is identified, possibly redesigned, and separated from the general inmate population.
- Clinical staff conduct screenings.
- Counselors develop treatment plans for each inmate and manage those plans with the inmates.
- Dispensing nurses dispense medications.

Identify outcomes that come from these activities. Short-term outcomes might be the number of inmates with an OUD who stay in the OTP, and the number of inmates who spend less time in isolation. Longer term outcomes could include:

- The number of inmates connected with external resources in preparation for release from prison.
- The number of inmates leaving the prison with transition kits containing information on where to continue receiving their medications.
- The number of inmates connected to community services, such as housing, job placement, and continued access to treatment.
- Reduction in the number of overdose deaths for inmates who are released back into the community.

Develop an action plan. Action plans are tools jurisdictions can use to assign specific tasks to specific individuals who are required to take specific steps to implement the methodology. For example:

- The Human Resources department could be assigned all matters related to recruiting and hiring specialty staff.
- A facility’s manager could be assigned the task of creating a dedicated and safe environment for the treatment program, including secure storage of medications stored on-site.
- The office of procurement could work with treatment program staff to identify an external consultant who would evaluate all aspects of the implementation, including its success in changing the number or rate of overdose deaths.

Estimate costs. Once the action plan is completed, it is easy to estimate costs in this simplified example. Using the CODAC budget from Sept. 1, 2019 to June 30, 2020 as a reference, Table 4.1 shows the estimated cost for the proposed OTP program and for all three FDA-approved medications.

This estimate assumes the program will serve 400 patients throughout the year, providing an equal mix of methadone and buprenorphine to program participants. The methadone cost calculation assumes 200 patients, times 365 days, times \$20.21 per dose. The buprenorphine estimate assumes 200 patients, times 365 days, times \$18.91 per dose.

TABLE 4.1: ESTIMATING COSTS FOR AN OPIOID TREATMENT PROGRAM

Input	Annual Unit Cost	Total Cost
Renovation of Dedicated Prison Space (one-time cost)	\$40,000	\$40,000
Pharmacist (1 part-time)	25% of \$48,000 annual salary	\$12,000
Program Manager (1)	\$95,000	\$95,000
Counselors (4)	\$60,000 per counselor	\$240,000
Charge Nurse (1)	\$80,000	\$80,000
Dispensing Nurses (6)	\$70,000 per dispensing nurse	\$420,000
Medications (bundled cost estimate)	\$20.21 (methadone); \$18.91 (buprenorphine)	\$2,855,760
Program Evaluator	\$75,000	\$75,000
TOTAL COST (Year 1)		\$3,817,760

These costs presented in Table 4.1 do not reflect total program costs. Rather, they represent additional costs that need to be added to the prison's existing budget to implement the new program. Costs already covered within the prison's ongoing budget include administrative services such as payroll, inmate officers, and transportation for other external medical services.

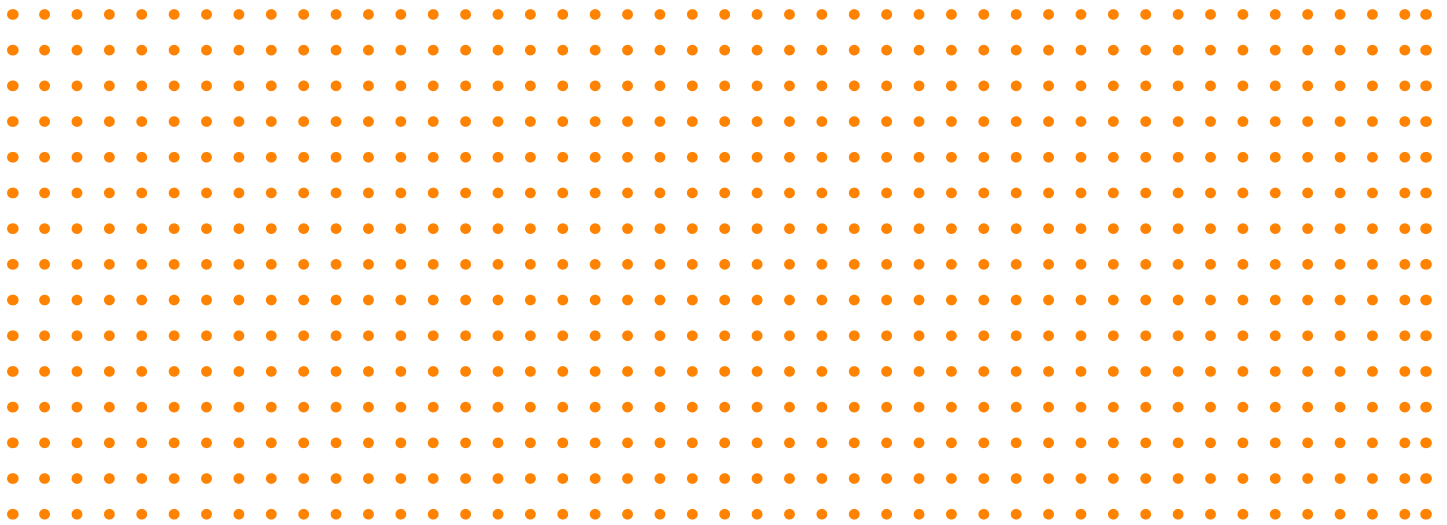
Additionally, the costs presented in Table 4.1 are for the first year. Setting aside wage adjustments, all else being equal, year 2 costs would drop by the full cost of the facility renovation.

This simple example provides insight in the methodology of estimating the cost of a new OTP within a state prison system. Costs for other treatment interventions would be conducted in a similar way.

CONCLUSION

"Withholding or failing to have available all classes of U.S. Food and Drug Administration-approved medication for the treatment of opioid use disorders in any care or criminal justice setting is denying appropriate medical treatment," according to the National Academies (2019).

Improving access to evidence-based OUD care for the criminal justice population presents an enormous opportunity for states and localities to make their communities healthier and safer, and to save significant funds.



CHAPTER 5: Prevention of Opioid Misuse and its Harmful Effects on Children and Families

Decreasing the incidence of opioid misuse is essential to preventing the development of opioid use disorder (OUD) and its associated harms. Many individuals misusing illicit opioids were initially exposed via prescription opioid analgesics. Therefore, policies that limit the supply and improve the safety of opioid analgesics prescribed in health care settings have the potential to decrease misuse of prescription opioid analgesics, and also subsequent illicit opioid use. (Cicero et al., 2014; National Academies of Sciences, Engineering, and Medicine, 2017; Substance Abuse and Mental Health Services Administration, 2019).

Children whose parents misuse opioids, or have OUD, are at increased risk of number of adverse outcomes, including:

- Neonatal opioid withdrawal syndrome (NOWS).
- Physical and mental health problems.
- Developmental delay.
- Child neglect, maltreatment, and abuse.
- Family instability and involvement with the child welfare system (Patrick et al., 2019; Winkelman et al., 2018; Anda et al., 2006; Feder et al., 2019; Ornoy et al., 2001).

Because of these adverse outcomes, there is a pressing need to scale up effective interventions that prevent opioid misuse, and its harmful consequences for children.

Scientific Standards Used to Judge Effectiveness of Prevention Policies

Evidence for each of the policies reviewed in this report was initially compiled through systematic searches of electronic databases of research articles published in English. These searches were then supplemented by additional targeted literature searches focusing on specific policies. The evidence review presented here was based on the primary sources.

STUDY CLASSIFICATION

This chapter uses the same classification system from the Centers for Disease Control and Prevention (CDC) that other chapters of this report use to rate evidence as well-supported, supported, or promising. However, Chapter 5 also uses a separate classification system—the modified GRADE approach—to rate the quality of evidence for policies and interventions related to opioid analgesic prescribing. The modified GRADE approach (Mauri et al., 2019) uses the following criteria to rate the strength of evidence:

- High quality: Evidence is derived from consistent findings across multiple randomized controlled trials (RCT).
 - Moderate quality: Evidence is derived from consistent findings across multiple observational studies with stronger research designs.
- Low quality: Evidence is derived from consistent findings across multiple observational studies with weaker research designs.
 - Very low quality: Few studies are available and have weaker research designs or inconsistent findings.

The modified GRADE approach was adopted for policies related to opioid analgesic prescribing because many of these policies consist of statewide regulations or programs that often cannot be evaluated using RCTs. Evidence on such policies consists primarily of observational studies with varying degrees of rigor. When compared with the CDC criteria, the modified GRADE criteria allow for more accurate comparison of the strength of observational studies that have different designs. Therefore, the GRADE criteria are better suited to rating the evidence base for policies related to opioid analgesic prescribing.

Table 5.1 presents an approximate crosswalk of the CDC and modified GRADE evidence rating criteria. The table illustrates how the modified GRADE criteria allow for more refined evidence ratings when applied to observational studies that might be classified as “supported” or “promising” by the CDC criteria.

TABLE 5.1: CROSSWALK OF CDC AND MODIFIED GRADE EVIDENCE RATINGS

CDC	Modified GRADE
Well-Supported	High quality
Supported	Moderate or Low quality
Promising	Low or Very Low quality

PRIORITIZED RESEARCH FINDINGS

Prevention Policies

The review of prevention policies presented here was restricted to studies of policies and interventions implemented in the United States. This decision was made because nearly all prevention-related policies and interventions are heavily intertwined with or influenced by the regulatory, financing, and social safety net infrastructures of the countries in which they are implemented. It is important for the purposes of this report to evaluate the effectiveness of different prevention policies in the unique context of the United States.

Children and Families

In reviewing interventions to mitigate harms experienced by children whose parents misuse addictive substances, this report prioritizes studies that exclusively or primarily examined families affected by opioid misuse. In cases where such evidence was limited, the review also considered studies that included families affected by misuse of other addictive substances. There were two reasons for including these studies:

1. The evidence base for interventions that specifically or exclusively target families affected by opioid misuse is more limited.

2. Opioids are far from the only addictive substances that may have harmful consequences for families. Alcohol, cocaine, and methamphetamine misuse also affects many adults with children. Many effective interventions are designed to serve families with diverse substance misuse challenges and, therefore, are relevant to families affected by the opioid crisis.

Policies and Interventions to Limit Supply and Improve Safety

HOW FINDINGS ARE ORGANIZED

This report categorizes policies and interventions that limit the supply and improve the safety of opioid analgesics, as follows:

- State-level policies.
- Insurer policies.
- Health system interventions.

MEASURING POLICY AND INTERVENTION OUTCOMES

Policies that limit the supply and improve the safety of opioid analgesics prescribed in health care settings have two ultimate goals:

1. To improve patients’ health outcomes by decreasing the incidence of opioid misuse and OUD.
2. To subsequently decrease negative opioid-related outcomes, such as opioid overdose.

Few evaluations examine policy impacts on patient health outcomes. Evidence of policy effectiveness is therefore based primarily on intermediate outcome measures, such as:

- Opioid analgesic prescribing/dispensing.
- Opioid analgesic prescribing safety related to dose, duration of therapy, or co-prescribing with benzodiazepines.
- Provider knowledge of opioid analgesic prescribing safety.

WHAT THE EVIDENCE SHOWS

Table 5.2 summarizes specific policies and interventions examined in this report, their key components, and the quality of evidence supporting their effectiveness.

TABLE 5.2:

Strength of the Evidence for Policies to Limit the Supply and Improve the Safety of Opioid Analgesic Prescriptions

Policy/Intervention	Summary and Key Components	Level of Supporting Evidence
State-Level Policies		
Prescription Drug Monitoring Programs (PDMPs)	Electronic databases collect and monitor the prescribing and dispensing of controlled substances. • Prescribers and pharmacists and, in some states, law enforcement consult the databases. • Data-sharing across state lines varies. • Controlled substances included in the databases vary by state. • Screening identifies patients at risk for opioid use disorder.	Low ²

Policy/Intervention	Summary and Key Components	Level of Supporting Evidence
Robust PDMP Features	Robust PDMP features, include: • Mandatory access provisions: Prescribers and pharmacists must query the PDMP before prescribing/dispensing opioids. • Registration mandates: Prescribers and pharmacists must register with the PDMP before prescribing/dispensing opioids.	Low to Moderate (for mandatory access) ³
Pain Clinic Laws	Laws regulate health care facilities specializing in pain treatment. Requirements may relate to: • Personnel. • Facility operations. • Inspections and oversight.	Low ⁴
Continuing Medical Education (CME) Requirements	States impose requirements for pain management education. • May be mandated by state medical boards as a condition of medical licensure.	Very low ⁵
State Opioid Prescribing Guidelines	Providers receive state guidance on opioid analgesic prescribing. • State medical boards or departments of public health typically issue the guidance. • Recommendations vary, but commonly address: • Opioid selection, dose, duration, and discontinuation. • Treatment agreements. • Screening for OUD and related risk factors. • Monitoring strategies, including urine drug testing and visit frequency.	Low ⁶
Opioid Prescription Limitation Laws	Laws regulate the characteristics of opioid prescriptions. Laws most commonly: • Address dose and duration limits. • Are restricted to acute pain treatment. • Offer exemptions for certain patient populations, like cancer patients.	Low ⁷
Doctor-Shopping Laws	Laws restrict patients from filling multiple opioid prescriptions from different prescribers or at different pharmacies within a short timeframe.	Very Low ⁸
State Electronic Prescribing Mandates	• Laws permit prescribers to transmit controlled-substances prescriptions to pharmacies through a secure electronic platform.	Very Low ⁹
Nurse Practitioner (NP) Independent Prescribing Authority	• Laws permit NPs to prescribe controlled substances without physician oversight.	Very Low ¹⁰

Policy/Intervention	Summary and Key Components	Level of Supporting Evidence
Insurer Policies		
Drug Supply Management Policies	Insurer policies limit opioid selection, dose, quantity, or duration; or mandate further insurer oversight of opioid prescribing. Examples include: • Quantity/dose limits. • Prior authorization (PA). • Utilization review. • Provider and pharmacy lock-ins.	Moderate (with strongest evidence from Medicaid PA programs) ¹¹
Health System Interventions		
Provider Education on Pain Management	Education programs focus on pain and opioid treatment. Modalities include: • CME courses. • Residency curriculum. • Telementoring. • Academic detailing.	Low ¹²
Clinical Guideline Implementation and Dissemination	Guidance to providers on opioid analgesic prescribing, developed and disseminated by health care organizations. • Guidelines may address opioid selection, dose, duration, discontinuation, and monitoring. • Dissemination strategies vary and may include email, hard copy, meetings, staff education, or academic detailing.	Low ¹³
Clinical Health System Interventions	Diverse interventions are designed to improve the safety of opioid prescribing and pain management. May include: • Electronic health record alerts and decision-support tools. • Patient registries. • Provider feedback and peer comparisons. • Standardized pain care plans. • Pharmacist consultation. • Multidisciplinary pain care.	Moderate ¹⁴

1. Includes review articles and selected representative primary sources. The review of the evidence was based on all relevant primary sources identified and, therefore, included a much larger number of articles.

2. Haegerich et al., 2019; Mauri et al., 2019; Rhodes et al., 2019.

3. Haegerich et al., 2019; Haffajee et al., 2018; Mauri et al., 2019.

4. Haegerich et al., 2019; Mauri et al., 2019.

5. Katzman et al., 2014.

6. Fulton-Kehoe et al., 2015; Mauri et al., 2019; Sullivan et al., 2016; Weiner et al., 2017.

7. Agarwal et al., 2019; Mauri et al., 2019; Sacks et al., 2019.

8. Kuo et al., 2016; Mauri et al., 2019; Meara et al., 2016.

9. Danovich et al., 2019.

10. Shirle et al., 2016.

11. Barnett et al., 2018; Dillender et al., 2018; Hartung et al., 2018; Mauri et al., 2019.

12. Anderson et al., 2017; Haegerich et al., 2019; Kattan et al., 2016.

13. Haegerich et al., 2019; Quanbeck et al., 2018.

14. Haegerich et al., 2019; Lin et al., 2017; Michael et al., 2018; Von Korff et al., 2016.

Most of the policies and interventions examined had low- or very low-quality evidence of their effects on opioid analgesic supply and prescribing safety. However, several types of policies showed moderate-quality evidence of their ability to reduce opioid analgesic prescribing and dispensing. The following three policies, which may be effective, include:

1. Prescription Drug Monitoring Programs (PDMP) with mandatory access provisions.
2. Insurer drug supply management policies. The strongest evidence came from Prior Authorization (PA) programs, particularly in the Medicaid program.
3. Clinical health system interventions. Promising evidence exists on clinical decision support interventions, and interventions that notify providers of higher-risk patients.

These three policies represent a subset of policies with the greatest evidentiary support for achieving reductions in opioid analgesic prescribing and dispensing. However, the moderate quality of the evidence indicates that there is some uncertainty about the magnitude of changes that these policies can achieve.

There are several other important limitations to the evidence base for policies to limit the supply and improve the safety of opioid analgesic prescribing:

- Evidence is very limited and of very low to low quality for the impacts of any of the policies reviewed on patient behavior and health outcomes.
- There is a paucity of rigorous evidence on potential unintended consequences of policies targeting opioid analgesic prescribing, particularly in key populations. These populations include patients with chronic pain who are on long-term opioid therapy, or racial/ethnic minorities in whom undertreatment of pain appears to be more prevalent.

IMPLEMENTATION AND SCALING CONSIDERATIONS FOR EFFECTIVE POLICIES

States weighing whether to establish or expand potentially effective policies—such as PDMPs with robust features, insurer drug supply management policies, and clinical health systems interventions—should consider how those policies will be affected by several important local trends, including:

- Current rates of opioid analgesic prescribing.
- Recent trends in opioid analgesic prescribing.
- Extent of illicit opioid markets.
- Availability of non-opioid treatment for pain.
- Availability of effective OUD treatment.

Vulnerable Settings

Policies to limit the supply and improve the safety of opioid analgesic prescribing may be more beneficial in locales with higher prescribing rates for opioid analgesics than in states that have already achieved low or falling rates of opioid prescribing.

Efforts to decrease opioid analgesic prescribing may have unintended negative consequences in locales with well-developed illicit opioid markets, limited availability of non-opioid pain treatments, and limited availability of effective OUD treatment. Unintended consequences of concern include:

- Pain undertreatment.
- Abrupt discontinuation or tapering of chronic opioid analgesic therapy.
- The possibility that patients may substitute illicit opioids for prescription opioids.

Negative health consequences, such as HCV infection (Fenton et al., 2019; Lagisetty et al., 2019; Powell et al., 2019).

Systematically assessing the impact of prescribing policies on health outcomes, and monitoring for negative unintended consequences of these policies, is recommended, especially in vulnerable settings. Such locales might consider:

- Providing access to non-opioid pain treatments and OUD treatment concurrently while, or even prior to, implementing large-scale policies to limit prescription opioid supply.
- Piloting proposed policies on a smaller scale and monitoring adverse consequences prior to scale-up.
- Scaling back on policies with limited benefits and/or demonstrated harms or targeting those policies more appropriately.

Additional implementation and scaling considerations for each specific type of policy are summarized below.

PDMPs with Robust Features

PDMP featuring electronic databases to collect and monitor the prescribing and dispensing of controlled substances have been adopted by nearly every state. However, their features vary.

Program Implementation: Several studies (Haffajee, 2019; Mastarone et al., 2019; Mauri et al., 2019; Patrick, Fry, et al., 2016; Reist et al., 2020; Weiner et al., 2019) suggest that effective and acceptable PDMPs feature:

- A requirement that prescribers and pharmacies query the PDMP before prescribing or dispensing opioid analgesics.
- Interoperability across states.
- Provisions that help facilitate ease of use by providers.
- Monitoring of a larger number of medications that carry the potential for abuse.
- Data updates that take place at least weekly.

Mandatory Access Requirements: Several studies (Buchmueller & Carey, 2018; Elder et al., 2018; Freeman et al., 2019; Reist et al., 2020) support the following approaches to improving ease of use and acceptability of mandatory access requirements:

- Using a health information technology platform that can be integrated easily into existing electronic health records systems in physician offices and pharmacies.
- Educating prescribers and pharmacists regarding program features and requirements.
- Engaging prescribers and pharmacists in efforts to improve database design and usability.

Mitigating Unintended Consequences: Several implementation strategies have the potential to mitigate adverse unintended consequences of robust PDMPs:

- Consider exempting prescribers and dispensers from requirements to query the database for certain patients, including those with terminal illness or those enrolled in a hospice program.
- Create algorithms that identify risky prescription-fill patterns more accurately and that prompt providers to consider alternative pain treatments and/or refer the patient for OUD treatment, if appropriate.

Costs of Effective Policies: Estimated costs for implementation of a robust PDMP range from \$450,000 to over \$1.5 million. Annual operating costs are estimated to range from approximately \$125,000 to \$1 million (Sacco et al., 2018).

Insurer Drug Supply Management Policies

State Medicaid Programs: The following key implementation and scaling considerations might help state Medicaid programs manage opioid analgesic supply and prescribing safety for their beneficiaries:

- Implementing management techniques, such as prior authorization (PA), utilization review (UR), lock-in, or quantity/dose limit.
- Establishing appropriate criteria for exemptions from management techniques for certain patient groups, like hospice and palliative care patients.
- Informing prescribers and pharmacists about opioid management policies.
- Hiring sufficient personnel to consider appeals promptly, based on patients' individual needs.
- Covering alternative pain therapies and OUD therapies that can substitute for opioid analgesics when access is restricted.

Commercial Insurers: Some commercial insurers, including Blue Shield of California, have implemented statewide drug supply management programs, including utilization review, which show early evidence of reducing opioid analgesic prescriptions. States can consider how to engage additional private insurers in these initiatives through:

- Legislative mandates requiring drug supply management policies as a condition of insurance company operation within a state.
- Financial incentives or subsidies to help commercial insurers defray some costs of implementation and enforcement.
- Voluntary guidance recommendations that commercial insurers cover alternative therapies and OUD treatment if they are limiting opioid analgesic supply.

Unintended Consequence: Faced with insurer drug supply management policies, beneficiaries may seek to fill opioid prescriptions through alternative routes, such as paying with cash (Naumann et al., 2018; Roberts et al., 2019). States could monitor for this outcome by using PDMPs to track individual opioid purchases across payers and payment mechanisms.

Costs of Effective Policies: Estimated costs of implementing a supply management program at the insurer level vary and are rarely specific to the opioid analgesic domain.

Requiring that clinicians receive prior authorization (PA) before prescribing certain interventions can reduce health expenditures. For example, studies show PA-related savings of:

- \$12 million to \$3 million per month across Medicare beneficiaries in seven states for power mobility devices.
- \$5.33 million over 13 months in a Centers for Medicare and Medicaid Services demonstration project for non-emergent hyperbaric oxygen therapy.
- Tens of thousands of dollars per patient per year for specialty drugs in Medicare Part D.

Health Systems Interventions

Health system interventions to address opioid prescription supply and quality are highly varied. There is insufficient evidence, at this time, to recommend any specific type of intervention. However, there are promising findings from evaluations of:

- Clinical decision support tools that provide clinicians, administrative staff, patients, caregivers, or other members of the care team with information that is filtered or targeted to a specific person or situation.
- Interventions that notify providers about patients at higher risk for opioid misuse. Promising findings point particularly to unsolicited PDMP reports, registries, and electronic health record alerts (Michael et al., 2018; Patel et al., 2018; Ringwalt et al., 2015; Von Korff et al., 2016).

States may facilitate the development, adoption, and dissemination of promising interventions by:

- Creating opportunities for different health systems to share with each other their experiences and best practices.
- Offering financial incentives for health systems to successfully implement clinical innovations in safe opioid prescribing.
- Subsidizing the costs of developing and adopting effective interventions.

These savings require other tradeoffs, however (Turner et al., 2019). For example, when Texas Workers Compensation implemented a closed formulary that established a list of non-preferred opioid analgesics requiring PA, it reduced spending on nonpreferred drugs per person by 2.3 to 3.1 percent several months after the program began (Dillender, 2016; 2018). However, there was no evidence that spending on preferred drugs or non-pharmacy medical care increased to compensate for the decreased spending on non-preferred drugs.

Please note that these types of analyses are typically limited because they do not capture comprehensively all spending and costs borne by patients. Typically, these analyses also fail to incorporate the costs that providers incur while implementing PA, or certain other supply management policies.

Estimates of PA implementation costs for physician practices vary and range from between \$2,200 and \$3,400 per physician to \$80,000 annually per physician in 2010 dollars. (Turner et al., 2019). A comprehensive analysis of the costs of insurer-level policies related to opioid analgesic prescribing, particularly PA, would better inform implementation.

Costs of Effective Policies: Health system interventions to improve the safety of opioid analgesic prescribing are highly varied in their components and scope. Accordingly, implementation costs can be expected to vary considerably, based on the specific intervention model.

This review identified clinical decision support interventions, and interventions that notify providers of high-risk patients, as the most promising models. Since high-risk notifications typically use the same programming infrastructure as clinical decision support interventions, this review of intervention costs focuses on clinical decision support.

Costs varied widely in a systematic review of studies on the estimated costs of implementing clinical decision support tools for cardiovascular disease prevention within existing electronic health records. Cost ranges included:

- \$43 to \$170 per patient in 2015 dollars for annual implementation.
- \$4,800 to \$7,300 for small practices of one to four physicians.
- \$20,600 to \$50,000 for medium-sized practices of five to 24 physicians (Jacob et al., 2017).

Limitations: All of these estimates derived from studies exploring the use of clinical decision support interventions in clinics, not hospitals or other care settings. In addition, the interventions described in the studies addressed cardiovascular

disease risk factors, not the use of opioid analgesics. However, the basic programming infrastructure required to implement

clinical decision support is not expected to differ substantially across specific conditions.

LOW-VALUE OR POTENTIALLY HARMFUL POLICIES

The abrupt cessation or overly aggressive tapering of chronic, long-term opioid therapy is discouraged. There is extensive clinical knowledge and emerging research evidence showing that these practices present high risk of harms to patients with chronic pain, without apparent benefits (Fenton et al., 2019; Lagisetty et al., 2019; Oliva et al., 2020).

Policies and Interventions to Mitigate Harms Experienced by Children Whose Parents Misuse Opioids

MEASURING POLICY AND INTERVENTION OUTCOMES

The ultimate goal of policies and interventions discussed in this section is to improve the health and well-being of children whose parents currently misuse opioids or have a history of opioid misuse and are in recovery. Generally, evaluations of these interventions use a broad range of outcome measures that may:

- Directly capture child health outcomes like birth weight, incidence of neonatal opioid withdrawal syndrome (NOWS), or maltreatment.
- Assess intermediate predictors associated with child well-being like parenting practices or foster care placements.

The specific measures used to evaluate interventions to improve health and well-being of children often vary based on the parent-child life stage targeted by the intervention.

Prenatal Stage

Outcome measures for interventions targeting the prenatal stage, such as home visiting, integrated substance use disorder (SUD) treatment, and family services, commonly include:

- Maternal substance use and smoking.
- Maternal SUD treatment receipt and retention.
- Maternal mental health.
- Prenatal care use.
- Infant birth weight.
- Birth complications.

Perinatal Stage

Outcome measures for Interventions targeting the perinatal stage, such as NOWS treatment protocols, commonly include:

- Frequency and duration of pharmacologic treatment—such as opioids and other adjunctive agents—for a newborn child with NOWS
- Transfers to the neonatal intensive care unit (NICU).
- Inpatient length of stay.

Postnatal and Early Childhood Stages

Outcome measures for interventions targeting the postnatal and early childhood phases, such as family drug treatment court and early intervention, commonly include:

- Parents' substance use.
- Parents' SUD treatment receipt and retention.
- Parenting attitudes and practices, as measured by validated scales.
- Child maltreatment.
- Child mental health.
- Children's problem behaviors, as measured using validated scales.
- Children's substance use.
- Foster placements.
- Family reunification.

WHAT THE EVIDENCE SHOWS

Table 5.3 summarizes specific policies and interventions examined in this report, their key components, and the quality of evidence supporting their effectiveness.

TABLE 5.3

Strength of the Evidence for Interventions to Mitigate Harms Experienced by Children Whose Parents Misuse Opioids¹

Life Stage	Policy/Intervention	Summary and Key Components	Level of Supporting Evidence
Prenatal, Perinatal, Postnatal/Early Childhood	Integrated Substance Use Disorder (SUD) Treatment with Health and Family Services.	Comprehensive treatment programs that provide evidence-based SUD treatment, together with at least one of the following additional services: • Prenatal care and education. • Adult physical/mental health services. • Child physical/mental health services. • Parenting skills training. • Life skills training. • Employment assistance. Services may be co-located or coordinated across different locations.	Supported ²
Prenatal, Perinatal, Postnatal/Early Childhood	Home Visiting Programs	Nurses or paraprofessionals conduct regular visits to the homes of pregnant women to promote recommended prenatal and preventive health care and strengthen parenting practices. • Visits typically begin in pregnancy and continue through the perinatal period, with some programs extending visits throughout infancy. • Additional services provided vary across programs and may include connecting families to education and employment resources. • Model programs include the Nurse Family Partnership, and Child FIRST.	Supported ³
Perinatal	Standardization of Hospital Management of Neonatal Opioid Withdrawal Syndrome (NOWS)	Quality improvement initiatives to promote the use of evidence-based NOWS therapies. • Ultimate goals are typically to minimize opioid pharmacotherapy, transfer to the neonatal intensive care unit (NICU), and length of inpatient stay. • Recommended practices may vary but commonly include standardized infant assessment and treatment, prioritization of non-pharmacologic treatments, rooming-in and parental presence, and breastfeeding support. • Strategies to achieve standardization vary but may include clinical protocols, care bundles, and staff training.	Promising ⁴

Life Stage	Policy/Intervention	Summary and Key Components	Level of Supporting Evidence
Perinatal	NOWS-Dedicated Treatment Settings	Designation of NOWS-specific care settings, such as hospital inpatient units, NICUs, or residential treatment facilities.	Undetermined ⁵
Perinatal	NOWS Outpatient Opioid Weaning	Protocols allow opioid tapering for infants with NOWS to be completed at home with close monitoring, rather than in the hospital.	Undetermined ⁶ (Some studies indicate possible harms.)
Postnatal/Early Childhood	Family Skills Training Interventions	- Interventions to improve: - Parenting skills, including discipline, supervision, problem solving. - Childrens' life skills, including socioemotional regulation, and peer pressure resistance. - Family communication. - Interventions may also include case management services. - Training can be delivered in individual or group formats and diverse settings, including homes, schools, and health facilities. - Model programs include the Strengthening Families Program and Families Facing the Future.	Well-Supported ⁷
Postnatal/Early Childhood	Early Intervention	Specialized courts monitor treatment for parents with SUD who have a pending child abuse or neglect case, with the goal of facilitating parents' recovery and family reunification. Features: - SUD treatment and wraparound services. - Frequent court hearings and drug testing. - Rewards/sanctions linked to treatment adherence. - Involvement of representatives from the judicial, child welfare, and SUD treatment systems. - A single judge may oversee treatment and child welfare proceedings in an integrated model, or these tasks may be divided among multiple judges.	Supported ⁸
Postnatal/Early Childhood		The Program for Infants and Toddlers with Disabilities, a provision of the Individuals with Disabilities Education Act (IDEA Part C), promotes healthy development among young children with developmental delay or risk factors for developmental delay. Services vary, but may include: - Health care services. - Early education. - Referrals to community-based care agencies. - Case management. IDEA Part C is a federal grant program. However, state agencies administer the early intervention programs and influence their features and implementation.	Supported ⁹

Life Stage	Policy/Intervention	Summary and Key Components	Level of Supporting Evidence
Postnatal/Early Childhood	Family Therapy	Behavioral therapy engages adults with SUD and their family members to improve family communication and reduce conflict.	Promising ¹⁰
Postnatal/Early Childhood	Intensive Case Management/ Recovery Coaches	Case managers/recovery coaches are assigned to parents with SUD and assist with: - Care coordination. - Reducing barriers to service use. - Patient outreach. - Assessment of clinical and social service needs. Interventions can be embedded in a range of settings, including SUD treatment programs and child welfare agencies.	Promising ¹¹
Postnatal/Early Childhood	Screening, Brief Intervention, and Referral to Treatment (SBIRT) for Parents' SUD by Pediatricians	Pediatric primary care-based intervention to screen for adverse childhood experiences including parents' SUD. SBIRT features a validated instrument and brief motivational interviewing to engage parents and refer to treatment. Education on pain and opioid treatment. Model program example: Safe Environment for Every Kid.	Promising ¹²

1. Includes review articles and selected representative primary sources. Evidence review was based on all relevant primary sources identified and, therefore, included a much larger number of articles.

2. Milligan et al., 2011; Neger & Prinz, 2015; Niccols et al., 2012.

3. Azzi-Lessing, 2013; Lowell et al., 2011; Olds, 2006.

4. Patrick, Schumacher et al., 2016; Whalen et al., 2019.

5. Whalen et al., 2019.

6. Maalouf et al., 2018; Murphy-Oikonen & McQueen, 2018.

7. Catalano et al., 1999; Kumpfer & Brown, 2019; Kumpfer & Fowler, 2007.

8. Green et al., 2007; Ogbonnaya & Keeney, 2018

9. Bono et al., 2007; Katz et al., 2014; Ullery & Katz, 2017

10. Bartle-Haring et al., 2018; Kumpfer et al., 2003; O'Farrell & Schein, 2011

11. Dauber et al., 2012; Ryan et al., 2008; Ryan et al., 2017

12. Dubowitz, 2014

Strongest Evidence

The following interventions have the strongest evidence base and are most likely to be effective in mitigating harms experienced by children whose parents misuse opioids:

1. Integrated SUD Treatment with Health and Family Services.
2. Home Visiting Programs.
3. Family Skills Training Interventions.
4. Family Drug Treatment Courts (FDTCT).

The standardization of hospital NODS management is a particularly promising intervention. The evidence supporting this intervention is derived primarily from uncontrolled studies. However, these studies warrant strong consideration, since they have found consistent positive impacts across a large number of institutions. In addition, these interventions have a firm practical and clinical grounding.

Promising Evidence for Family Therapy

Family therapy is rated as promising given this section's focus on child well-being. Evidence of family therapy's positive impacts on children of adults with SUD is limited. Note that family therapy is considered well-supported overall, based on its positive impacts on patients with OUD. Evidence-based OUD treatment for parents has been shown to improve child and family outcomes even without additional integrated health and family services. However, integrating these services achieves even larger benefits for children.

Limitations

There are several important limitations associated with the evidence base for interventions to mitigate harms to children whose parents misuse opioids:

- Evidence of the impacts on direct measures of child health and well-being are limited.
- Certain intermediate measures of child well-being used in studies discussed here may be challenging to interpret without understanding the child's broader environment. For example, foster placements are often viewed as an undesirable outcome but, in some instances, may be beneficial.
- With some exceptions, most studies follow children for a limited period of time. Therefore, it is uncertain whether observed benefits are sustained over the long term.
- Studies of certain interventions—including home visiting programs, parenting skills interventions, and intensive case management—enrolled a diverse group of vulnerable families, not all of whom were affected by SUD. Therefore, there is some uncertainty about whether similar program impacts would be observed among a SUD-only, or OUD-only, population.

IMPLEMENTATION AND SCALING CONSIDERATIONS FOR EFFECTIVE POLICIES

This chapter reviews implementation and scaling considerations for the interventions considered most likely to be effective, such as integrated SUD treatment, home visiting programs, family skills training interventions, FDTs, and standardization of hospital NWS management. The following considerations are relevant to all such interventions:

- **Screening for Program Eligibility:** Systematic screening for program eligibility, followed by referral, should be conducted across multiple settings to connect families to appropriate interventions. These settings include hospitals, outpatient clinics, Medicaid, child welfare agencies, Head Start and other childcare programs, and Temporary Assistance for Needy Families.
- **Covered Benefits:** State Medicaid programs could include effective programs as covered benefits in order to improve access and affordability. States may use legislative mandates to require commercial insurers to cover these programs or may encourage coverage through financial incentives or subsidies.
- **Training:** Impacts are generally greater when programs are implemented by highly trained individuals who are health professionals, rather than paraprofessionals. Locales with health professional shortages may not have an adequate supply of trained providers to deliver interventions. Substituting paraprofessionals may lower costs of implementation but may also weaken program impacts.
- **Interventions:** Longer and more intensive interventions are typically required for higher-risk families with multiple vulnerabilities in addition to OUD. This requirement may increase implementation costs.
- **Higher-Risk Families:** Higher-risk families are more likely to face difficulties engaging with and completing interventions. These difficulties may weaken program impacts or interfere with efforts to target evidence-based programs to the families with greatest need.
- **Early Intervention:** Interventions beginning earlier in pregnancy and childhood are typically more effective than those beginning later in childhood (van der Put et al., 2018).

Additional implementation and scaling considerations for each specific type of intervention are summarized below.

Integrated SUD Treatment with Health and Family Services

Effective SUD treatments that are integrated with health and family services have several features:

- Close relationships and coordination between:
 - Hospitals.
 - Specialty OUD treatment programs.
 - Primary and prenatal care providers.
 - Relevant state agencies like Medicaid and child welfare agencies.
 - Community-based social services (Meyer & Phillips, 2015; March & Smith, 2011).
- Service co-location.
- Services matched to a client's individual needs.
- Implementation of programs that:
 - Combine and coordinate services across multiple sectors, like health care and child welfare services.
 - Can be facilitated by data sharing, harmonization of treatment goals and quality assurance processes, and flexible financing like interagency joint financing agreements (Marsh & Smith, 2011).

Costs: Programs that integrate SUD treatment with health and family services are resource-intensive, so it is advisable to target them to the highest-risk families and communities.

This review did not identify any published estimates of the costs of integrating SUD treatment with health or family services. The cost of integrating additional services into an established SUD treatment program will vary considerably, depending on the specific types of integrated services and whether they:

- Are co-located with SUD treatment.
- Are delivered and financed by partner organizations.
- Must be financed by the SUD program.
- Require collaboration and data-sharing between treatment providers.

Effective integrated treatment programs tend to have co-located services, and close coordination and data sharing among treatment providers. These programs are likely to incur the incidental costs of:

- Securing additional space for co-located services, either through construction of new offices, rental of additional existing office space, or reconfiguration of existing office space to accommodate additional providers.
- Developing and implementing a protocol for screening SUD treatment clients for additional service needs and eligibility and connecting clients with appropriate on-site providers.
- Staff time and training to execute screening and referral protocols, and to coordinate among service providers.
- Additional staff recruitment, training, and materials needed to provide additional services, if those services cannot be delivered and financed by partner organizations.

Home Visiting Programs

Features of effective home visiting programs include:

- Home visits are initiated in the prenatal period (Peacock et al., 2013).
- Staff are highly trained in providing culturally competent care, and addressing challenges such as mental illness, SUD, trauma, and domestic violence.
 - Model programs with the strongest evidence of positive impacts, such as the Nurse Family Partnership, typically use trained nurses, rather than paraprofessionals, as home visitors.
 - Some programs, like Child FIRST, have achieved positive impacts using social workers with a bachelor's or master's degree as home visitors.

- Home visitors receive frequent supervision by trained professionals.
- Home visitors collaborate with other service providers, including professionals in the health care system, early intervention programs like IDEA Part C, and child welfare agencies (Azzi-Lessing, 2013).

Costs: Home visiting programs may be challenging to implement in rural and sparsely populated communities due to increased travel time and costs. These programs are resource-intensive, so it is advisable to target them to the highest-risk families and communities.

The average cost per family served in a home visiting program is \$6,583 in 2012 dollars, based on a cost survey of five rigorously studied home visiting programs implemented across 19 different agencies (Burwick et al., 2014). Studied programs included Nurse Family Partnership, Healthy Families America, SafeCare, Parents as Teachers, and Positive Parenting Program.

Costs per family served varied widely across programs, ranging from \$2,372 for Parents as Teachers, to \$8,000 for the Nurse Family Partnership. The higher cost of the Nurse Family Partnership program was attributed to the fact that it was the only program among the five programs studies that required home visitors to have a bachelor's degree in nursing. Salaries for these home visitors tended to be higher than salaries in other programs. Notably, these cost estimates are all derived from "real-world" programs rather than randomized controlled trials (RCT).

Family Skills Training Interventions

Effective family skills training programs:

- Typically lasts between seven and 15 sessions.
- Target children age 3 through adolescence.
- Are adapted to be age appropriate.
- Use trained and supervised staff, including prevention specialists, to deliver interventions.
- Involve both parents.
- Use culturally-sensitive program adaptations to improve retention of families from racial/ethnic minority backgrounds.
- Offer incentives for attendance to improve overall recruitment (Kumpfer, 2014; Von Korff et al., 2016).

Certain family skills training programs, including the Strengthening Families Program, have been successfully adapted from the traditional group format to a DVD-format that allows for program delivery at a lower cost in multiple settings, including schools, health facilities, and child welfare and juvenile justice settings (Von Korff et al., 2016).

Costs of Effective Policies: Family skills training interventions are moderately resource-intensive and could be prioritized in states and sub-state regions with a higher burden of parental OUD.

Published cost estimates are available for the Strengthening Families Program, a model program that has been rigorously evaluated in multiple RCTs. Using the group-based service delivery format, the average cost for a single-child family is \$1,662 in 2011 dollars (Johnson-Motoyama, 2013). These cost estimates are derived from "real-world" program settings, not RCTs.

Family Drug Treatment Courts (FDTC)

Family Drug Treatment Courts (FDTC) programs feature:

- Frequent contact with the court (Lloyd, 2015).
- Early involvement of families affected by SUD (Choi, 2012).
- Access to medication treatment for clients with OUD. Certain courts prohibit medication treatment for OUD (Tabashneck, 2018).
- Collaboration among judicial, child welfare, and SUD treatment programs to develop consistent policies and coordinate case management (Choi, 2012).
- Integrated models in which a single judge oversees compliance with both OUD treatment and child welfare proceedings. This model may be more effective than models in which monitoring is shared by multiple judges/courts (Chuang et al., 2012; Green et al., 2007; van Wormer & Hsieh, 2016).

There is longstanding evidence of disparities in the treatment of racial/ethnic minorities by the court, child welfare, and health care systems (Choi, 2012). Monitoring the outcomes of minority families served by FDTCs is critical to preventing and addressing racial/ethnic disparities in FDTC program outcomes.

Costs of Effective Policies: FDTCs are resource-intensive, so it is advisable to target them to the highest-risk families and communities. Published operating cost estimates for FDTCs range from approximately \$8,300 to \$10,900 per single-child family served per year, in 2014 dollars (Brook et al., 2016; Burrus et al., 2011; Zeller, Hornby & Ferguson, 2007).

Standardization of Hospital NOWS Management

Components of successful quality-improvement initiatives for hospital NOWS management have typically included (Whalen et al., 2019):

- Standardized screening and assessment tools to diagnose and rate the severity of NOWS.
- Rooming-in and parental presence.
- Breastfeeding support.
- Prioritization of non-pharmacologic therapies like a standard, non-pharmacologic bundle.
- Protocol for initiation, titration, and weaning of pharmacotherapy with opioids or other agents.

Medicaid covers 43 percent of all births and 80 percent of NOWS-affected births (Martin et al., 2018; Winkelman et al., 2018). As a result, state Medicaid programs have considerable leverage to encourage the adoption and standardization of evidence-based NOWS management practices. This could be achieved through, for example, enhanced reimbursement rates for facilities achieving a high rate of guideline-concordant care. State health departments can also encourage the wider dissemination of evidence-based NOWS treatment protocols by:

- Mandating protocol adoption or development as a condition of hospital licensure/accreditation.
- Offering financial incentives or subsidies for protocol adoption and integration into electronic health records.

Costs of Effective Policies: Initiatives designed to standardize hospital NOWS management are moderately resource-intensive, so they might be prioritized in states and sub-state regions with a higher burden of parental OUD.

This review did not identify any published cost estimates for implementing interventions to standardize NOWS management in hospitals. However, such interventions are believed to be cost-effective since they have been associated with substantial savings in NICU and inpatient costs for affected infants, including:

- A decrease in average hospital costs for opioid-exposed newborns from \$11,000 to \$5,300 per newborn in 2015 dollars. These savings were reported by Children's Hospital at Dartmouth-Hitchcock for prenatal care and OUD treatment center programs featuring:
 - Standardized infant-centered NOWS assessment.
 - Non-pharmacologic interventions like rooming-in and volunteer "cuddlers."
 - Protocols for the use of pharmacologic treatments.
 - Education outreach to at-risk pregnant women at prenatal care and OUD treatment centers

These savings were driven by decreased use of pharmacologic treatment and decreased length-of-stay among infants requiring pharmacologic treatment (Holmes et al., 2016).

- Decreases in hospital costs by \$27,090 per patient, in 2015 dollars. These savings were reported by the University of Louisville Hospital for implementation of a more aggressive morphine-weaning protocol, together with changes in non-opioid adjunctive therapy (Devlin et al., 2017).

Neither of these studies reported the costs of implementing standardized care protocols. However, other implementing institutions have reported that these protocols are typically limited to retraining existing staff, devoting staff time to engaging and educating families, and establishing relationships with community partners (Dickes et al., 2017). As a result, it has been argued that such interventions are likely to be cost-effective (Summey et al., 2017).

A NOTE ABOUT COSTS

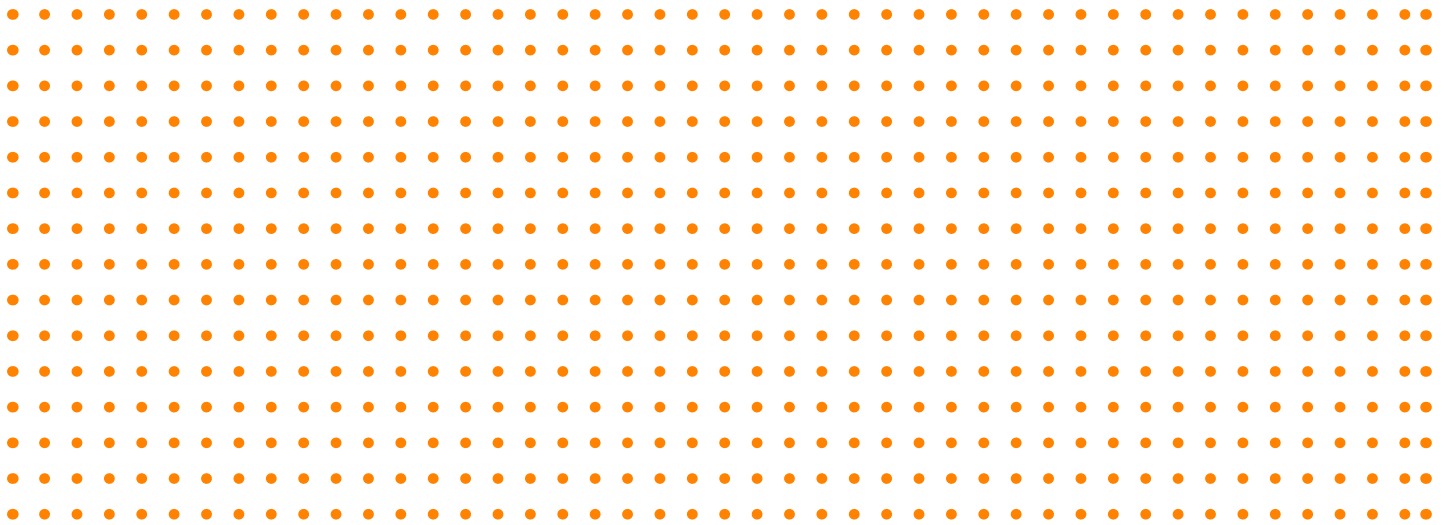
Funding streams that could be augmented with abatement funds relate to Title V Maternal and Child Health Services Block Grants, IDEA Part C Early Intervention, and Head Start, to the extent that interventions can be delivered through Head Start or Early Head Start programs.

LOW-VALUE OR POTENTIALLY HARMFUL POLICIES

Laws and policies that punish pregnant women for opioid misuse are potentially harmful, given widespread clinical experience and emerging research evidence indicating that such initiatives might impede access to both OUD treatment and prenatal care, thereby harming the health of the mother and infant (Faherty et al., 2019; Patrick & Schiff, 2017).

Prenatal care offers a critical window of opportunity for the detection and treatment of women's physical health problems, including, but not limited to:

- Other non-opioid SUD.
- SUD complications such as HIV and HCV.
- Psychiatric comorbidities (Faherty et al., 2019; Patrick & Schiff, 2017).



CHAPTER 6: Data Infrastructure

Data collection and analysis systems are often seen as a luxury when money for providing services is constrained. Yet, it is impossible to judge whether opioid-related amelioration efforts are having any impact without accurate, ongoing, monitoring of the severity, location, and type of opioid-related problems in a state or community. Data infrastructure is also an essential tool for mapping the resources available to address the opioid crisis, including prevention professionals, police officers, and hospital beds. Data can also inform a community’s plans to deploy those resources and identify gaps that should be targeted for additional investment.

Certain features of the opioid crisis complicate data monitoring:

- 1. Opioid misuse is illegal, and often involves other illegal behaviors, such as stealing, doctor shopping, and prescription fraud. Understandably, people are unlikely to self-report.
- 2. Addiction is a deeply stigmatized condition that individuals may not wish to acknowledge.
- 3. The addicted population is often hard to reach. This population includes individuals who are homeless, shuttle in and out of jails and hospitals, or drift from community to community.

Data monitoring systems built entirely on household surveys are likely to produce inaccurate data. Better systems would use a range of data-collection methods, including biological and administrative measures like wastewater analysis, urine screens of individuals entering jails, and medical diagnostic data from hospitals and clinics.

Existing systems for monitoring state-level data have inconsistent coverage, quality, and utility. The federal government has disinvested from drug-related monitoring in recent years, canceling the Arrestee Drug Abuse Monitoring (ADAM) program, which gathered vital data from drug-using individuals entering jails, and the Drug Abuse Warning Network (DAWN) program, which tracked substance-related emergency room visits.

Many of the surviving national data-monitoring efforts are inadequate for a variety of reasons that lessen their utility for state policy formation and evaluation. These monitoring efforts:

- Don’t measure opioid-related variables with sufficient precision. The Behavior Risk Factors Surveillance System and National Forensic Laboratory Information System fit into this category.

- Assess opioid-related variables at the national level but can't provide any state-level data. This category includes the National Electronic Injury Surveillance System, National Hospital Medical Care Survey, National Ambulatory Medical Care Survey, Federal Workplace Drug Testing Program, and Monitoring the Future.
- Provide state-level data only for a subset of states. This includes the Medical Expenditure Panel Survey.
- Only provide state-level data every few years and with a considerable time lag. The National Survey on Drug Use and Health is an example.

Existing Systems That Provide Relevant, State-Level Data

Table 6.1 lists a range of variables that states should measure as they make investments in ameliorating the impact of the opioid epidemic. A number of these variables can be assessed—in many cases, imperfectly—using existing measurement systems that can support state-level analyses. Table 6.2 provides notes on the systems mentioned in Table 6.1.

TABLE 6.1: STATE-LEVEL MEASUREMENT VARIABLES AND EXISTING ASSESSMENT SYSTEMS

Variables	Measurement Systems
Prevalence and incidence of opioid misuse in youth and adults.	• National Survey on Drug Use and Health (NSDUH) • Quest Diagnostics (QD)
Prevalence and incidence of opioid injection in youth and adults.	• NSDUH • Youth Risk Behavior Surveillance System (YRBS)
Prevalence and incidence of opioid use disorder (OUD) in youth and adults.	• NSDUH
Fatal and non-fatal opioid overdoses by drugs involved.	• Medicare • National Emergency Medical Service Officials Information System (NEMSIS) • Optum Clinformatics Datamart (OCDM) • State Poison Control Center (SPCC). • Wide-ranging Online Data for Epidemiologic Research (WONDER)
Opioid-related emergency room admissions.	• Medicare • OCDM
Opioid-related arrests.	• Uniform Crime Reports/National Incident-Based Reporting System (UCR/NIBRS)
High-dose opioid prescribing, benzodiazepine-opioid co-prescribing, per capita prescribing.	• Automation of Reports and Consolidated Orders System (ARCOS) • IQVIA (formerly Quintiles and IMS Health, Inc.) • Medicare • OCDM
Drug-related foster care placements.	• Administration for Children and Families (ACF)

Variables	Measurement Systems
Number of individuals in opioid addiction treatment.	• OCDM • Treatment Episode Dataset (TEDS) • Medicare
Number of opioid treatment programs and aggregated maximum caseload.	• Substance Abuse and Mental Health Services Administration (SAMHSA)
Number of physicians who have X-waivers permitting them to prescribe Suboxone (buprenorphine/naloxone) for patients with OUD, and the number of physicians who write these prescriptions.	• SAMHSA
Residential treatment beds.	• National Survey of Substance Abuse Treatment Services (N-SSATS)
Number of addiction care personnel by discipline.	• Professional Associations
Number of syringe exchange programs.	• American Foundation for AIDS Research (AmfAR)
Naloxone use.	• IQVIA • NEMSIS
Opioid-related incarcerations.	• None
Prevalence and incidence of infectious disease among opioid-using population.	• None
Number of people with OUD who are homeless.	• None
Supportive/recovery housing allowing medications, compared to housing not allowing medications.	• None
Number of drop-off sites for excess medication.	• None
Staffing, services, and individuals served by harm reduction programs outside of government.	• None

TABLE 6.2: NOTES FOR DATA SOURCES

Data Source	Available Data
Administration for Children and Families (ACF)	• Administrative data on reason for placement in foster care. • Drug-specific data is inconsistent, although opioids are sometimes specifically coded.
American Foundation for AIDS Research (amfAR)	• Administrative data on number and location of syringe exchange programs by state. • No data on staffing or number of individuals served.

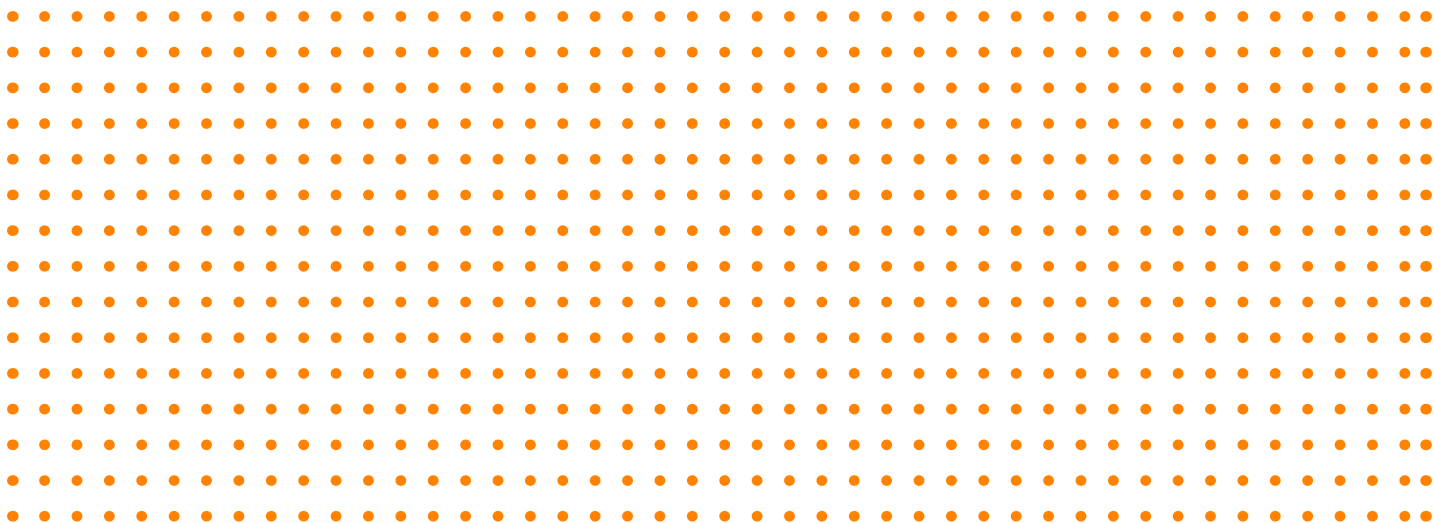
Data Source	Available Data
Automation of Reports and Consolidated Orders System (ARCOS)	Administrative data on the provision of prescription opioids collected from manufacturers and distributors.
IQVIA	Administrative data on prescription drug sales and spending.
Medicare	- Administrative data from the federal insurance program is available in commercially assembled data packages. - Includes opioid-related prescribing and care utilization data.
National Emergency Medical Service Officials Information System (NEMSIS)	Administrative data on use of naloxone by emergency medical services.
National Survey on Drug Use and Health (NSDUH)	- State-level, biennial estimates of self-reported opioid use and misuse, opioid use disorder, and treatment receipt among the general population, age 12 and older, not including people who are incarcerated and live in jails. - Severely underestimates heroin use, misuse, and disorder.
National Survey of Substance Abuse Treatment Services (N-SSATS)	Survey of structure and content of all facilities known by the federal government to provide substance use disorder services.
Optum Clinformatics Datamart (OCDM)	Nationally representative private insurance administrative data on opioid-related prescribing and care utilization.
Prescription Drug Monitoring Program (PDMP)	- Administrative tracking of some or all controlled substance prescribing. - Variations in whether states require prescribers to register and use PDMP, and what substances are covered.
Professional Associations	Member registries maintained by the American Society of Addiction Medicine, American Academy of Addiction Psychiatry, National Association of Alcoholism and Drug Abuse Counselors, American Psychological Association Addictions Division, and International Nurses Society on Addiction.
Quest Diagnostics (QD)	- Urinalysis results of large, non-representative sample of workers. - Data available down to the three-digit zip code level.
Substance Abuse and Mental Health Services Administration (SAMHSA)	Administrative data on accredited opioid treatment programs and X-waivered buprenorphine prescribers.
State Poison Control Center (SPCC)	- Administrative data on reported analgesic drug poisonings, including those occurring in children and during pregnancy. - Differentiates intentional and accidental poisonings.

Data Source	Available Data
Treatment Episode Dataset (TEDS)	- Administrative data on number and type of addiction specialty care patients, including those with primary and secondary drug problems. - Limited or no data on programs that receive no public funding.
Uniform Crime Reports/National Incident-Based Reporting System (UCR/NIBRS)	Administrative law enforcement data on opioid-related arrests, including arrests for possession of opioids, heroin, and unspecified synthetic drugs.
Wide-ranging Online Data for Epidemiologic Research (WONDER)	Administrative data on causes of mortality in the U.S., maintained by Centers for Disease Control and Prevention.
Youth Risk Behavior Surveillance System (YRBS)	Data on self-reported prescription opioid misuse, heroin use, and injection drug use among middle and high school students.

Data Infrastructure Investments for States

States should consider making three data-related investments as they tackle the opioid crisis:

1. Regularly extract state-level data from the datasets listed in Table 6.2. This could be accomplished in a cost-efficient manner if states pooled resources to support a single analytic team that could regularly populate state dashboards.
2. Improve the assessment of variables already captured, to some extent, by existing systems. The most obvious candidates are:
 - Expand state prescription drug monitoring to include all opioids, benzodiazepines, and Z-drugs.
 - Mandate universal coverage of all prescriptions.
 - Use wastewater analysis at key sites to correct for error in existing measures of population-level consumption of licit and illicit opioids.
 - Create surveys of populations currently missed by household surveys, including the homeless. These surveys will help to correct for errors in existing measures of population-level consumption of licit and illicit opioids, opioid use disorder, and overdose prevalence.
3. Create new systems to measure variables for which there currently is no assessment. These systems might collect statewide data on:
 - Harm reduction services that are not tracked in administrative databases because the services are not run by government agencies. Measure staffing, services provided, and individuals participating in such services as syringe exchange programs, fentanyl strip distribution programs, and naloxone distribution initiatives.
 - Urinalysis and interviews conducted with individuals entering a representative sample of jails. Use this data to assess the prevalence of opioid and other drug use among incarcerated people and to gather market data about the price and availability of opioids. The defunct ADAM program's protocols can serve as a basis for designing such data collection efforts.
 - Pill drop-off sites operated by pharmacies, hospitals, and other organizations. Measure the prevalence of these sites, the number of individuals served, and the volume of controlled medications collected.
 - The number and type of drug-related prevention programming in schools and communities, and the evidence base for this programming.



CHAPTER 7: Policy Infrastructure

Policy Context

An estimated 20 percent of people with opioid use disorder (OUD) receive treatment, and only about 34 percent of those treated receive evidence-based treatment (Blanco et al., 2013; Knudsen 2015). The reasons for these strikingly low rates are related to the availability and quality of care.

This review of successful strategies for supporting interventions for OUD touches on both availability and quality of care, but gives special attention to regulations governing the supply of treatment options and efforts to increase the likelihood that a given treatment yields the best possible outcomes.

Historically, virtually all addiction treatment has been provided by specialty substance use disorder (SUD) “programs” with standardized durations and regimens of counseling and behavioral therapies for all patients. The national network of over 15,000 SUD treatment programs was created with federal funds in the 1960s in response to the heroin crisis. Licensing and regulatory control, and most of the recurrent funding, for these addiction programs were kept separate from mainstream health care.

Most regulations governing specialty SUD programs are enforced by state agencies charged with administering the federal Substance Abuse Prevention and Treatment (SAPT) block grant. These agencies regulate SUD treatment providers in 35 states and the District of Columbia (MACPAC, 2019). The regulatory system licenses or certifies facilities and programs, while government agencies also contract with SUD providers to treat people with SUD problems, especially among the low-income population.

In most states, the licensing standards for SUD programs focus on an overarching process, including requirements that all patients be assessed or that individual treatment plans be provided. However, the standards offer little guidance about how to implement the required processes. For example, licensing requirements typically offer only minimal guidance on the types of staffing required, often suggesting that staffing should be based on patient needs.

Enforcement of standards is nearly always driven by complaints. If an investigation finds violations, a remediation plan must be developed. The consequences for violating standards are uniformly weak. Financial penalties, if they exist at all, are small.

The Medicaid program, which currently enrolls more than 72 million people, provides health insurance coverage for a population that is at high risk for OUD. Medicaid’s benefits structure, provider participation requirements, and payment

policies can have a powerful effect on the supply and quality of SUD care. In addition, the federal government offers states the opportunity to obtain waivers that allow them to use federal Medicaid dollars to pay for residential SUD care.

STATE REGULATIONS THAT PROMOTE IMPROVED EFFECTIVENESS OF TREATMENT

States could enhance an individual's likelihood of receiving effective specialty OUD care by adopting licensing and contracting standards that:

- Require the availability of medication for opioid use disorder (MOUD) and the medical personnel that must administer MOUD.
- Prohibit treatment programs from screening out people who are being treated with medications.

Evidence from quasi-experimental studies shows that medical supervision and accreditation standards can promote the use of buprenorphine (Ducharme & Abraham, 2008; Knudsen et al., 2006). Aligning the standards for substance use disorder treatment facilities with the standards for other health care facilities would institutionalize the evidence-based treatment in SUD programs.

Medicaid Can Have a Powerful Influence on Care

There are several key policies in the Medicaid program that have been shown to promote the adoption of evidence-based treatments and harm reduction activities.

For example, Medicaid expansion results in coverage of a high-risk population and drives screening and treatment resources to low-income populations with relatively high prevalence of OUD (Wen et al., 2017). This, in turn, increases the use of treatment using buprenorphine and the distribution of naloxone (Maclean and Saloner, 2017; Clemans-Cope et al., 2019).

Despite these improvements, however, barriers to the receipt of evidence-based treatment remain (GAO, 2020). These barriers include:

- Failures to screen and refer to treatment patients with an OUD.
- Shortages of health professionals trained and certified to deliver MOUD.
- State requirements regarding the distribution and reimbursement of physician-administered MOUD.
- Lack of enforcement of federal requirements that states cover medications that the Food and Drug Administration has approved for treatment of OUD.

States can take a variety of actions to increase access to evidence-based treatments for Medicaid recipients and other people in treatment for OUD. Those actions include:

- Promote the identification of OUD cases through screening and referral requirements for all relevant treatment settings.
- Allow nurse practitioners and physician assistants to become certified and able to administer buprenorphine.
- Relax strict requirements for how physician-administered MOUD is distributed and reimbursed.
- Enforce federal requirements for coverage of MOUD in the Medicaid program.

Beyond the Medicaid Program: States have policy tools available that have been demonstrated to increase access to SUD treatment and promote wider distribution of naloxone. State governments can work through their insurance commissioners to influence the availability and affordability of treatment for OUD. Strategies include:

- Enforce the provisions for parity coverage under the terms of The Mental Health Parity and Addiction Equity Act (MHPAEA) and the Affordable Care Act (ACA). The implementation of coverage provisions from MHPAEA and the ACA is highly variable across the states
- Establish a standard for network access that health plans operating in a state must follow (McGinty et al., 2015).
- Enforce key laws and regulations governing opioid prescribing safety activities that private insurers must follow, including drug supply management policies. A state can carry out this enforcement by allocating funding and personnel to enforcement activities.

Easing Restrictions on Naloxone: States should consider making policy changes that expand the availability of naloxone, a competitive opioid-receptor antagonist that reverses the effects of an opioid overdose when administered promptly and in an appropriate dose. States can:

- Take actions to make naloxone easier to distribute and obtain. While there have been substantial increases in the distribution of naloxone, it remains a highly effective and underused harm reduction mechanism (Giglio et al., 2015; Walley et al., 2013).
- Invest in expanded training and supply of naloxone and require its use. This expansion would likely save lives. Recent survey data shows that fewer than 33 percent of chain drug store pharmacies report distributing naloxone (Giglioi and colleagues (2015) report the effectiveness of providing education and training about the administration of naloxone to lay people who are proximate to people at risk for potential overdoses. While police are frequently first responders to overdoses, less than 20 percent of police departments currently carry naloxone.

Many policy changes at the state level may not require spending opioid abatement funds. For instance, states can pass laws that:

- Permit third-party prescriptions for individuals not at risk for overdose but in a position to revive someone at risk for overdose (Gertner et al., 2018; McClellan et al., 2018).
- Give pharmacists the authority to either prescribe naloxone or dispense naloxone without a prescription (Abouk et al., 2019).
- Authorize state health officials to issue a standing order allowing all licensed pharmacies in a jurisdiction to dispense naloxone without individual-level prescriptions (Gertner et al., 2018; Xu et al., 2018).
- Provide immunity from criminal, civil, and professional sanctions for prescribers and dispensers of naloxone and laypersons involved in administering naloxone (Gertner et al., 2018; McClellan et al., 2018).
- Include coverage of take-home naloxone in state Medicaid benefit packages (Frank & Fry, 2019; Kaiser Family Foundation, 2018).
- Mandate co-prescribing of naloxone for individuals at high-risk for overdose

OBSERVATIONS ON THE COST OF IMPLEMENTING POLICY INFRASTRUCTURE CHANGES

Evidence regarding the costs of maintaining a licensing and enforcement system for OUD treatment programs comes from the fees that states charge these programs to support its licensing assessments and renewals. Available data assembled by the Medicaid and CHIP Payment and Access Commission suggest that the base cost of these programs ranges from \$500 to \$1,200 per licensed organization, plus a variable charge of between \$3 and \$35 per bed.

The imposition of these fees would likely cause a reduction in the supply of specialty SUD services in the short run. This reduction would decrease access and potentially raise the prices charged by SUD providers.

Expanding licensing requirements for physician extenders, and assessing the extenders' adherence to expanded requirements, is estimated to cost an average of \$100 per professional per year. Expansion of licensure, especially for physician assistants and nurse practitioners, would result in expanded access and some potential savings related to the substitution of lower-cost professionals for physicians. However, most budgets would experience higher net costs.

Policy Infrastructure for Initiatives to Limit the Supply and Improve the Safety of Opioid Analgesics Prescribed by Health Care Providers

States can use several approaches to facilitate the implementation and scaling of evidence-based policies to promote safer opioid analgesic prescribing. The strongest evidence of specific legislative and agency measures that effectively limit the supply of opioid analgesics prescribed in health care settings comes from evaluations of prescription drug monitoring programs (PDMP), through which electronic databases collect and monitor the prescribing and dispensing of controlled substances.

PRESCRIPTION DRUG MONITORING PROGRAMS

State health departments, together with law enforcement agencies, are typically responsible for the funding, implementation, and design of PDMPs. These departments, along with state legislatures, influence the implementation of PDMP “best practices” that have been shown to enhance program effectiveness. “Robust” PDMP features are still evolving, but seem to include:

- Mandatory registration and access, with appropriate patient exemptions.
- Ability for prescribers to designate others to access the PDMP on their behalf.
- Comprehensive data for controlled substances.
- Data updates at least weekly (Haffajee, 2019; Mauri et al., 2019; Patrick, et al., 2016).

States that incorporate these robust PDMP elements, either through legislative mandates or program design decisions made at the agency-level, are more likely to achieve reductions in higher-risk opioid prescriptions than states in which PDMPs lack such features (Mauri et al., 2020).

Additional PDMP features are believed by prescribers to enhance program effectiveness but have limited supporting evidence. These features include:

- Capabilities that ease use by prescribers and pharmacists.
- Algorithms that help to identify higher-risk patients.
- Education and outreach to providers (Mastarone et al., 2020; Reist et al., 2020; Weiner et al., 2019).

OTHER EVIDENCE-BASED POLICIES

Other evidence-based policies include:

- Insurer drug supply management policies. The strongest evidence for these policies comes from prior authorization programs, particularly in Medicaid.
- Clinical health system interventions that influence opioid analgesic prescribing.

State legislatures, health departments, and other state agencies have several critical functions related to supporting the implementation of these policies and interventions. In particular, there is evidence that drug supply management policies related to opioid analgesics, like prior authorization, could help state Medicaid programs decrease risky prescribing practices like high-dose prescriptions and use of long-acting formulations (Hartung et al., 2018; Keast et al., 2018; Morden et al., 2008).

Generally, there have been limited evaluations of approaches taken by state health departments and other agencies to promote the implementation of evidence-based drug supply management policies by insurers. Evaluations of clinical health system interventions by health care organizations are also limited.

Two examples shed light on existing state initiatives that promote the implementation of evidence-based policies to improve the safety of opioid analgesic prescribing.

- **Encouraging Information-Sharing and Coordination:** State health departments might facilitate information-sharing and coordination among payers to promote the broader implementation of drug-supply management policies. For example, North Carolina regularly convenes payers with the goal of improving and harmonizing policies to limit the supply of prescription opioid analgesics (North Carolina Department of Health and Human Services, 2018).
- **Adopting Laws:** State legislatures may take even stronger action by adopting laws encouraging or mandating safe prescribing practices by private health plans. For example, Utah passed legislation in 2017 urging all payers to enact policies promoting safer pain management, both by limiting risky opioid analgesic prescribing and facilitating access to non-opioid pain treatment (Office of the Inspector General, 2019).

Note that evidence to support the effectiveness of specific state approaches is lacking at this time.

Policy Infrastructure for Initiatives to Prevent Harms to Children Whose Parents Misuse Opioids

States have a few mechanisms at their disposal to facilitate the implementation and scaling of evidence-based policies to mitigate harms to children in families affected by opioid misuse. Preliminary evidence suggests these state policy levers may benefit children whose parents misuse opioids:

- Expansion of Children's Health Insurance Program (CHIP) and Medicaid.
- Repeal of laws and policies that take a punitive approach to SUD in pregnancy and among parents.

CHIP AND MEDICAID EXPANSION

CHIP and Medicaid cover nearly 40 percent of children in the U.S., and 40 percent of women giving birth. However, access to these programs is not uniform across states due to differences in income eligibility limits (Kaiser Family Foundation, 2020; 2020a). CHIP and Medicaid may improve children's health through several channels:

- Increased use of care by children.
- Greater access to MOUD for parents with OUD.
- Improved prenatal care.

REPEAL OF LAWS/POLICIES THAT PUNISH SUBSTANCE MISUSE IN PREGNANCY

Several states have laws/policies that approach SUD during pregnancy or parenthood in a punitive or potentially punitive manner. Examples include laws/policies that:

- Define substance misuse in pregnancy as child abuse or neglect.
- Criminalize substance misuse in pregnancy.
- Consider substance misuse in pregnancy as grounds for civil commitment.
- Require reporting of suspected substance misuse in pregnancy to state or local health officials.
- Mandate testing of pregnant women with suspected substance misuse, or infants with suspected substance exposure (Faherty et al., 2019).

The prevalence of punitive and potentially punitive laws and policies has increased since 2000. At present, 31 states and the District of Columbia have enacted laws and policies intended to discourage substance misuse among pregnant women and parents (Faherty et al., 2019; Guttmacher Institute, 2020).

There is little evidence to support the effectiveness of these laws in decreasing parental substance misuse (Patrick & Schiff, 2017). Rather, a growing body of literature indicates that these laws and policies might:

- Hamper detection of OUD in pregnancy (Gressler & Shaya, 2019).
- Discourage pregnant women with OUD from receiving addiction treatment (Angelotta et al., 2016).
- Delay or discourage use of prenatal care (Roberts & Pies, 2011; Krans & Patrick, 2016).

All of the outcomes listed above are associated with poorer maternal and infant health (Cantwell et al., 2011; Carmichael et al., 2002; Castello et al., 2012;). The odds of neonatal opioid withdrawal syndrome (NOWS) among neonates is actually higher in states with such laws and policies (Faherty et al., 2019).

This evidence suggests that repealing laws and policies that take a punitive approach toward SUD in pregnancy is an important policy lever states can use to improve the health of pregnant women with OUD and their infants.

EXISTING STATE INITIATIVES

The following existing state initiatives are designed to mitigate harms to children whose parents misuse opioids. These initiatives have not yet been evaluated to determine their effectiveness in improving child health outcomes or the adoption of evidence-based policies. However, strategies that have been recommended by state and local practitioners, based on their perceived benefits, are noted.

BUILDING INTERAGENCY COLLABORATIONS

Most evidence-based and promising interventions identified in this review combines services that are traditionally coordinated by separate state agencies, such as state health departments, child welfare agencies, early education programs, and state courts. Family drug treatment courts, for example, combine specialty SUD treatment and child welfare services with court monitoring.

There is evidence that integration and even co-location of different, yet complementary, services is associated with larger benefits to children and families (Milligan et al., 2011). State and local practitioners identify strong interagency collaboration as critical to ensuring the success of these initiatives, and to advancing integrated service delivery and a comprehensive system of care for pregnancy and early childhood in high-risk families (Association of State and Territorial Health Officials, 2018; Dennis et al., 2015; Smith & Mogro-Wilson, 2008).

Several measures are thought to support effective interagency collaboration to address the needs of children affected by their parents' opioid misuse:

- Frequent interagency communication (Drabble, 2011; Huebner et al., 2017; Iachini et al., 2015; Jose & Wetzler, 2019; Meyer & Phillips, 2015).
- Data-sharing across collaborating agencies (Marsh & Smith, 2011).
- Co-location of services (He & Phillips, 2017; Milligan et al., 2011; Niccols et al., 2012).
- A single funding stream to finance joint initiatives
- (Association of State and Territorial Health Officials, 2018; Marsh & Smith, 2011).
- Harmonized intervention goals, performance measures, and monitoring/oversight processes across partner agencies (Drabble, 2007; Jose & Wetzler, 2019).
- Cross-training of staff from partnering agencies to improve their understanding of each other's work (Drabble, 2011; Huebner et al., 2017; Marsh & Smith, 2011).

Interagency Collaborations in Home Visiting Programs

Home visiting programs offer some examples of how interagency collaborations are being pursued on-the-ground.

- **Streamlining Financing:** Texas created a single funding stream to support a home visiting program. The program is managed by that state's Department of Family and Protective Services but combines funding from several federal grants. These grants include Program for Infants and Toddlers with Disabilities, a provision of the Individuals with Disabilities Education Act (IDEA Part C); Maternal, Infant and Early Childhood Home Visiting Program; state general funds; and Temporary Assistance for Needy Families.
- **Facilitating Data-Sharing:** Georgia built a centralized home visiting data system to facilitate data sharing between home visiting programs and the multiple state agencies serving families affected by SUD. The system receives referrals for home visiting from multiple access points, including health care organizations, child welfare, and community partners. These referrals can then be viewed and coordinated by multiple agencies (Association of State and Territorial Health Officials, 2018).

MEDICAID REFORMS

Medicaid is a critical source of health care coverage for pregnant women and children affected by the opioid crisis. State Medicaid programs cover nearly half of all births in the U.S., and 80 percent of NOWS-involved births (Martin et al., 2017; Winkelman et al.,

2018). As a result, there is tremendous potential for states to use their Medicaid programs to support the implementation and financing of evidence-based interventions to mitigate harm to children. Such opportunities include:

- Reimbursing components of evidence-based, multisectoral interventions, such as home visiting programs and family skills interventions. Numerous states reimburse case management services provided by these programs (Witgert & Richardson, 2012).
- Requiring that Medicaid managed care organization networks include providers of evidence-based interventions like home visiting services, and integrate SUD treatment with other services, as is required in Minnesota (Normile et al., 2017; Witgert & Richardson, 2012).
- Developing and operating the state's own home visiting and family skills intervention programs. This has been achieved by Michigan's Maternal Infant Health Program, a home visiting program operated by the state Medicaid program to ensure access among low-income pregnant women (Michigan Department of Health and Human Services, 2015; Witgert & Richardson, 2012).

WORKFORCE TRAINING AND DEVELOPMENT

State health departments, child welfare agencies, and agencies charged with coordinating early education services can support the implementation of evidence-based interventions by providing or subsidizing specialized training and ongoing technical assistance to help providers meet the needs of families affected by OUD. The following examples illustrate different approaches states have taken.

The Association of State and Territorial Health Officials (2018) reports that Georgia's Department of Public Health:

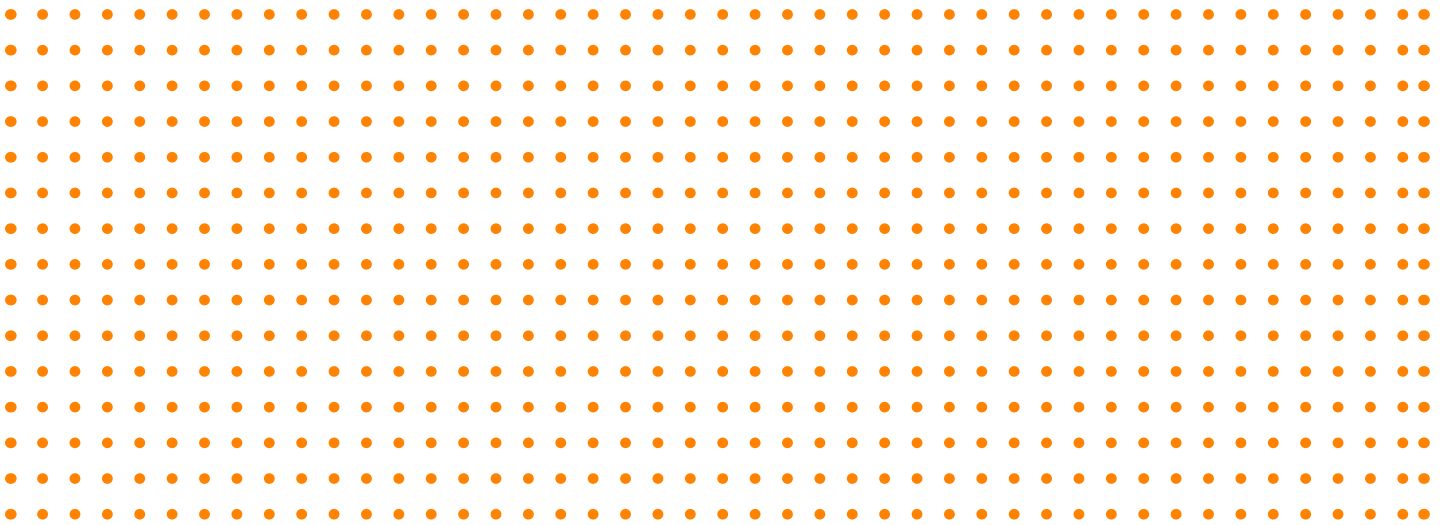
- Organized and funded training so its home visiting workforce could obtain associate certificates in child development.
- Provides technical assistance to home visitors.
- Worked in partnership with the Department of Early Care and Learning to develop a training repository listing mandatory trainings and recommended professional education opportunities.

Maryland's state health department has provided training in services for substance-exposed newborns to early childhood professionals across multiple disciplines and agencies (Health Resources and Services Administration, 2019).

QUALITY ASSURANCE

State agencies can support quality improvement initiatives by monitoring how well programs in the state adhere to best practices for evidence-based interventions.

Maryland's Home Visiting Consortium, for example, provides quality oversight for state-funded home visiting programs (Maryland Children's Cabinet, 2017). The consortium includes private stakeholders and public officials from different agencies that oversee early childhood programs.



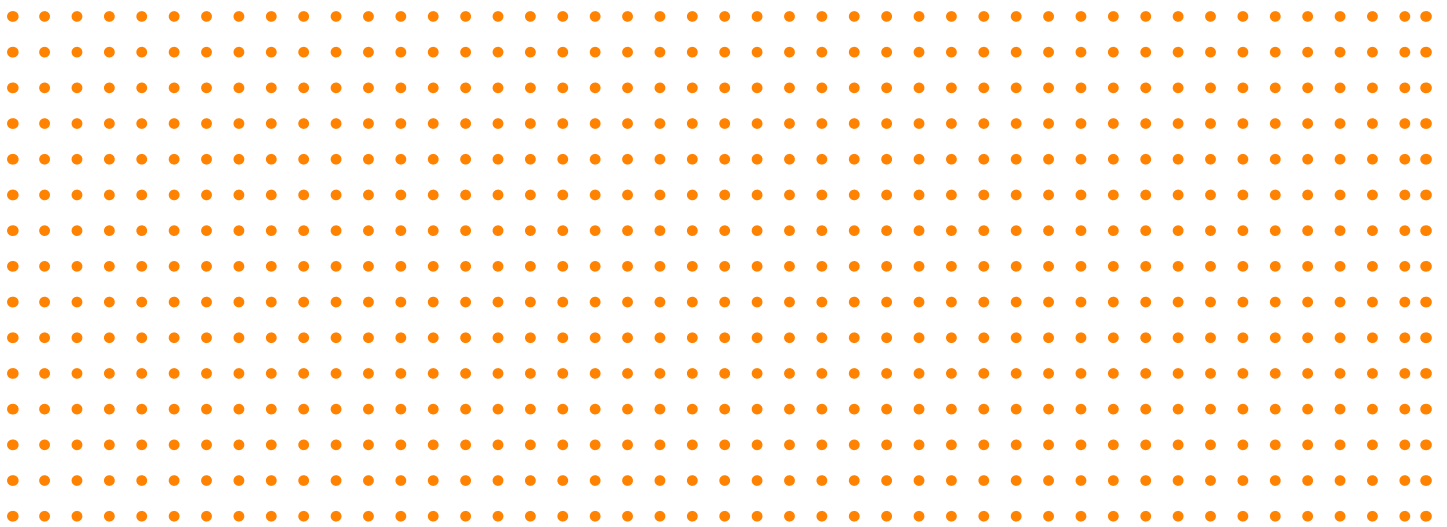
FINAL OBSERVATIONS

For a generation or more, the U.S. has made little investment in building the capacity of the substance use disorder treatment system. That system has largely been financed through grants and contracts from the state and federal governments. It has not been subject to the requirements of modern health care, including the critical need to promote evidence-based treatment.

As a result, a range of practices have been allowed to co-exist, leaving to chance whether consumers receive treatments that work or treatments that may be ineffective or even harmful.

Abatement funds from opioid-related litigation offer an opportunity for a significant resetting of how we will deliver care for opioid use disorder (OUD) in the future. The abatement funds being considered would dramatically alter spending on OUD care in the U.S. Thus, promoting “what works” is of critical import.

Our hope is that the information contained in this report will help guide the use of new funds so they will have maximal impact on addressing the opioid epidemic in the U.S.



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Chapter 5: Prevention of Opioid Misuse and its Harmful Effects on Children and Families

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Chapter 7: Policy Infrastructure

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