



California Health Care Foundation



Recovery Within Reach: Medication-Assisted Treatment of Opioid Addiction Comes to Primary Care

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The treatment of addiction is widely misunderstood, and the disease remains clouded in stigma and shame. For opioid addiction in particular (including prescription painkillers and heroin), medication-assisted treatment (MAT) — treatment that combines medication with behavioral health services — has been proven to save lives and increase recovery rates, yet only 10% of those who need such treatment can access it. This paper explores several options for expanding access to MAT for those who are addicted to opioids and provides recommendations for California.

Introduction

The United States is in the grip of an opioid addiction and overdose epidemic that shows no signs of abating. The numbers tell a grim tale:

- ▶ Nearly 22 million Americans are thought to have some kind of substance use disorder; of these, 1.9 million are addicted to prescription painkillers, and an estimated 586,000 are addicted to heroin.
- ▶ Only 10% of people with substance use problems are receiving help.
- ▶ Since 2008, more than 115,000 Americans have died from overdoses of prescription painkillers (7,400 deaths in California over the last five years), and nearly 39,000 have died from heroin overdoses: an overall death rate of 9 per 100,000 in 2014.¹ More people age 25 to 64 died from drug overdose than from auto accidents in 2013.²
- ▶ Deaths from heroin overdose alone jumped five-fold between 2001 and 2013, and rose another 28% from 2013 to 2014; deaths from prescription opioids quadrupled from 1999 to 2011, and the numbers continue to go up each year, despite increased awareness of the epidemic.³
- ▶ In California, it is estimated that 370,000 of the 2.9 million people who are newly eligible for Medicaid may be in need of substance use disorder treatment.⁴

Fortunately, recent developments provide opportunities to address this challenge. Passage of the Affordable Care Act (ACA) in 2010 expanded private health insurance and Medicaid coverage to millions of low- and middle-income adults, and for the first time, both public and private insurance are mandated to cover substance

use treatment. The federal Mental Health Parity and Addiction Equity Act of 2008, although still not enforced everywhere, requires insurers to pay for proven addiction treatments at the same level as treatment for physical diseases. In 2015, President Obama and Secretary of Health and Human Services Sylvia Burwell announced the federal government's commitment to fighting the overdose epidemic with increased federal resources, explicitly focusing on MAT as one solution.

Along with these major advances in policy, evidence is accumulating that addiction is a chronic disease, like diabetes or hypertension, and that a person's substance use is best treated as part of an overall physical and mental health care plan. MAT for opioid addiction — specifically, buprenorphine and methadone — has been shown to increase recovery rates, decrease overdose deaths, decrease criminal activity, and lower the risk of hepatitis and HIV.⁵ Medications significantly improve retention in treatment and reduce the risk of overdose death by helping patients stay sober since they reduce cravings and feelings of withdrawal, stabilize the abnormal brain chemistry created by opioid addiction, and allow people to manage the stress and challenges of changing lifestyles and behaviors.

Previously prohibited from treating addiction outside of specially licensed opioid treatment programs, physicians are now able to prescribe and dispense buprenorphine in their offices thanks to the Drug Addiction Treatment Act of 2000 (DATA 2000).

“The ability to prescribe buprenorphine transformed my practice. It brings great meaning to my practice to see the dramatic before and after picture. My patients with addictions experience stability for the first time in years and start putting their lives back together.”

— Gary Pace, MD, Alexander Valley Healthcare

The understanding of addiction as a chronic condition has implications for insurance coverage and public policy as well. Although research has found that relapse rates are high when patients are weaned off buprenorphine too soon, length of treatment is often still determined

by an insurance limit or clinic protocol, rather than based on patient need. “Many people are forced off their treatment due to arbitrary insurance requirements, financial problems, or their physician’s insistence,” stated R. Corey Waller, MD, addiction specialist and medical director of an integrated treatment clinic for patients with complex care needs in Michigan. “If a patient has diabetes and makes a mistake once a month — bingeing on Krispy Kremes — the doctor doesn’t punish them and cut them off insulin. But people on addiction treatment find they must be perfect 365 days out of the year, because one mistake can mean they are kicked off treatment, lose a child to foster care, or end up in jail.”

Even as the nation grapples with the opioid addiction epidemic, buprenorphine is still underutilized. Only half of the physicians who are authorized to prescribe buprenorphine do so. Physicians cite many reasons for not prescribing the drug: lack of time, worries about

negative reactions from other patients or the community, inadequate staff support, concern about Drug Enforcement Administration (DEA) investigation, and paperwork requirements.^{6,7} At the same time, many practices around the country have overcome these barriers through a variety of approaches. This report reviews 10 common elements of successful buprenorphine programs, describes model practices, and provides tips for communities that are starting new programs.

Methodology

This report is based on a review of the current literature related to buprenorphine, with a focus on identifying best practices in place or emerging around the integration of MAT into primary care settings, as well as interviews conducted with 18 experts in the field. Interviews elicited information about the role of MAT in the overall spectrum

Neurobiology 101: Addiction and the Brain

“We need three things to survive [besides oxygen]: food, water, and dopamine — and dopamine is the most important. If you deprive study subjects of water for three days, then put them in a functional MRI and place water on their lips, the relative size of the craving is like a baseball. Do the same with food, and it is like a basketball. Then take someone with an addiction to opioids, up to one year after their last use, and talk about OxyContin while they are in a functional MRI, and the relative size of that craving is the size of a baseball field.

“Why? Because dopamine is the chemical behind our drive to live and survive. It rewards us with feelings of pleasure, satisfaction, and well-being when we pursue things that are good for survival. It punishes us with feelings of desperation, illness, and hopelessness when we pursue things that are bad for survival. Our limbic system is fine-tuned to keep our dopamine levels between 40 ng/dl (a terrible day — when you can’t get out of bed and get anything done) and 100 ng/dl (the best day ever — when you feel invincible).

“Long-term opioid use changes the system — sometimes permanently. The first hit of heroin brings dopamine levels up to 1,000. However, our brain is

designed to keep us in balance — excess dopamine over time causes our brain to ramp up systems to get back to normal: less dopamine gets released each time, the number of dopamine receptors go down, and the ‘anti-dopamine’ inhibition system ramps up and works in overdrive. Over time, the same dose of heroin or OxyContin causes less and less dopamine release, until the point where the brain can’t get beyond 10 to 20 ng/dl without help. Daily pills or daily heroin is required just to feel normal. Functional MRI studies have shown that these brain changes take one to two years to recover, and in many people, after long enough use, the brain never recovers.

“This is why people are 14 times more likely to die if they don’t use buprenorphine or methadone for treatment. These meds stabilize the dopamine system and bring it back to normal, and since they are long-acting, they take people out of the cycle of withdrawal and craving. If our goal is to punish people and make them feel terrible, then we require abstinence, consign them to lives at 10 to 20 ng/dl dopamine levels, and judge them for not being able to get their lives together. If we follow science, data, and math, we will use the treatments that work and save lives.”

Source: Excerpt of a 2015 presentation for CHCF by addiction specialist R. Corey Waller, MD, medical director of the Center for Integrative Medicine at Spectrum Health Medical Group in Michigan.

of opioid use disorder treatments, barriers to the spread and scale of MAT, and successful MAT model programs operating around the country.

Researchers conducted hour-long interviews with the key informants (see Appendix A) and identified common elements across the successful buprenorphine treatment programs and approaches. This paper describes successful programs and strategies that can serve as models for practices starting new MAT programs, as well as selected programs that exemplify one of three approaches for addressing common barriers that practices might encounter when developing and implementing MAT.

Historical Context

Addiction to opioids has plagued Americans for more than a century, and many of the policies and programs to treat opioid addiction date back to the early 1900s. Heroin, invented as a treatment for addiction and prescribed by physicians, was quickly recognized as the first failed attempt to curb addiction with an opioid medication.⁸ The first law to criminalize substance use, the Harrison Act, was interpreted by the Supreme Court in 1920 to apply to physicians: The law prohibits physicians from using opioids to treat addiction. This law still stands today.

“I absolutely believe this is a primary care issue. There is also a role for addiction specialists for complex patients. But 65% to 70% that present in primary care can be managed in a primary care setting.”

— Ako Jacintho, MD, HealthRIGHT 360

It was not until the 1950s, when a heroin epidemic was raging in New York, that the first medication to successfully treat opioid addiction was developed — methadone, which is still the most prevalent form of MAT. Because of the Harrison Act, a separate freestanding system of federally licensed and regulated programs was created outside of the medical system to dispense this drug. As a result, in part, of this history, physicians became wary of treating opioid addiction, contributing to the commonly

held view that addiction is not a medical illness or disease but a moral failing and lack of willpower.

It took another 50 years for the federal government to allow physicians to prescribe an opioid, buprenorphine, to patients with opioid addiction. The DATA 2000 law allows physicians to obtain a waiver from the DEA, which grants permission to prescribe buprenorphine for addiction treatment in an office setting. Under DATA 2000, physicians are required to complete eight hours of training and to file a Notification of Intent to Prescribe to the Substance Abuse and Mental Health Services Administration (SAMHSA). Physicians are limited to a total of 30 patients in the first year, after which they may increase their caseload to 100 patients. These limits apply equally to physicians who have taken an eight-hour training course and to those board-certified in addiction medicine. Although there are federal efforts to lift the restriction on how many patients a physician may treat, this cap currently severely limits access to MAT for new patients and has created waiting lists in many parts of California.

Summary of the Research

MAT with buprenorphine for opioid addiction has been in use in Europe since 1995 and in the US since 2002. MAT research is an active arena, with new findings continually emerging. This section provides a brief review of the research into buprenorphine, and compares it to other treatments for opioid addiction.

Buprenorphine in MAT. Buprenorphine has several advantages over other treatments for opioid addiction. Like methadone, it is a potent pain reliever, it stabilizes brain function for those whose neurobiology has been damaged from long-term opioid use, and it is long-acting, decreasing the experience of euphoria (which can trigger cravings and relapse). Unlike methadone, buprenorphine is a partial agonist, meaning that it has a ceiling effect on the body’s respiratory centers — even with high doses, it does not impact breathing, and therefore deaths from buprenorphine alone are extremely rare. Finally, buprenorphine blocks the effects of other opioids — people are much less likely to die from overdose when they use heroin or other drugs, and will not feel the high from their use.

In the context of MAT, buprenorphine is recommended to be delivered as part of a comprehensive treatment approach. Experts interviewed for this report emphasized the importance of behavioral health services — such as cognitive-behavioral therapies, counseling, and mindfulness training — combined with medication treatment. They also emphasized, however, that patients should not be refused buprenorphine treatment if they cannot, or will not, access behavioral treatment.

The evidence is still unclear about which behavioral approaches are most effective when combined with MAT. Although most buprenorphine studies include a behavioral health component, one randomized controlled trial of buprenorphine for prescription drug addiction compared brief medical visits to intensive counseling and found that counseling added no additional benefit.⁹ A 2016 review of the literature by the American Society of

Addiction Medicine (ASAM) found mixed support in the literature for behavioral interventions — just three of eight studies found a positive benefit — but recommended a comprehensive (medical and behavioral) approach.¹⁰

The strong opinion of most experts interviewed was that stabilizing the brain through buprenorphine or methadone was a prerequisite for most people to meaningfully engage in counseling and lifestyle change — and that medication alone does not help patients change the people and environments that can trigger relapse. At the same time, patients in regions with few addiction counseling resources can still benefit from buprenorphine treatment alone. With the proliferation of online communities and virtual technologies, people without easy access to face-to-face counseling have other options. The growth of telemedicine also has potential to increase patient access to professional behavioral health services.

Medication-Assisted Treatment for Opioid Addiction

Medication-assisted treatment (MAT) uses medication, in conjunction with counseling and behavioral therapies as well as support from family and friends, to help people with opioid use disorders recover from their addiction. Medication reduces the cravings and restores a sober state of mind, so that patients can address both the causes and the effects of their addiction.

MAT is available in specially licensed opioid treatment programs (OTPs) or office-based opioid treatment (OBOT) settings. These medications are approved for addiction treatment in the US:

- ▶ **Methadone** can only be dispensed in an OTP. Methadone is an agonist, which means it acts like an opioid in many ways: treats pain, prevents withdrawal, and stops breathing at high doses. Because methadone is long-acting (more than 24 hours), it provides a stabilizing effect on the brain and is less likely to cause a high compared to short-acting opioids such as heroin and oxycodone.
- ▶ **Buprenorphine** can be provided in an OTP or OBOT. Buprenorphine is a partial agonist, which means it acts like an opioid in some ways (treats pain, prevents withdrawal) and acts like an anti-opioid (blocking opioid effects) in other ways: It does not stop a person from breathing and blocks

the “high” effect of other opioids. Because it is long-acting (more than 24 hours), buprenorphine provides a stabilizing effect on the brain and is less likely to cause a high. A buprenorphine implant is in development.

- ▶ **Naltrexone**, which is approved for both alcoholism and opioid use disorder, can be prescribed by any licensed clinician in any setting. Naltrexone is a pure opioid antagonist, which means it blocks all effects of opioids: if an opioid is taken while naltrexone is in the patient’s system, there is no pain relief, high, or effect on breathing. It is long-acting, so it can be used on a daily (pill) or monthly (injection) basis; a six-month implant (subcutaneous) is in development.
- ▶ **Naloxone**, an overdose reversal agent, is available over the counter at pharmacies, can be prescribed by any licensed clinician, and can be dispensed with a standing clinician order in community settings. Naloxone is a pure opioid antagonist, it works instantly and wears off quickly, and it is used to reverse opioid overdose and prevent death.

The major characteristics of these medications are summarized in Appendix 1.

Short-term versus long-term buprenorphine treatment. Although buprenorphine can be used in short-term detoxification programs, experts increasingly discourage this approach and encourage maintaining MAT over the long term.¹¹ Studies have shown that patients who stop taking buprenorphine during the first few months of their treatment experience high rates of relapse, even with intensive behavioral support.¹²

“There is a misconception that if we just had enough counseling and psychosocial support, we would not need the medication. Medication maintenance works; even enriched, very intensive psychosocial support alone does not. Another misconception is that buprenorphine treatment should always include counseling. The POATS study suggested that counseling did not influence outcome. So, discharging people because they don’t go to counseling is like stopping insulin when someone doesn’t make it to the nutritionist.”

— Judith Martin, MD, Substance Use Services
San Francisco Department of Public Health

In late 2015, the National Institute on Drug Abuse reported the results of a long-term study, the Prescription Opioid Addiction Treatment Study, or POATS trial, which evaluated the impact of buprenorphine on prescription opioid addiction. Patients were given 12 weeks of buprenorphine treatment and then were tapered off of it completely. Although 50% of the patients were abstinent from drugs at the end of the 12 weeks, this number rapidly collapsed to 9% after discontinuation of the buprenorphine. Most patients who relapsed went back to buprenorphine therapy. Patients using buprenorphine at the 18-month interview were more than twice as likely to report abstinence as those who were not (80% versus 37%). At the 42-month interview, the advantage associated with current opioid agonist treatment was still large (80% versus 51%).¹³

Without long-term treatment, people often return to the drug to which they were addicted, and the dose their bodies tolerated prior to treatment can, at that point, cause overdose death.

Behavioral treatment alone. Research has shown that treating opioid addiction with behavioral or social model approaches alone often puts patients at high risk and is ineffective. Social model approaches help patients change how they think about themselves and their addiction, and use peers to encourage lifestyle changes. Twelve-step programs and sober living facilities are examples of these approaches.

Without access to MAT, fewer than 25% of people with opioid addiction are able to remain abstinent for a full year.¹⁴ Nevertheless, many treatment facilities either don’t offer, or strongly discourage, MAT: a problem described in detail in the 2015 Huffington Post article “Dying to Be Free.”¹⁵

One frequently cited Swedish study randomized a heroin-using population to buprenorphine or placebo, after a detoxification period; both groups received cognitive-based therapy, individual counseling, and drug screens. Four out of the 20 patients in the placebo group died during the one-year study; none of the patients in the buprenorphine arm died, and 75% of them stayed in treatment.¹⁶

Andrew Kolodny, chief medical officer for Phoenix House, in a keynote speech at the California Prescription Drug Abuse Summit, summarized a viewpoint common to many addiction experts: “For any other disease, if a trial showed a 20% placebo death rate, it would be unethical to repeat that trial and withhold effective treatment. Yet we repeat this experiment every day across this country. Patients are denied access to effective treatment — buprenorphine or methadone — and are forced into ineffective treatment, or no treatment at all.” A 2015 Johns Hopkins evidence review stated, “While some studies support improved effectiveness of combining psychosocial therapies with buprenorphine and methadone maintenance, abstinence-based psychosocial approaches that shun medication-assisted treatment are lacking evidence to support the practice.”¹⁷

Naltrexone. Naltrexone, also used to treat opioid addiction, can be prescribed in primary care settings. While

naltrexone has been shown to be effective in treating alcoholism, studies of naltrexone for opioid addiction have had mixed results.¹⁸ Oral naltrexone has not been found to be better than a placebo, and many studies of injectable naltrexone have been short term (up to six months), and focused on involuntary use (e.g., maintaining professional licenses, obtaining work vouchers, or satisfying parole requirements).^{19,20}

For example, an Irish study offered work vouchers to unemployed people with opioid addiction and also offered them naltrexone treatment. When naltrexone was voluntary, only 26% accepted all naltrexone injections for six months. When acceptance of naltrexone was required to obtain the work voucher, 74% of those completed the six-month treatment course.²¹ Some experts express concern about promoting naltrexone as first-line treatment for opioid addiction, due to high dropout rates and the risk of subsequent overdose death, as well as the lack of data on long-term impact.²²

Methadone. Studies comparing methadone and buprenorphine show that methadone leads to better treatment retention, but do not show a major difference in mortality or illicit drug use.²³ Because methadone cannot be prescribed for addiction outside of a licensed opioid treatment program, while buprenorphine is available to primary care physicians, this paper focuses exclusively on buprenorphine.

Overcoming Challenges

More than 900,000 US physicians can write prescriptions for opioid painkillers, such as OxyContin and Vicodin, and are already registered with the DEA. However, fewer than 32,000 have obtained a DATA 2000 waiver to prescribe buprenorphine, and only a fraction of those licensed actually prescribe it.²⁴

California has fewer than 2,800 physicians who can prescribe buprenorphine — approximately seven physicians per 100,000 residents.²⁵ These prescribing physicians are not evenly distributed across the state. Less than 50% of people addicted to opioids in California have access to a physician who can prescribe buprenorphine — a rate that falls below the national average.²⁶ For example, as of 2015, the City and County of San Francisco had 43.6 waived physicians per 100,000 residents (the highest

rate in the state), while Plumas and Lassen Counties (ranked No. 1 and No. 3, respectively, for opioid death rates in California) had no waived physicians at all.²⁷ Moreover, because the number of physicians who prescribe buprenorphine report caring for an average of between 26 and 39 patients — substantially fewer than the 100 allowed — the actual capacity in California is likely even lower.²⁸

To increase patient access to buprenorphine, it is critical to increase both the number of physicians who have obtained the DATA 2000 waiver and the willingness of those with the waiver to prescribe the medication. With a severe shortage of addiction specialists, and relatively few substance use treatment programs in general, primary care providers are assuming greater responsibility for managing patients with addiction. There are, however, several barriers and challenges that primary care physicians face on this front, including those discussed in the following sections.

Lack of Physician Training

Medical schools provide little training in addiction medicine or in developing the kinds of skills, including communication and empathy, important to substance use treatment. Other factors that inhibit physicians' willingness to prescribe buprenorphine include concerns about their own lack of clinical training on buprenorphine and clinical protocols; the amount of time needed to start and manage patients on buprenorphine; record-keeping requirements; and their ability to provide access to appropriate mental health and substance use counseling.

Stigma of Addiction

Societal stigma associated with substance use disorder — the belief that addiction is the result of moral failing and lack of willpower — extends to the medical profession. There is not yet full acceptance and understanding of substance use as a chronic, relapsing disease that requires ongoing treatment. Clinicians and their staff members are concerned about community perception — they don't want to be known as the "addiction practice" — and believe that patients with substance use disorders will be disruptive to their practice and to other patients in the waiting room.

“The word ‘addiction’ is not something people can say, and physicians don’t feel comfortable with it. There is no other illness for which physicians are this unwilling to call it what it is.”

— Ako Jacintho, MD, HealthRIGHT 360

Bias Against MAT

Historically, addiction treatment has been rooted in concepts of abstinence and the social model approach. This social model is heavily reliant on laypeople, many of whom are former addicts, to provide recovery services and support — for example, in a 12-step program such as Alcoholics Anonymous.

Medical care and treatment with medications have not been well integrated into traditional addiction treatment programs that focus solely on this social model. Despite the scientific evidence behind the effectiveness of MAT, the social model field has been slow to adopt and recommend medication treatment. Twelve-step peer groups provide important support for many patients, but some of these programs require participants to discontinue any medications while in recovery.

“Strong cultural norms still dictate much of the policy and practices surrounding substance use treatments, as opposed to addressing it as a chronic disease, with evidence-based interventions.”

— James J. Gasper, PharmD, BCPP
California Department of Health Care Services

Similarly, many within the medical and criminal justice communities, as well as some policymakers, see patients who use medication-assisted treatment as replacing one addiction with another. Most prison systems, for example, prohibit inmate access to buprenorphine, although some are piloting the use of the opioid blocker naltrexone in its long-acting injection formulation, Vivitrol. “Vivitrol is not a narcotic and therefore not a controlled substance,”

writes Christine Vestal in a *Stateline* series called “Deadly Bias: Why Medication Isn’t Reaching the Addicts Who Need It.” “The other two medications, buprenorphine and methadone, are narcotics, which are anathema to most criminal justice systems.”²⁹

Policy and Regulatory Issues

State and federal regulations complicate the provision of buprenorphine in treatment of opioid use disorder. Federal regulations require physicians to be trained and certified to prescribe buprenorphine, and cap the number of patients they can treat. Many in the field are advocating to increase or eliminate the cap and to expand prescription rights to nurse practitioners and physician assistants. At the time of this publication, the US Department of Health and Human Services is reviewing these policies and considering changes, with the goal of doubling the number of providers certified to prescribe buprenorphine. In addition, the involvement of the DEA, and the knowledge that a random DEA monitoring visit could occur at any time, discourages physicians who might otherwise be willing to prescribe the medication.

Confidentiality is also an issue. The federal regulation governing the confidentiality of drug and alcohol treatment records, 42 CFR Part 2, can make it difficult for providers to communicate about a patient’s care.³⁰ Recognizing the need to update and modernize these regulations, on February 9, 2016, SAMHSA released a Notice of Proposed Rulemaking on 42 CFR Part 2, which includes a number of changes to the provisions governing research, evaluations, and consent requirements.

Another regulatory barrier was recently removed by the state of California. As of June 1, 2015, Medi-Cal no longer requires Treatment Authorization Requests for most buprenorphine products when prescribed by a physician authorized to use buprenorphine for treatment of opioid use disorder. Use of buprenorphine still requires authorization when used solely for pain management.

Financing

Interviews for this report were focused on safety-net providers and on Medi-Cal, California’s Medicaid program. A full discussion of financing of MAT is beyond the scope of the paper. However, a few barriers to adoption of MAT across payers emerged in the research.

Although the 2008 Mental Health Parity and Addiction Equity Act requires all health plans to cover effective addiction treatment, the law is not yet consistently enforced, and health plans vary widely in their coverage. Not all health plans cover buprenorphine without authorization, for example, and many cover it only for a short period of time.

Medi-Cal does make buprenorphine available without authorization. However, not all pharmacies stock buprenorphine, and not all pharmacists know that for Medi-Cal patients, the payer is the state Medi-Cal fee-for-service program, and not the patient's Medi-Cal managed care plan. In addition, finding a physician who not only prescribes buprenorphine, but also accepts Medi-Cal, can be difficult.

For Federally Qualified Health Centers (FQHCs) seeking to add addiction services, covering physician services is simple: the Medi-Cal health plans cover the costs of physician services in primary care settings, whether the visit is for primary care or addiction treatment. However, covering the costs of other addiction-related services, such

as behavioral health treatment, addiction counseling, and group visits, can be more complicated. California prohibits FQHCs from billing two visits on a single day, which limits clinics' ability to offer same-day integrated services and can deter patients who may be required to return on additional days to receive the full complement of services. California also limits the types of providers for whom FQHCs can bill.

Common Elements of Successful Programs

The authors conducted in-depth interviews with 18 clinicians and experts, all familiar with successful strategies for incorporating buprenorphine into primary care practices. The research revealed 10 elements common to successful programs:

1. **A champion.** Any clinical practice that wants to incorporate buprenorphine must have champions at the administrative and clinical levels. Because all staff

Medi-Cal Funding Streams for Addiction

Medi-Cal's coverage of addiction services is complex. Most substance use disorder services for Medi-Cal beneficiaries are provided through Drug Medi-Cal (DMC). In addition, managed care plans have new responsibilities to provide limited substance use disorder services, and some specific services are available through fee-for-service Medi-Cal. Depending on their contracting arrangements, FQHCs and other primary care providers may or may not interact with all of these programs. Providers treating patients with both mental illness and addiction must navigate a separate set of Medi-Cal benefits that finance mental health services, largely carved out from the addiction and physical health benefits.

Medi-Cal covers MAT in two ways:

- ▶ MAT in outpatient settings is covered through Medi-Cal managed care or Medi-Cal FFS, depending on the medication. Since 2015 buprenorphine has been available through these mechanisms without the requirement of a Treatment Authorization Request.
- ▶ Drug Medi-Cal services, representing the state's largest investment in addiction treatment, are generally carved out of Medi-Cal managed care and offered through county-administered substance use disorder programs. The range of available services varies substantially between counties, but generally includes MAT, outpatient treatment services, and residential services. Services reimbursed by DMC must be medically necessary, provided under the supervision of a physician, and provided at a DHCS-certified site.

California's Drug Medi-Cal Organized Delivery System (DMC-ODS) waiver, which was approved in August 2015, is the first of its kind in the country. It will significantly expand the range of services available through the DMC program. Under the DMC-ODS waiver, counties that choose to participate must provide a full continuum of treatment (from outpatient to residential) and ensure better coordination between the various systems, including creating a single point of entry. The waiver also seeks to cover more of the costs associated with MAT, including intake, counseling, and medication management, and requires that all narcotic treatment programs provide a full range of MAT services. Counties are expected to begin implementation of DMC-ODS programs in 2017.

— especially those at the front desk — must support the decision to treat patients with substance use disorders, it is critical that executive leadership send a consistent message to the entire organization as well as provide training and support to staff.

“Attitude is a big issue. Providers have to be willing to do this.”

— Colleen LaBelle, BSN, RN, Boston Medical Center

- 2. Staffing for administrative activities.** The DEA conducts random site visits to physician offices that have buprenorphine waivers, to ensure that these offices can produce medical records showing dates and amounts of medications prescribed for each patient, and can document that they have not exceeded their maximum number of actively treated patients. These reports can be pulled from the electronic health record.³¹ Some clinics keep separate logs, maintained by a medical assistant or other staff, to ensure that physicians stay within the limit.
- 3. Team-based approach.** One of the benefits of the office-based opioid treatment model is the ability of a clinical care team to develop trusting relationships with patients. Team models enable the clinic, using a variety of practitioners, to provide patients with the wraparound support services they need. Patients new to treatment, or patients with complex needs, often require extensive monitoring to determine appropriate dosing and to ensure that the patient stabilizes. Clinics can designate a nurse care manager, nurse practitioner, physician assistant, social worker, health educator, or other staff member to be the main point of contact and manage the program details, while the physician is responsible for the addiction diagnosis, prescription management, and periodic follow-up visits. Team-based approaches can thus provide a high level of patient support while not overburdening physicians.
- 4. Connection to behavioral health services.** All buprenorphine protocols and guidelines recommend that patients receive behavioral health services as part of their treatment. Counseling, support groups, and 12-step programs are important components of a comprehensive approach to treating substance use

disorder. Many interviewees noted that since some 12-step programs consider MAT to be substance use and discourage it, it is essential to identify programs that support patients in taking buprenorphine. Patients who refuse counseling or who do not have access to such services should not be disqualified from buprenorphine treatment.

- 5. Mentoring support.** Mentoring programs that support providers and improve their confidence in treating opioid use disorders allow clinicians to learn from their peers about treatment approaches, particularly for complex patients. By providing access to expert guidance, these mentoring services promote the use of evidence-based practices, and can improve the scope and strengthen the infrastructure of a primary care practice. Several such virtual programs are available:
 - ▶ **The Clinician Consultation Center Warm Line** (855-300-3595) provides free phone consultations and advice from addiction specialists.
 - ▶ **The Providers’ Clinical Support System (PCSS)-MAT program** is a national mentoring resource designed to match new prescribers with mentors

Rural and Small Clinics

Small clinics and clinics in rural communities may not have the resources to hire additional staff for administrative and programmatic support, but can still incorporate buprenorphine into their practices. Dr. Gary Pace, chief medical officer of Alexander Valley Healthcare, talked about adding a buprenorphine treatment program to his rural community health center:

“It works the best with a nurse manager or behavioral health person who can oversee these things, but it can work in other ways too. Given the state of the world right now, it is an important service to provide, so I would suggest people go ahead with it, even without that kind of support. The staff will need a little training, because bringing these folks into a practice puts a strain on the front desk and the MAs. Also, the provider will benefit from having some sort of mentor [with whom] they can discuss cases that come up.”

to help them incorporate medication-assisted treatment into their practices. The PCSS-MAT website also includes training and clinical resources.

- ▶ **Project ECHO** (Extension for Community Healthcare Outcomes) is a video tele-mentoring program, described on page 20.

“Mentorship and guided practice from specialists allows primary care clinicians to support each other and learn together how to make this work.”

— Miriam Komaromy, MD
Project ECHO, New Mexico

- 6. Two waived doctors per practice.** Having at least two physicians with waivers to prescribe buprenorphine is becoming a recognized best practice for primary care practices using MAT. Because patients on buprenorphine need frequent visits and follow-up, it can be challenging for a single physician to meet the needs of those patients in a timely fashion. Having at least one additional physician who can prescribe, even without taking on a large caseload, can provide needed backup and mitigate one obstacle often cited by physicians, as well as provide on-site peer support.
- 7. Assessment of patient readiness.** Before beginning treatment with buprenorphine, patients should be assessed for their opioid use disorder, the presence of other drugs, and the stage of withdrawal. The assessment should also include the level of support they have from family and friends and their overall readiness for treatment. Experienced practitioners believe the most important criterion is motivation, because adherence is critical.

Most people with opioid use disorder can benefit significantly from buprenorphine and can be seen in an office setting. However, many protocols, including those written by the American Society of Addiction Medicine, note that people with certain conditions — active alcohol use disorders, psychiatric instability, and use of benzodiazepines — may require a higher level of care and monitoring than is usually provided

Incorporating Addiction Treatment into Clinician Training

Medical schools have traditionally not provided new physicians with adequate education or training on addiction or addiction medicine. Even primary care-focused physicians do not graduate with an understanding of how to treat patients with substance use disorders.

To address this need and increase the number of DEA-waivered physicians, Contra Costa County offers SAMHSA-approved DEA waiver courses for residents and staff physicians; in addition, residents can rotate through two of three buprenorphine treatment clinics to prepare them to provide services. Over the last 10 years, these efforts have resulted in 29 primary care physicians, two county jail MDs, and four hospitalists becoming waived, with two physicians achieving the maximum 100-patient capacity. Collectively, they wrote 188 prescriptions during the first nine months of 2015. Nearly 75% of residents who were surveyed following the training indicated that they either already had or would obtain a waiver before graduation.

Similarly, the San Francisco Office-based Buprenorphine Induction Clinic (OBIC) provides educational opportunities for nurse practitioners and for residents in general internal medicine and family medicine. In 2017, OBIC will be part of a new addiction medicine fellowship program at UCSF.

in an office setting.³² For these conditions, methadone maintenance in a licensed opioid treatment program with comprehensive services may be the best choice.

Unfortunately, not all communities have such resources. “If there is no methadone clinic in the region,” said Marwan Haddad, MD, of the Community Health Center in Connecticut, “it may be much safer for the patient to be on buprenorphine than to attempt complete abstinence or to continue to actively use illicit drugs. The clinician should inform the patient of risks and alternatives, document these in the chart, and use buprenorphine with close monitoring if it is deemed in the best interest of the patient.”

- 8. An induction approach that fits.** Most protocols recommend observing patients during the induction process to ensure that the patient properly takes the medication, to monitor effects, and to establish appropriate dosage levels. In some cases, pharmacies have established separate waiting rooms to conduct the observed dosing.

Increasingly, however, physicians have found that patients do not need to be observed and that home induction can be safe and effective, an approach that is supported by the literature and ASAM practice guidelines.^{33,34} The ASAM Guideline Committee recommends that the prescribing physicians or patients should be experienced with buprenorphine to do home-based induction.

“We do both — home and office,” Waller said. “If [they are] emotionally stable and have support at home, then that works. But we also have it in the office. It’s dependent on their biggest anxiety. Induction is really important to get that emotional connection to the medication.”³⁵

- 9. Pharmacists willing to partner.** Many primary care settings do not maintain an on-site pharmacy, although some do keep a small supply of buprenorphine. Primary care practices generally refer their patients to community pharmacies. Nevertheless, developing a deeper relationship with at least one pharmacy is essential, given the importance of being able to fill prescriptions in a timely manner.

“We identify a local independent pharmacy and ask them to stock buprenorphine and work with our population. The main advantage is customer service, so that patients can get their medication in a timely manner. If you go a day or two without, you can induce withdrawal. The relationship also allows for more efficient patient monitoring.”

— Bethany DiPaula, PharmD, BCPP
Howard County Health Department

Tips for Getting Started

The work of early adopters of office-based opioid treatment has resulted in best practices that may help those interested in incorporating buprenorphine treatment into their practice. These tips are based on a review of recent literature and interviews with many leaders.

For physicians

- ▶ Create an appropriate goal for each new physician, allowing them to start slow. For example, start and learn with five patients.
- ▶ Find a mentor or peer support.
- ▶ Enable newly waived physicians to provide backup to experienced physicians before developing their own caseload.
- ▶ Build a team approach, including using support staff to assist with the administrative tasks and patient engagement.
- ▶ Proactively address confidentiality issues by explaining disclosure restrictions and consent requirements at the onset of treatment.
- ▶ Build a relationship with a primary pharmacy (if off-site), and agree upon the venue for induction.

For clinic leaders

- ▶ To the extent feasible, develop a collaborative care model that utilizes allied health professionals as primary points of contact for patients.
- ▶ Provide training for the entire staff to combat stigma and create a climate of acceptance for patients with substance use disorder.
- ▶ Engage administration, the finance department, and the clinical team to develop sustainable ways to cover costs.
- ▶ Incorporate motivational interviewing skills to assess the readiness of the patient to quit or reduce opioid use.
- ▶ Use support groups to help with patient retention.

For pharmacists

- ▶ Build relationships with primary care practices.
- ▶ Observe patients when renewing prescriptions to assess whether the patient presents with concerns, such as signs of alcohol use or being sedated; alert the physician/RN care manager.
- ▶ Assist with drug monitoring; make phone calls to patients and physicians.

For example, insurance issues can delay a pharmacy providing medication. Pharmacists do not always realize they need to send the claim to state Medi-Cal and not to the managed care plan. Pharmacists can also partner with the primary care practice by monitoring patients for obvious signs of substance use, such as the smell of alcohol on a patient's breath, or signs of potential diversion, such as filling multiple opioid medications. Some pharmacies have even set up a separate window to provide privacy during observed dosing.

10. Sustainable financing. Many of the programs reviewed for this research are grant funded. Sustainable financing for buprenorphine is an ongoing concern. Although buprenorphine itself is covered by Medi-Cal, funding for the administrative support, as well as for collaborative care teams, is often harder to come by.

Some early adopters have developed solutions. For example, one clinic runs group sessions for patients with opioid addiction. During the group session,

patients are individually pulled out for a physician visit, during which they receive their next prescription for buprenorphine. Although group sessions are not covered, the clinic can bill for the medical face-to-face encounters.

A similar strategy to ensure reimbursement for team care involves having a nurse or behavioral health provider manage the patient's care, with a physician seeing the patient at the end of the visit to review the treatment plan and write prescriptions.

Another financing approach that several states have pursued is the Health Homes Medicaid state plan option under Section 2703 of the ACA. Under this program, states can receive a 90:10 federal Medicaid match for certain services provided to specified populations. States can establish health home models tailored to individuals with opioid use disorders as a way to develop comprehensive programs that include case management and counseling.³⁶

The Business Case for Office-Based Opioid Therapy

Although the extra staff for providing buprenorphine in primary care clinics may pose initial financial challenges, the OBOT-B clinic in Massachusetts (see page 17) has demonstrated the business case for doing so.

In Massachusetts, a registered nurse (RN) is allowed to bill for an individual medical visit at the same rate as a physician. Assuming the nurse is managing an average of 90 patients at any one time, the FQHC estimates it can generate enough revenue to cover the cost of the nurse care manager, including overhead and administrative costs, and net approximately \$180,000 per full-time NCM.

While FQHCs cannot bill Medi-Cal for nursing visits, clinics have solved this problem through team care. Petaluma Health Center (PHC) has three full-time nurses covering three provider teams (each team has three full-

time equivalents, or FTEs, of primary care providers). The nurse independently sees patients for management of wounds, anticoagulation, medication reconciliation, and complex care, as well as performing triage and medication refill duties. Each RN visit concludes with a brief face-to-face visit with a primary care provider to review and reinforce the patient's care plan, and to allow the visit to be billed to Medi-Cal.

The clinic estimates that this system grosses \$800,000 in Medi-Cal revenue, and nets the clinic at least \$250,000 annually, after accounting for one clinician FTE and three nurse salaries. PHC also estimates that about \$100,000 in annual incentive bonus income (from the Medi-Cal plan's pay-for-performance program) is credited to the nurses' role in improving performance in quality measures for the clinic.

Sources: LaBelle, Colleen T., *Role of OBOT Nurse Care Manager in Federally Qualified Health Centers, Providers' Clinical Support System*, pcssmat.org (PDF). Massachusetts Department of Public Health Bureau of Substance Abuse Services 2010 cost modeling report. Correspondence with Petaluma Health Center staff. Communication with Petaluma Health Center administration, February 2016.

Model Programs and Approaches

While the medical community generally recognizes the importance of increasing access to buprenorphine treatment for patients with opioid addiction, regulatory and practical barriers prevent many practices from adopting this treatment as part of general primary care. This section describes successful programs and strategies used by practices around the country that can serve as models for new programs. Each model illustrates solutions to core challenges: (1) managing inductions (separate versus integrated models), (2) distributing work (varying approaches to team care), and (3) expanding primary care skill sets (programs to provide mentoring and support).

Managing Inductions: Separate Clinics, Integrated Models, and Emergency Departments

New patients going through induction (the process of starting buprenorphine treatment) often benefit from personalized education, coaching, and monitoring to ensure a smooth start, and to minimize discomfort from withdrawal symptoms. The induction process can be time-consuming for primary care practices, especially when protocols require frequent patient visits during the first two weeks. To meet the needs of patients being treated with buprenorphine, two primary models have emerged: a freestanding induction clinic, separate from the primary care site, and an integrated model, where buprenorphine induction is built into primary care. Innovative approaches are also being explored, such as collaboration between clinics and residential treatment facilities to offer induction in group visits, and partnering with an emergency department to allow induction in the ED, with close outpatient follow-up.

Buprenorphine induction clinic: **San Francisco Health Network**

Background. The San Francisco Department of Public Health, now called the San Francisco Health Network (SFHN), created the country's first induction clinic in 2003, in response to provider concerns about the time involved in getting patients started on buprenorphine.

San Francisco's Office-based Buprenorphine Induction Clinic (OBIC) is in the same building in which county behavioral health services are offered, providing patients with access to substance use and mental health services, as well as referrals to wraparound services, such as housing and social services. Because OBIC is funded through a contract with SFHN, the clinic sees only safety-net patients — people who reside in the county and are eligible for county-supported health care, including Medi-Cal. Patients can be referred to the clinic from public clinics or community providers, including homeless service providers, or self-refer by walking in for treatment.

Approach. New patients are assessed at an orientation appointment with a nurse practitioner and substance use counselor, which involves a comprehensive health history, including assessment of mental health and substance use. If more intensive services are needed, the patient is referred to care at the appropriate level, such as a methadone clinic or other treatment.

"I really find that the combination of the orientation appointment plus support during the first week are the critical elements to helping patients understand that we want them to succeed."

— Matt Tierney, APRN, San Francisco OBIC

OBIC does not dispense or administer buprenorphine, and therefore does not need to maintain the required records for these functions. Rather, a prescription for the medication is sent downstairs to the behavioral health pharmacy, which has a private window for observed dosing. A specialty pharmacist gives patients their first dose and observes that the medication has been properly dissolved. Although patients are not required to use the SFHN pharmacy, many patients appreciate the support provided and continue to use it. In addition, if the pharmacists have concerns — for example, if a patient appears sedated or intoxicated — they can send the patient upstairs to OBIC for an assessment.

Patients return every day during the first week for observed dosing. Providers develop a specific care plan for each patient. After the first week, patients may come

in every two to three days and obtain a prescription for buprenorphine, which they can take at home. Once an appropriate dose of buprenorphine is achieved and the patient is determined to be stable, that patient's ongoing care is transferred to a primary care clinician or psychiatrist, who continues to manage the prescriptions. The transition time can vary but typically takes from 6 to 10 weeks, depending on the direction from the primary care provider: Some providers want to see the patient after one week; others prefer a longer transition period.

Staffing. The clinic staff includes the following:

- ▶ 2 FTE nurse practitioners
- ▶ 0.5 FTE physician/medical director
- ▶ 1 FTE state-certified substance use counselor
- ▶ 1 FTE administrative assistant

In 2015, the clinic hired a full-time analyst to help the clinic participate in the new Drug Medi-Cal waiver and to bill Medi-Cal for its services.

Results. The clinic maintains a census of 30 to 40 patients, induces an average of 10 to 12 new patients a month, and provides an average of 147 clinical encounters a month. Approximately 43% of patients are successfully transferred to primary care providers, 11% are referred to methadone clinics or other more intensive resources, and 19% drop out during the induction process. The OBIC has initiated treatment for well over 1,300 patients since its inception, and most patients presenting for treatment are seen on the same day or provided with an appointment.

Integration of buprenorphine within a primary care clinic: HealthRIGHT 360

Background. HealthRIGHT 360 is a family of integrated health programs that provides care and treatment to over 27,000 people a year in 11 California counties. Formed from the merger of Walden House, a residential drug treatment facility, and the Haight Ashbury Free clinic in 2011, HealthRIGHT 360 offers a variety of primary care, mental health, and substance use treatment programs.

Approach. The clinic does not operate a separate buprenorphine program; rather, buprenorphine treatment is fully integrated into the primary care practice. Because safety-net patients often have complicated

medical issues, treating the substance use disorder in the primary care setting enables physicians to manage all of a patient's issues in an integrated and holistic way.

HealthRIGHT 360 providers manage the care of patients on buprenorphine but do not dispense the medication. The clinic works with a local pharmacy, and patients induce (take their medication) at home. Initially, patients receive prescriptions for three days' worth of medication, with careful instructions about how to take the medication and what to expect in terms of symptoms. At each visit, patients take a urine drug test and are assessed to see how the medication is working.

“Every single patient takes it home. I’m not giving them a lot of medication, and I give them proper instructions. When I give them the urine tox test, I’ll see if the buprenorphine is there. So that’s how we monitor.”

— Ako Jacintho, MD, HealthRIGHT 360

Staffing. When HealthRIGHT 360 began its buprenorphine service in 2011, it made two critical staffing changes to ensure full integration of the new program into the primary care practice. First, the clinic designated a medical assistant to keep a log of each physician's patients to comply with the federal caps: 30 patients in the first year of the waiver, and 100 after one year.

Next, the clinic changed its schedule to accommodate frequent visits and drop-ins by its buprenorphine patients. In the first week of treatment, physicians see their patients daily, since many are homeless or have other complex medical and social needs. A typical clinic schedule, in which patients are booked every 15 minutes, is not flexible enough to manage drop-ins or frequent return visits. With the revised schedule, physicians are booked with two patients per hour for 15 minutes each, with the remaining half hour reserved for drop-ins and patient consultations that require a longer visit.

This scheduling approach allows the clinic to better meet patient needs without lowering productivity. When fully staffed, HealthRIGHT 360 will have seven waived physicians across three primary care clinics. Physicians often

see the same number of patients in a day as they did before the schedule change, even though they are only prescheduled with half that number. Although the clinic designed this scheduling system to address the challenges of treating buprenorphine patients, it is used throughout the clinic, even with nurse practitioners and physician assistants. The drop-in slots allow the clinic to serve its many homeless patients and others who have difficulty scheduling and keeping appointments.

Results. HealthRIGHT 360 reports that about 60% of patients who start buprenorphine continue treatment. As with the treatment of any chronic disease, some patients relapse, and success is defined as staying in or returning to treatment. Many patients continue with buprenorphine for many years. The strong and trusted relationship with their primary care provider helps patients recognize their addiction and motivates them to want to treat it. Physicians are inspired by witnessing the progress of their patients over the long term — seeing people with addiction lead more stable lives — and by knowing that they are actively preventing overdose deaths.

Community Health Center: Another Integration Success Story

Findings from HealthRIGHT 360 are consistent with other primary care practices, such as Community Health Center of Middletown, Connecticut, which has also integrated buprenorphine into the FQHC's primary care practice. The clinic has experienced retention rates of approximately 60%, as well as improved health outcomes for comorbid medical conditions. The program has been so successful that Community Health Center now runs a buprenorphine tele-mentoring program, Project ECHO, where clinicians around the country receive twice-monthly coaching and case review through live video feeds in a group discussion (see page 21).

Inductions in group visits, residential programs, and the emergency department: Contra Costa County

The Contra Costa County buprenorphine clinic holds treatment groups three times a week. Patients fill their first dose at the on-site pharmacy, and take their pill at the beginning of the group visit, so the physician can monitor the process. Patients going through induction

benefit from the support and reassurance they receive from other patients.

Patients in detoxification and residential programs who are appropriate for buprenorphine therapy can be induced either in the buprenorphine clinic or in the local emergency department (ED) after their program intake. An emergency physician administers the first dose, observes the patient, and then discharges that patient back to the treatment program. The patients receive ongoing prescriptions through the buprenorphine clinic.

The DATA 2000 regulations include an exemption that allows unwaivered physicians to administer, but not prescribe, buprenorphine for up to 72 hours to facilitate a patient entering a treatment program. If ED staff are trained and willing, and have relationships to ensure prompt referral for ongoing care, the ED can become an entry point for addiction treatment. A randomized study from Yale found that 78% of patients given buprenorphine in the ED were still engaged in treatment 30 days later, compared to 37% of those offered a standard treatment referral.³⁷ Buprenorphine induction in the ED requires a new mind-set: If physicians and staff consider addiction an uncontrolled chronic disease that can be acutely stabilized in the ED and then handed off for outpatient management, the ED could be a patient-centered access point for people unable to find service any other way.

Distributing Work: Varying Approaches to Team Care

Team approaches can make it easier for busy physicians to take on the care of patients with opioid use disorder. A variety of practitioners can be involved, including nurse care managers, clinical pharmacists, and social workers. Models that share care between physicians and other disciplines are described below.

Nurse-run buprenorphine clinics: Boston Medical Center

Background. In 2003, Boston Medical Center (BMC), an inner-city academic medical center, started one of the first office-based opioid treatment (OBOT) programs in the country, in direct response to the high demand for buprenorphine treatment. Early support for the program was provided by the Massachusetts Department of Public Health, Bureau of Substance Use Services. To encourage the spread of OBOT, Massachusetts provided funding to

any interested Federally Qualified Health Center (FQHC) within the state to cover the cost of a nurse care manager. In addition, BMC provides in-depth on-site and off-site technical assistance and staff training on all aspects of implementing OBOT, including how to bill for services to become self-sustaining, and supports a learning community for participating clinics. To date, OBOT has been implemented in 19 funded health centers throughout the state, and 9 additional health centers that don't receive state funding for the nurse are also supported with technical assistance.

“Physicians have been more than willing to take this on with the support of the nurse care managers in these settings.”

— Colleen LaBelle, RN
Boston Medical Center

Approach. The BMC OBOT approach is based on a team care model. Physicians are responsible for writing buprenorphine prescriptions, while nurse care managers (NCMs) oversee the care of patients from orientation and induction through maintenance and ongoing care. The treatment model includes three stages³⁸:

1. Phone screening followed by in-depth intake evaluations and assessment by the NCM, followed by a brief physician visit to confirm the diagnosis of opioid use disorder and appropriateness for OBOT or referral to other options
2. NCM-managed education, induction, and stabilization
3. Maintenance or discharge (voluntary or involuntary)

Most inductions are done in the clinic setting so that the NCM can be certain that the medication is being taken correctly. After an hour, if all is proceeding well, patients take the second dose and leave. Patients can pick up the remainder of a week's supply of the medication from the pharmacy and are instructed on how to take the medications at home. The patient checks in with the NCM by phone the afternoon of the induction, as well as the following morning and as needed. The NCM contacts a physician with any issues, and notes are entered in the electronic medical record and routed to the waived provider. The patient returns the following week for a follow-up visit with the NCM. At this point, the nurse

assesses the patient and provides additional education, and the waived physician prescribes a one-week supply of the medication. Prescriptions can then be extended to every other week, usually after four to six weeks, and eventually to monthly, after the patient demonstrates three months of adherence. Ongoing monitoring for drug use occurs during the maintenance period along with counseling. If needed, the visit frequency can be increased or decreased based on the team's assessment and patient needs. The NCM generally sees 75 patients per week, including inductions.

For the first three months, all patients are required to participate in behavioral health counseling; these services are offered on-site and off-site. After the first three months, patients are encouraged to continue behavioral health counseling and participate in support services that are available on-site and embedded in primary care clinics. The BMC clinic has access to a psychiatrist for medications and consultation, and all NCMs are certified in addiction. Patients are also encouraged, but not required, to participate in a 12-step group. If patients don't engage in counseling, the team will maintain weekly visits and try to book counseling around scheduled follow-up.

Billing for Nursing Care in California

In Massachusetts, unlike California, nurses are Medicaid providers and can bill for independent patient services. In California, Medi-Cal will only reimburse visits by certain provider types (e.g., physicians, physician assistants, nurse practitioners, psychologists, and licensed social workers). Clinics where nurses work independently often use a team billing model, where a physician or other Medi-Cal provider sees the patient after an in-depth nurse visit. The nurse component of the visit is not reimbursed, but the licensed clinician can bill Medi-Cal for a face-to-face brief visit (e.g., codes 99212 or 99213). Because the clinician can work this visit into an otherwise busy schedule, the increased clinician productivity can cover the cost of the nurse clinics (for more on the economics of this approach, see the box on page 14).

See the California Health Care Foundation publication *RN Role Reimagined: How Empowering Registered Nurses Can Improve Primary Care*, for more details.

Staffing. BMC program staff includes the following:

- ▶ 0.20 FTE nurse program director, who supervises the NCMs and program coordinator, and integrates care with OBOT physicians
- ▶ 4 FTE NCMs at a ratio of 1 per approximately 150 patients
- ▶ 1 FTE medical assistant
- ▶ 1 FTE program coordinator, who collects standardized intake information for people requesting OBOT
- ▶ 14 physicians who see OBOT patients as part of their practice every three to four months or more frequently if medically necessary

New NCMs participate in a one-day buprenorphine training program on addiction. Then, they go to BMC

and shadow nurses in the clinic for hands-on experience with patient care roles, including assessing and educating patients, obtaining informed consent, developing treatment plans, overseeing medication management, referring to other addiction treatment, monitoring for treatment adherence, and communicating with prescribing physicians, addiction counselors, and pharmacists.

Physicians authorize multiple buprenorphine refills, with the understanding that the pharmacist or nurse care manager may cancel the refill if the patient is not adhering to program requirements. The OBOT physicians review the NCM assessments, including blood work, and routine and random urine drug screening; perform physical examinations; and prescribe buprenorphine. Physicians follow up with patients at least every three to four months or more frequently, depending on the complexity of the patient, and the NCM provides care in the interim.

Pharmacist-Physician Collaborative Care Model

Office-based opioid treatment team models can involve a variety of allied health professionals. One innovative approach incorporates a clinical pharmacist to oversee medication management. Managing this patient population can be very time intensive. Clinical pharmacists can assist in monitoring and patient follow-up, which can also reduce the risk of drug diversion (transfer of the legally prescribed medication to another person for illicit use), as they can observe dosing in the first week of the program, when patients are at highest risk of leaving the program. As with other models, substance use counselors are also part of the care team.

The results of a pilot physician-pharmacist collaborative practice for buprenorphine in Columbia, Maryland, found a 73% retention rate after one year. Before this program was implemented in Maryland, the health department outsourced medication-assisted treatment services. The health department determined that it saved \$22,000 by providing direct patient care through the pilot collaborative.

A similar model will be launched in 2016 at the TRUST clinic in downtown Oakland, a clinic designed for high-risk patients who are homeless or at risk of becoming homeless. At this clinic, primary care is offered by two teams currently managed by a physician and a nurse practitioner. Each primary care provider is responsible for assessing new patients and referring them to the pharmacist program when appropriate.

The pharmacist, whose time has been donated by Alameda County Behavioral Health Care Services, works on-site one day a week and will handle all assessments, inductions, and buprenorphine stabilization visits until the patients are ready to continue maintenance therapy with their TRUST primary care provider. Inductions will take place either in clinic or at the patient's home, and the pharmacist will be available by phone to answer patients' questions. The primary care physician or psychiatrist will be responsible for confirming the diagnosis, assuring that the treatment is appropriate, and writing buprenorphine prescriptions and refills. Since buprenorphine is a Schedule III drug, special prescription forms are not necessary, and refills can be called in by the primary care provider when needed.

Since California's Medi-Cal program currently does not reimburse pharmacist visits, the TRUST clinic is reliant on Mental Health Services Act grants, and donations of time and services. California's proposed Alternative Payment Model, if implemented, would allow FQHCs like the TRUST clinic to manage all patient needs on a monthly global capitated payment. This new payment model would provide clinics with sustainable funds to cover care teams that include non-billable providers, such as pharmacists and nurses, as well as to cover phone and email visits.

Results. Between 2007 and 2013, 19 community health centers (CHCs) were enrolled in the OBOT program at BMC. As of 2013, 67% of the patients receiving buprenorphine across all sites were in treatment for more than 12 months, which represents a steady increase over the prior three years (32%, 56%, and 65% staying in treatment in 2010, 2011, and 2012, respectively).³⁹

In addition, the number of patients served increased from 178 in the last five months of the first calendar year of the program (2007) to 1,210 in 2012, the last full year of complete data availability. Finally, the number of waived physicians in the grant-supported CHCs increased from the initial 24 to 114 three years later.

Expanding Primary Care Provider Skill Sets: Mentoring and Support

Experts and buprenorphine providers believe that mentoring and peer support for primary care physicians are critical elements to a successful program. For clinics without local experts, remote phone or video mentoring can help new providers solve problems and answer clinical questions. Another option is the hub-and-spoke model, which triages patients and directs complex patients to the hub (often an established opioid treatment program with addiction specialists), while less complex patients can be managed at spokes (often primary care practices). Primary care providers can turn to the hub specialists to help with clinical questions, and patients can go through their inductions at hubs and be referred to spokes for maintenance.

Other options, not profiled in this paper, include the [Clinician Consultation Warm Line](#) (855-300-3595), which provides free phone consultations and advice from addiction specialists, and the [Providers' Clinical Support System-MAT program](#), which provides clinical and training resources, and links physicians with mentors. California mentors report that this service is underutilized, despite availability of willing specialists.

Tele-mentoring technology: Project ECHO, New Mexico

Background. Project ECHO (Extension for Community Healthcare Outcomes) is a tele-mentoring, collaborative model of medical education and care management. Unlike telemedicine services, the ECHO model does not provide care directly to patients. Rather, it provides to

frontline clinicians, especially those in rural and underserved areas, with knowledge and support to manage patients with complex conditions.

ECHO brings a specialist (or specialty team) together by video teleconference with a dozen or more primary care providers at different sites, usually once a week for many months. These teleconferences involve didactic sessions and case reviews, creating a continuous learning system that builds primary care skills until the provider can manage complex cases with no (or little) support.⁴⁰ Two noteworthy Project ECHO models have emerged that provide mentoring support to physicians treating patients with buprenorphine.

“Our mission is to democratize medical knowledge and get best practice care to underserved people all over the world.”

— Miriam Komaromy, MD
University of New Mexico

Approach. The University of New Mexico (UNM) launched Project ECHO in 2003, and the ECHO model is now used to assist clinicians with the treatment of nearly 40 health conditions. In late 2005, UNM developed an Integrated Addiction and Psychiatry (IAP) teleECHO Clinic to expand patient access to medical and behavioral treatment for addiction and mental illness in communities throughout New Mexico; a specific buprenorphine module is included as part of this clinic.

The IAP teleECHO Clinic follows the same basic structure of all Project ECHO initiatives: Primary care teams participate in case-based learning that includes a mix of didactic presentations and review of actual cases using de-identified patient information. The clinics are supported by free, widely available teleconferencing technology.⁴¹ During IAP weekly teleECHO clinic sessions, many of which focus on treatment of opioid use disorder with buprenorphine, primary care clinicians from multiple sites present patient cases to the specialist teams and to each other, discuss new developments relating to their patients, receive feedback and recommendations from the specialists, and determine treatment. Prior to the case presentations, the specialist team from UNM leads a 20- to 30-minute lecture on a particular mental health

and substance use issue, covering a defined curriculum. Informal email and phone consultation with the UNM specialists is available between sessions. Participation is free, since the program is grant funded, and participants may receive CME and CEU credits.

Staffing. IAP teleECHO is staffed by a multidisciplinary team of experts from UNM, which includes psychiatrists, addiction specialists, nurses, counselors, and community health workers.

Results. The IAP teleEcho Clinic has been successfully operating for 11 years, providing over 10,000 hours of no-cost CME credits to clinical teams. New Mexico has seen a dramatic increase in the number of physicians with buprenorphine waivers. From 2006 to 2014, the clinic conducted 20 six-month ECHO sessions for 375 physicians, 135 mid-level providers, and 259 support staff members, and New Mexico now has, on a per capita basis, the fourth-highest number of buprenorphine-waivered physicians in the US.⁴²

Tele-mentoring technology: **Project ECHO, Connecticut**

Background. The Connecticut version of Project ECHO is a program of the Weitzman Institute, a nonprofit research institute embedded within Community Health Center (CHC), the largest FQHC in Connecticut. CHC operates in 13 cities and over 200 service locations across the state, delivering care to more than 130,000 patients.⁴³ To address the gap between supply and demand for MAT across the country, CHC adapted the highly successful Project ECHO model from UNM and now offers an ECHO buprenorphine and ECHO pain management program to FQHCs and other safety-net providers in several states. Unlike Project ECHO UNM, CHC's Project ECHO is not affiliated with a university; instead, it relies on a robust network of specialists, some internal and others from partner organizations across the country. It is the only FQHC to operate its own Project ECHO.

Approach. The CHC Project ECHO uses a cloud-based videoconferencing system that is user-friendly, secure, and HIPAA-compliant. Participants can connect via computer, smartphone, or tablet computer, and no additional infrastructure is required. Each session lasts two hours and includes a 20-minute didactic presentation by a member of the faculty, followed by preselected case presentations. The faculty reviews and discusses the cases

with the presenting primary care provider, raises key issues, answers clinical questions, and generalizes findings to other situations. The participating primary care providers supply the patient cases for discussion prior to each meeting.

The ECHO pain management team meets every two weeks, and the ECHO buprenorphine team meets monthly. These meetings focus on protocols for dispensing buprenorphine, and on the systems and support needed to put a buprenorphine or pain management program into practice. For Project ECHO pain, offline support is available from other ECHO participants and faculty to participating clinics and providers between calls through the collaborative website PainNet.net, launched in 2015. PainNet archives ECHO video sessions, provides a forum to ask and answer questions, and posts advice that is visible to all clinics participating in CHC's ECHO programs.

“MAT is best provided using a team approach. You have to take stock of your resources and realize you don't have to do it on your own as a doctor. Support leads to greater provider and patient satisfaction.”

— Marwan Haddad, MD
Community Health Center, Connecticut

Staffing. CHC's Project ECHO provides the expert faculty, which consists of four to six experts from a variety of disciplines. The faculty includes primary care physicians, experts in addiction medicine, substance use counselors, and social workers. Faculty are from CHC's own staff as well as from a pain clinic in Arizona.

Results. CHC's Project ECHO has grown tremendously in the past three years and has served over 140 clinic sites in 19 states on the following subjects: pain, buprenorphine, HIV, hepatitis C, and pediatric and adolescent behavioral health. It is supported by a wide range of grants and state Medicaid agencies, as well as, on occasion, participant fees. In September 2015, CHC developed a customized project for Maine Quality Counts on buprenorphine and pain management, and received funding from SAMHSA-HRSA Center for Integrated Health Solutions to pilot a mentoring program for medical providers and their teams at FQHCs across the country.

Hub-and-spoke model: Vermont

Background. Before the Affordable Care Act was enacted, Vermont launched an ambitious effort to reform its health care delivery system. Vermont's Blueprint for Health guides this transformation effort in a coordinated manner at the state, regional, and local levels. The cornerstone of the Blueprint model is the patient-centered medical home (PCMH) and multidisciplinary support services in the form of community health teams. These teams consist of nurses, social workers, and community health workers who are collectively funded by health care payers.

Vermont's model for providing MAT to individuals with opioid use disorder is built on the health care infrastructure created by the Vermont Blueprint for Health and the state's network of independent opioid treatment programs (OTPs), otherwise known as methadone clinics. As is the case in most states, OTP programs in Vermont have operated independently of the health care system for many years, as they have historically been stigmatized by the traditional health care system. When buprenorphine became available, many physician practices and clinics — from FQHCs to obstetricians — began prescribing it, but seldom in connection to behavioral health or other support services, important best practices for buprenorphine treatment.

Approach. With a focus on developing PCMHs under its Blueprint for Health, Vermont sought to better integrate the different providers involved into a more cohesive and coordinated system. The health homes option of the Affordable Care Act (Section 2703) provided Vermont with the opportunity to implement such a system. Section 2703 enables states to develop integrated and coordinated systems of care for populations with multiple chronic diseases or a mental illness, with 90% of the costs supported by the federal government for the first two years of operation.

Vermont developed a health home specifically for medication-assisted treatment of opioid use disorder. The program uses a hub-and-spoke model, with OTPs being designated as regional hubs, and physician offices functioning as the spokes.

OTP hubs conduct the initial assessment of patients to determine whether they are appropriate candidates for methadone or buprenorphine and in what setting,

using a standardized Treatment Need Questionnaire.⁴⁶ Patients are sometimes evaluated at a general medical practice. OTP hubs will then induce the patient onto either buprenorphine or methadone. If using buprenorphine, the hubs will continually assess the patients and, once stabilized, transfer them to the most convenient spoke. The spokes — clinics and physician offices — are designed to provide buprenorphine to patients with less complex addiction conditions, and maintain patients on buprenorphine once they are induced and stabilized by the hub. Hubs also provide prescribing physicians with a structured program to which they can refer patients who fail to thrive in the office-based setting. Finally, hubs provide spokes with consultation and a mentorship relationship with a specialist.

“Part of the problem in getting physicians to use this medication is fear of the patient population — they justifiably don't want to be out on an island without sufficient resources to manage complex cases. If you have a hub that they can refer a patient back to, it gives them reassurance. The hub provides a structured program and peer support for prescribers.”

— Jason Kletter, PhD, Bay Area Addiction Research and Treatment (BAART) Programs

Staffing. To become a hub, an OTP must dispense methadone and buprenorphine and provide services required under the health home program, such as care coordination and transitions of care. In addition, the program must have consulting psychiatry personnel available. At a minimum, hub staff also includes a program director, an RN, a master's-level licensed clinician, and a cadre of counselors who provide counseling and case management to assist patients with social services and mental health needs.

The spoke practices receive additional staffing support: For every 100 active Medicaid beneficiaries receiving MAT, the spoke practices are provided with one RN and

Technology-Enabled Solutions to Increase Access to Treatment

An estimated 80% of people with opioid use disorder do not have access to treatment, and technology solutions are emerging to address the gap.⁴⁴

An electronic medication dispenser allows controlled release of daily doses and can be combined with interactive voice response phone technology and automated reminders to increase access to patients while decreasing demands on staff.⁴⁵ A small pilot study in Vermont showed similar retention rates and opioid abstinence scores compared to usual care, with far fewer office visits. Another product adds cloud-based monitoring and access to remote physicians or pharmacists, allowing patients to receive treatment while hundreds of miles away from the closest treatment center. While not yet widespread, these solutions hold promise for rural counties without sufficient local resources.

one addiction counselor or case manager assigned to it, paid for by Vermont's Medicaid program. These staff members are organized out of the Blueprint community health teams and are deployed to work directly in the practices under the supervision of the MAT prescriber.

Results. As of December 2014, 4,436 patients were receiving MAT — 2,464 in hubs and 1,972 in spokes.⁴⁷ As of the fourth quarter of 2015, there was a 30% increase in physicians prescribing and a 15% increase in physicians prescribing to more than 10 patients, thus significantly increasing the options for patients seeking MAT.

Hubs receive a monthly bundled rate of \$493 per member. (Only 30% of the rate is specific to health homes; thus, only 30% of the hub payment is matched at the 90% federal financial participation rate, or approximately \$148 per member per month.) The local Blueprint administrative entities receive monthly payments from Medicaid to hire and deploy the RN and licensed addiction/mental health counselor to the participating practices. Spokes receive a payment of \$106 per member per month.

Although all of the programs have exhausted the two years of enhanced federal funding, the state of Vermont has agreed to continue the program indefinitely at the regular Medicaid match rate.

Conclusion

With the opioid epidemic continuing to needlessly claim lives, there is growing urgency to expand access to treatment that works, such as buprenorphine. People with opioid use disorder can get this kind of help from their primary care physicians; however, not enough physicians are available to meet the need. A concerted effort is needed to encourage more physicians, particularly those who serve the Medi-Cal population, to provide the service.

The increased use of buprenorphine is also helping to change the way addiction is perceived by the medical community. Opioid use disorder is a chronic, relapsing disease. Similar to diabetes, if people stay on their medication and make the necessary lifestyle changes, their health and lives can improve tremendously. But they also sometimes relapse — more often than not, when they stop taking their medication. With a trusting provider-patient relationship, they can get back on treatment and the path to recovery.

Treating opioid use disorder in a primary care setting also enables physicians to treat addiction in the context of patients' overall health and to address all of their health care needs in a comprehensive and integrated way — a key tenet of patient-centered care.

Finally, investments in MAT and substance use treatment will pay off over the long run. According to a 2005 analysis that tracked methadone patients from age 18 to 60 and included such variables as the costs of treatment, criminal behavior, employment, and health care utilization, every dollar spent on methadone treatment yields \$38 in related economic benefits — seven times more than previously thought.⁴⁸ Relatedly, a study of the California law that allowed qualified drug offenders to enter treatment rather than jail found that the law saved the state close to \$100 million in its first year, allowing it to spend on average \$2,300 less per person than without the law.

Recent policy developments from the ACA to the Drug Medi-Cal waiver, coupled with a strong evidence base for the effectiveness of buprenorphine, are building a strong case for aggressive action to combat the current opioid epidemic. According to Michael Botticelli, director of the US Office of National Drug Control Policy, "There has never been a better time to confront the addiction problem we have in this country."⁴⁹ There has also never been a greater imperative to do so.

Appendix A. Medication-Assisted Treatment for Opioid Addiction: Major Characteristics

	METHADONE	BUPRENORPHINE BUPRENORPHINE/NALOXONE	NALTREXONE
Brand name(s)	Dolophine, Methadose	Suboxone, Subutex, Zubsolv, Belbuca	ReVia (oral), Vivitrol (intramuscular)
Effectiveness rates, defined as retention in treatment*	63% (range: 54% to 71%)	52% (range: 40% to 65%)	28% (range: 16% to 30%) Oral naltrexone not effective in opioid addiction†; no long-term studies on injectable naltrexone
Availability	Only from federally regulated treatment centers	From primary care providers, if they obtain a waiver from the federal government; also at treatment centers	From primary care providers; no special license or training is needed; also at treatment centers
Timing of induction / first dose	Can be taken at the start of recovery	First dose should not be taken before a patient experiences mild to moderate withdrawal	Patient must be off of all opioids for at least 7 to 10 days
Dosage frequency	Daily (usually observed)	Daily (can be given a month's supply)	Daily for oral; injectable lasts 30 days
Effects	<ul style="list-style-type: none"> ▶ Suppresses opioid withdrawal ▶ Reduces cravings ▶ Induces tolerance, which protects against overdose 	<ul style="list-style-type: none"> ▶ Suppresses opioid withdrawal ▶ Reduces cravings ▶ Induces tolerance, which protects against overdose 	<ul style="list-style-type: none"> ▶ Prevents a high if opioids are taken ▶ Does not suppress withdrawal or cravings ▶ Reverses tolerance, which may increase risk for overdose
Mechanism of action	Full opioid agonist (fully activates receptors)	Opioid partial agonist (activates receptors to relieve pain and withdrawal symptoms; does not cause respiratory depression)	Opioid antagonist (blocks receptors)

*Institute for Clinical and Economic Review, page 6, summarizes the Cochrane review of comparative effectiveness (see Appendix C).

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Appendix B. Interviewees

Daren Anderson, MD
Community Health Center of Middletown, Connecticut

Bethany DiPaula, PharmD, BCPP
University of Maryland and Howard County
Health Department

James J. Gasper, PharmD, BCPP
California Department of Health Care Services

Marwan Haddad, MD
Community Health Center, Connecticut

Willard Hunter, MD
Open Door Community Health Center

Ako Jacintho, MD
HealthRIGHT 360

Jason Kletter, PhD
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Judith Martin, MD
Substance Use Services
San Francisco Department of Public Health

Kathy Moses, MPH
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Ken Saffier, MD
Contra Costa County Regional Medical Center

Beth Tanzman, MSW
Vermont Blueprint for Health

Matt Tierny, APRN
San Francisco Department of Public Health and UCSF

Becky Vaughan
National Council for Behavioral Health

R. Corey Waller, MD
Center for Integrative Medicine
Spectrum Health Medical Group, Michigan

With further input from:

David Kan, MD
California Society of Addiction Medicine

Gary Pace, MD
Alexander Valley Healthcare

Thomas Renfree
County Behavioral Health Directors Association
of California

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Education, Protocols, Tool Kits, and Mentorship

The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, American Society of Addiction Medicine (May 27, 2015), www.asam.org (PDF).

American Society of Addiction Medicine and California Society of Addiction Medicine websites contain educational opportunities, training materials and resources, research, guidelines, etc., www.asam.org and www.csam-asam.org.

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Substance Abuse and Mental Health Services Administration website contains comprehensive resources and a treatment locator where patients can find buprenorphine-waivered physicians in their area, www.samhsa.gov.

The Clinician Consultation Center Warm Line (855-300-3595) provides free phone consultations and advice from addiction specialists, nccc.ucsf.edu.

Project ECHO provides remote tele-mentoring providing education, support, and guidance for clinics starting buprenorphine programs, quality.chc1.com/echo.

Providers' Clinical Support System for Medication Assisted Treatment website offers comprehensive MAT training resources and connections to mentors for providers new to buprenorphine, www.pcssmat.org.

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