California Health Care Foundation

Why Health Plans Should Go to the "MAT" in the Fight Against Opioid Addiction

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About the Authors

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About the Foundation

The California Health Care Foundation is dedicated to advancing meaningful, measurable improvements in the way the health care delivery system provides care to the people of California, particularly those with low incomes and those whose needs are not well served by the status quo. We work to ensure that people have access to the care they need, when they need it, at a price they can afford.

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What

The opioid epidemic in the United States continues to be an urgent health and social crisis. In 2015, the nation saw more than 33,000 opioid-related deaths, correlating with a fourfold increase in opioid prescribing over the last 15 years, the increasing availability (and lower costs) of street heroin and fentanyl, and the ongoing dearth of addiction treatment resources.[1,2] Prescription opioid misuse, addiction, and overdose cost the US over $78 billion annually in health care, criminal justice, and lost productivity.[3]

Why

While the epidemic requires a coordinated response from government and policymakers, law enforcement, and health care, health plans have a uniquely influential role. Along with community partners, health plans can influence opioid prescribing across large geographies through comparative data, provider educational campaigns, practice guidelines, formulary and utilization policies, and value-based payment. Plans can assess network adequacy and expand their networks to ensure better access to addiction and pain treatment, and can incentivize integration of behavioral health services. Plans have a strong business case for building better access to addiction treatment regardless of whether or not substance use disorders are the financial responsibility of the plan. Streamlining access to medication-assisted treatment (MAT — prescription medication combined with behavioral health) has been shown to lower emergency department and hospitalization costs,[4] lower hepatitis C and HIV rates, and decrease overdose deaths.

This report was commissioned for a health plan audience and aims to make the case for commercial and public plans to take action and make better access to MAT a top health plan priority, as part of a broader initiative aimed at lowering opioid-related morbidity and mortality.

How

The literature review and interviews with health plan leaders indicate that plans are working to increase treatment access through multiple coordinated approaches:

- **Pharmacy benefit:**
  - Changing formularies to promote safer opioid prescribing
  - Eliminating prior authorization requirements and copays for MAT and naloxone
  - Starting lock-in programs
  - Incentivizing or training local pharmacies to furnish naloxone without a prescription
- **Provider network:**
  - Assessing opioid use disorder prevalence and ensuring sufficient MAT access in all regions
  - Promoting new MAT access points in primary care, emergency departments, inpatient settings, and the justice system through supporting trainings, increased reimbursement, pay-for-performance (P4P) programs, or grants
  - Contracting with telehealth providers
  - Training providers to offer co-prescriptions of naloxone
  - Incentivizing behavioral health integration through P4P or direct grants
  - Working to increase access to MAT for pregnant women
  - Working with hospitals to ensure evidence-based treatment of neonatal abstinence syndrome
- **Medical management:**
  - Providing data analytics to identify patients at risk for addiction
  - Training case managers to guide members to treatment
  - Starting care management programs for addiction
  - Notifying prescribers of emergency department and hospital overdose admissions

- Supporting peer navigators in emergency departments
- Minimizing copays for addiction treatment (medications, prescriber visits, and behavioral health)

- **Data analytics:**
- Creating dashboards to measure progress on opioid prescribing and MAT access, and sharing them with providers and delegated medical groups
- Identifying outlier prescribers to provide education and, when appropriate, refer for fraud
- Identifying outlier members to refer to case management

- **Community engagement:**
- Working with local opioid safety coalitions to adopt community prescribing guidelines and ensure adequate access to MAT and naloxone
- Over 35 of California's 58 counties have active opioid safety coalitions; see www.chcf.org/oscn

"We don't require diabetics to prove they are attending nutrition visits… for their insurance to cover insulin — a medicine that is deadly in overdose. However, insurance companies frequently cut patients off treatment if we don't submit detailed clinical records proving attendance at counseling, and drug screens showing perfect compliance — something we don't see or expect in any other chronic disease."

— David Kan, MD, President, CSAM

Why Health Plans Should Go to the "MAT" in the Fight Against Opioid Addiction

The opioid epidemic in the United States continues to be an urgent health and social crisis. In 2015, the nation saw more than 33,000 opioid-related deaths, correlating with a fourfold increase in opioid prescribing over the last 15 years, the increasing availability (and lower costs) of street heroin and fentanyl, and the ongoing dearth of addiction treatment resources.[5,6] Prescription opioid misuse, addiction, and overdose cost the US over $78 billion annually in health care, criminal justice, and lost productivity.[7] The Centers for Disease Control and Prevention (CDC) estimates that the US spends $52.4 billion annually on the nonmedical use of opioids, $55.7 billion on misuse and addiction, and $20.4 billion associated with overdose. In 2012, total outpatient prescription opioid sales were estimated at $9 billion, an increase of 120% from 2002.[8]

While the epidemic requires a coordinated response from government and policymakers, law enforcement, and health care, health plans have a uniquely influential role. Along with community partners, health plans can influence opioid prescribing across large geographies through comparative data, provider educational campaigns, practice guidelines, formulary and utilization policies, and value-based payment. Plans can assess network adequacy and expand their networks to ensure better access to addiction and pain treatment, and can incentivize integration of behavioral health services. Plans have a strong business case for building better access to addiction treatment regardless of whether or not substance use disorders are the financial responsibility of the plan. Streamlining access to medication-assisted treatment (MAT — prescription medication combined with behavioral health) has been shown to lower emergency department and hospitalization costs,[9] lower hepatitis C and HIV rates, and decrease overdose deaths.

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Methods

Health Management Associates reviewed the literature and interviewed health plan leaders to understand current health plan policies and practices, collect data and evidence where available, and explore barriers and opportunities for commercial and public plans to improve access to MAT. The report also reviewed legislative actions affecting plans. This paper builds on the 2016 California Health Care Foundation (CHCF) report *Changing Course: The Role of Health Plans in Curbing the Opioid Epidemic*, which focuses on judicious prescribing practices, improving patient outcomes, addressing overuse, and working with others to increase safety in communities.

What Is MAT?

Modern addiction medicine treats opioid use disorder (OUD) as a chronic disease, since long-term opioid use can permanently change brain chemistry function and, as with other chronic diseases, there is no cure, meaning patients often require long-term management of relapse and remission. Like other chronic diseases, addiction requires both medication and lifestyle changes, and tends to relapse when treatment is unavailable or prematurely discontinued.

MAT is defined by the Substance Abuse and Mental Health Services Administration (SAMHSA) as the use of medications in combination with counseling and behavioral therapies for the treatment of substance use disorders (SUD). Improved access to MAT is one of three federal priorities for curbing the opioid epidemic, along with addressing opioid overprescribing practices and expanding distribution of naloxone, a drug that reverses the effect of opioids, for emergency treatment of an opioid overdose.[10] Without medication treatment, individuals with OUD are at high risk for overdose and death.[11]

The FDA has approved three medications for treatment of OUD: (1) methadone (generic oral and injectable forms, Dolophine or Methadose), (2) buprenorphine (generic sublingual tablets or Probuphine intradermal implant; buprenorphine is often combined with naloxone [available as Suboxone, Zubsolv, Bunavail, or generic sublingual tablets], since the naloxone component can deter misuse), and (3) naltrexone (generic tablets, ReVia, or Vivitrol long-acting injectable form). Methadone is a full opioid receptor agonist, meaning it fully binds to opioid receptors in the brain. Buprenorphine is a partial opioid receptor agonist, meaning it acts on some opioid receptors (those involved with pain, motivation, and cravings), but its moderate activity level limits respiratory suppression, the main cause of overdose death associated with full agonists. Other buprenorphine formulations are FDA-approved for pain but not addiction; more detailed information on buprenorphine is available from CHCF. Methadone and buprenorphine stabilize brain chemistry, thereby reducing or eliminating opioid withdrawal symptoms and cravings, and improving the individual's ability to plan, organize behavior, and participate in recovery.

Naltrexone is a full opioid receptor antagonist, meaning it blocks opioid receptors and prevents their activation, so illicit opioids taken do not produce euphoria. Naloxone, while not a medication for addiction treatment, is commonly prescribed to people with addiction to prevent accidental overdose. Naloxone, when administered in nasal spray or injection, fully displaces all opioids from their receptors. This action restores consciousness and respiration in the case of overdose, while resulting in immediate withdrawal symptoms for patients with opioid dependence. Fentanyl and carfentanyl, increasingly used illicitly, are so potent that multiple doses of naloxone are typically required to restore respiration.

Table 1 shows the medications available, how they work, and how they are provided. (See page 6.)

"A general principle of authorization is it should serve a function of weeding out inappropriate care. Since nearly all the care we reviewed was appropriate, our authorization requirements were adding unnecessary administrative burden on the plan and our providers, and making it more difficult for members to access treatment."

— Health plan leader

Table 1. Medications Used in Addiction Treatment

	WHERE IT CAN BE PROVIDED	FDA INDICATIONS	EFFECTIVENESS*	ADMINISTRATION
Methadone	**OUD.** Licensed opioid treatment programs. **Pain.** Any Drug Enforcement Agency (DEA)-licensed prescriber.	OUD and pain management	74% to 80%[12]	**OUD.** Daily pill, liquid, and wafer forms; injectable form in hospitalized patients unable to take oral medications **Pain.** Pill and injectable forms
Buprenorphine and buprenorphine/naloxone	Prescribed by community physicians and dispensed by pharmacies; available in some opioid treatment programs. Physicians receive federal waivers after eight hours of training; nurse practitioners and physician assistants require 24 hours. Patient panels are capped at 30, 100, and 275 per provider (depending on experience and setting).[13-15] Any DEA-licensed provider can prescribe buprenorphine for pain.	OUD and pain management (depending on formulation and dose)	60% to 90%[16]	**OUD.** Daily sublingual, buccal, film, and tablet, or six-month intradermal device **Pain.** Injectable, transdermal, and buccal film
Naltrexone	No restrictions.	Opioid and alcohol use disorders	**OUD.** 10% to 21%[17]	Daily pill or monthly injectable
Naloxone (used only for overdose reversal, not addiction treatment)	Any setting: prescribed or dispensed by a clinician, furnished by a pharmacy without a prescription (legal in several states), dispensed by lay staff in community settings (by standing order), or carried by law enforcement or other first responders.	To reverse respiratory suppression in suspected opioid overdose	May require high doses for extremely high-potency illicit drug use (e.g., fentanyl and carfentanyl)	Intranasal spray, or intravenous, intramuscular, or subcutaneous injectable

*Retention in treatment at 12 months with significant reduction or elimination of illicit drug use.

Review of Comparative Effectiveness of MAT

Extensive research has demonstrated the effectiveness of opioid agonist treatment (methadone and buprenorphine) in opioid use disorder. A meta-analysis of 50 studies showed methadone's retention rate ranging from 70% to 84% at one year, buprenorphine ranging from 60% to 90% at one year, with both treatments resulting in significant reductions in overdose death, illicit drug use, criminal activity, arrests, risk behaviors, HIV and hepatitis C incidence, as well as improvements in health status, functioning, and quality of life.[18]

In 2013, SAMHSA sponsored research to analyze meta-analyses, reviews, and individual studies from 1995 through 2012[19] as part of its Assessing the Evidence Base series. SAMHSA provided an overview of the findings on methadone and buprenorphine maintenance treatment in two peer-reviewed articles,[20] showing that methadone dosages greater than 60 mg and buprenorphine doses ranging from 16 to 32 mg produce similar reductions in illicit opioid use, with subtherapeutic doses leading to poorer health outcomes.

Short-term use of buprenorphine ("detox") is rarely effective[21] unless detox is followed by maintenance doses, since relapse generally occurs after medication discontinuation.[22] The risk of overdose death is increased in all forms of detoxification, including both medically supervised withdrawal and unplanned discontinuation of treatment.[23,24] A frequently cited 2003 *Lancet* article randomized patients to detox (with placebo) or buprenorphine maintenance, and found 4 out of 20 (20%) in the detox placebo group had died and none had engaged in treatment at 12 months, compared to no deaths in the buprenorphine group in the same period.[25]

A meta-analysis showed that the mortality rate doubled when buprenorphine was discontinued and tripled when methadone was discontinued.[26]

Naltrexone is approved for both alcohol and opioid use disorder, and has both an oral (daily) and injectable (monthly) formulation. Naltrexone completely blocks opioid receptor sites, which reduces cravings and prevents euphoria from opioid use. Naltrexone has a good evidence base for treatment of alcohol addiction[27,28] but limited evidence supporting its use in OUD.[29] A Cochrane meta-analysis of oral naltrexone showed no difference compared to placebo when comparing retention in treatment, use of illicit opioids, or side effects. Studies of injectable naltrexone show lowered cravings and illicit drug use compared to placebo but are limited by short duration (two months[30] to six months[31]) and high dropout rates. Unpublished manufacturer registry data (see Appendix B) showed that only 34 of 403 patients (9%) met goals of treatment at 12 months, and over 90% did not complete treatment, with 61 days as the median dropout rate.[32] For those who drop out of treatment, overdose rates are high — heroin overdose rates were three times higher with naltrexone compared to buprenorphine or methadone in an Australian study, and almost eight times higher after treatment ended.[33] Since the combination of high dropout rates and lowered tolerance can contribute to overdose rates, the evidence suggests that naltrexone should be used cautiously, especially in high-risk populations with longer addiction durations, less social support, and potentially higher overdose risk.[34] The evidence of benefit for naltrexone is much stronger for employed patients with substantial psychosocial support (such as executives[35] and health care providers[36]), and naltrexone is frequently used to prevent relapse for patients after complete detoxification from opioids.

Access Barriers to MAT

Despite the evidence that MAT is effective, only 10% of Americans seeking treatment can access it. Barriers to MAT include a shortage of primary care buprenorphine prescribers, addiction specialists, and opioid treatment programs; restrictive health plan authorization requirements; lack of sufficient behavioral health workforce; stigma (leading patients to avoid opioid treatment programs); and lack of provider knowledge and training.[37] Prior to the Affordable Care Act, addiction treatment was not an essential health benefit, and treatment was unavailable in many Medicaid programs and excluded (or severely restricted, with high consumer costs) in commercial plans. While addiction treatment is now an essential health benefit, incremental dismantling and defunding of the Affordable Care Act remains an ongoing threat to substance use disorder coverage.

Due to historical fragmentation of coverage, many opioid treatment programs do not accept health insurance, and many commercial plans have difficulty ensuring a network sufficient to meet demand. Most health plans do not have medical, pharmacy, or care management staff knowledgeable about addiction treatments, which can impact policy decisions and the resources available to providers and members. Finally, privacy restrictions, such as federal 42 CFR Part 2 regulations, result in challenges to coordinating care. As more care settings become integrated, confusion about what is and is not allowed has led California to publish a State Health Information Guidance document to facilitate data sharing between treatment providers.[38]

HEALTH PLAN STRATEGIES

Support new MAT access points through grants, enhanced reimbursement, or improvement initiatives:

- Provide or support buprenorphine waiver training programs for providers, residents, and staff teams; promote mentoring and coaching support for new prescribers, including the Providers' Clinical Support System and the Clinician Consultation Center's Substance Use Warmline.
- Incentivize providers to become buprenorphine prescribers through building payments into pay-for-performance (P4P) programs and increasing reimbursement for inductions and medication management.
- Incentivize behavioral health integration, including providing grants for practices building new MAT or mental health services.
- Work with local coalitions to identify new MAT access strategies, including new access points in emergency departments, jails, primary care, and specialties.
- Support quality improvement initiatives in emergency departments to start buprenorphine treatment in the ED.
- Work with local jails to provide all FDA-approved forms of MAT during incarceration or on re-entry.

Research found that less than one-quarter of publicly funded, and one-half of private-sector, addiction treatment programs reported using MAT.[39] According to SAMHSA, only 21% of SUD treatment centers offered methadone or buprenorphine maintenance in 2014.[40] Many rural areas have no access to opioid treatment programs, and offer very few behavioral health resources. Substance use treatment providers for jails and prisons have been slow to add MAT to their treatment regimens.[41] As of January 2017, fewer than a dozen state departments of corrections offered MAT in their drug treatment programs for incarcerated people, beyond limited methadone maintenance for pregnant women, despite two-thirds of American inmates suffering from addiction to alcohol or other drugs.[42,43] Moreover, only 130 local and county jails in 21 states provided MAT, and just 17 states' drug courts offered MAT,[44] and many of these only offered naltrexone. Arizona Medicaid responded to this problem by creating programs to facilitate enrollment in Medicaid and facilitate access to MAT on re-entry after incarceration.[45]

Few primary care providers have applied for and received the federal waivers needed to prescribe buprenorphine.[46] Nationally, only half of waivered providers treat any patients with buprenorphine, and those who do treat these patients work with only a small number. Barriers for primary care providers to prescribing buprenorphine include a lack of training and experience, administrative burdens (including health plan authorization requirements), lack of mentorship,[47] lack of available behavioral health resources,[48] and concerns about the impact of DEA site visits on providers and staff.

Insurance Barriers to MAT

Insurance authorization policies can present major obstacles for patients and providers, according to a 2014 *New England Journal of Medicine* article. These obstacles include limits on prescribed dosages, annual or lifetime medication limits, initial authorization and reauthorization requirements, inadequate coverage of counseling services, and "fail-first" criteria requiring that other therapies be attempted prior to MAT (e.g., requirements for initial trial of taper or detox, or failure of other medication).[49] A 2016 Urban Institute study[50] that included health plans available in six cities (Los Angeles included) showed that prescription drug coverage was less restrictive for treatments targeted to individuals with alcohol use disorders compared to treatment for those with opioid use disorders. Buprenorphine was also more often subject to quantity or prior authorization limits, while oral naltrexone was not subject to the same level of authorization limits.

A 2017 California Society of Addiction Medicine (CSAM) survey of its membership showed significant concern about the administrative barriers created by authorization requirements.[51] In particular, survey participants were concerned about step therapy, dose limitations, the burdens of proving counseling attendance, and the requirement for negative drug screens for ongoing therapy. Fifty-six percent of respondents found it difficult to access MAT for patients new to treatment due to insurance barriers, and 46% had difficulty getting approval for maintenance treatment. Only 35% of physicians found that authorization processes "went smoothly," with 41% experiencing situations where patients went without treatment due to authorization delays. Eleven percent of the surveyed physicians reported that they stopped prescribing medications for OUD and 12% reported witnessing other colleagues who stopped prescribing. Often one to two hours of employee time was required per patient to collect documentation for clinical justifications, drug screens, and counseling, and to call the health plan (which was required more than half the time). Over 38% of respondents reported that insurance companies required treatments proven ineffective (e.g., failure of short-term detox) before approving buprenorphine or methadone.

Patient cost-sharing requirements also hinder access to MAT; some plans have copayments as high as $60 or $75 per outpatient visit and $2,500 per inpatient stay.[52] When patients are starting buprenorphine, recommended practice is for them to initially receive a day or a week of medications at any one time, leading to much higher pharmacy copay burden compared to monthly prescriptions. Co-insurance costs can be even higher, and difficult for consumers to understand when comparing and shopping for plans. Consumers can have difficulty understanding drug formularies and cost-sharing requirements, which can make it difficult to choose a plan that provides affordable treatment.[53]

Health Plan Actions

Streamlining Access by Removing Authorization Requirements and Decreasing Financial Barriers

In an effort to decrease barriers for patients pursuing buprenorphine treatment, several large national health plans (Aetna, Anthem, Cigna, United HealthGroup, and others)[54] removed all authorization requirements from buprenorphine initiation and maintenance. Some plans include all formulations of buprenorphine — allowing easier access to buprenorphine for pain management as well as addiction — and some limit to just the FDA-approved formulations for addiction. In 2015, the California Department of Health Care Services (DHCS) joined several other states in removing the authorization requirement for buprenorphine in Medi-Cal (California's Medicaid);[55] in response, buprenorphine claims doubled from 2015 to 2016.[56] However, a 2015 study found that an increasing number of Medicaid programs covering MAT put prior authorization limitations in place, potentially impacting access.[57]

Recognizing that copays and deductibles can present significant financial barriers to treatment, especially as heroin prices continue to drop, the Massachusetts Health Connector (the state health insurance exchange) required all participating plans to remove all patient costs associated with MAT in 2016.[58] TRICARE, the insurance plan for active and retired military and family, cut all behavioral health copays in half.[59]

HEALTH PLAN STRATEGIES

- Remove authorization requirements for MAT.
- Remove or reduce copays for MAT (including pharmacy, medical, and behavioral health services).
- Remove authorization requirements and copays for naloxone.

Expanding Networks

In interviews, leaders discussed challenges on the provider supply side, including the limited number of physicians treating addiction and willing to participate in insurance networks. Since addiction treatment as an essential health benefit has only been in place since the 2014 implementation of the Affordable Care Act, a substantial number of opioid treatment programs are outside of insurance networks, and plans have difficulty identifying them as potential network providers. One commercial health plan leader noted that some clinicians who prescribe MAT "can keep their practices busy by not working with insurance companies" and that it is difficult to identify such providers and practices.

To increase MAT use, health plan leaders said they are working with providers to streamline internal reporting paperwork between primary care providers and the health plan, incentivize providers to start patients on buprenorphine by increasing reimbursement to reflect the additional time spent with patients, and encouraging physicians to use team-base models that allow licensed clinical social workers, nurses, or medical assistants to take on some of the administrative, educational, and care coordination functions to relieve the physician's burden of prescribing MAT. Some plans have undertaken efforts to identify and contract with opioid treatment programs, as well as telehealth providers of buprenorphine. One commercial plan created a code for providers to bill for induction visits separately so that the provider would be reimbursed at a higher rate due to the increased complexity of the office visit. Some health plan leaders stated that pilot programs in expanded reimbursement, pay-for-performance, and training have extended buprenorphine access points in their network, and they plan to continue these programs.

In areas of the country particularly hard-hit by the epidemic, some health plans are using innovative payment approaches to expand treatment networks.

For example, Medicaid and commercial health plans in Vermont participate in a hub-and-spoke bundled payment model supporting opioid treatment programs (hubs) and primary care and other outpatient offices (spokes) to deliver MAT services.[60] The model aims to create primary care and specialty mutual referral relationships for opioid use disorder treatment, with standardized protocols guiding referrals of complex patients to the hubs and stable

patients back to the spoke for ongoing buprenorphine maintenance treatment. In mid-2017, California launched a federally funded, statewide hub-and-spoke program modeled after Vermont's.[61] While Medi-Cal will reimburse treatment services, relationships with commercial health plans are yet to be determined as of publication.

HEALTH PLAN STRATEGIES

- Estimate opioid use disorder prevalence in membership; determine the volume of opioid treatment programs ("methadone clinics") and buprenorphine prescribers needed to meet the demand in each region.
- Identify and contract with opioid treatment programs in every region (to remove travel barriers).
- Work with local coalitions to identify new MAT access strategies, including new access points in emergency departments, jails, primary care, and specialties.
- Contract with MAT telehealth providers.
- Build hub-and-spoke networks, where opioid treatment programs are hubs that manage inductions and complex patients, and spokes are primary care providers treating milder addiction and providing maintenance.

Patient Identification, Engagement, and Care Management

Emergency department (ED) and inpatient admissions for complications from opioid use (including near overdose deaths) present a crucial opportunity for health plans to alert primary care providers, engage members in treatment, and reduce the incidence of future overdoses. Research shows that the weeks immediately following an overdose episode are characterized by extremely high risk of death.[62] In a landmark Yale study, treating patients with a dose of buprenorphine during their emergency department stay doubled the retention rate in treatment at 30 days. This model has been replicated in emergency departments across Rhode Island, combined with peer recovery coaches to facilitate entry into treatment.[63] According to a 2016 SAMHSA report, only about 11% of privately insured patients received the recommended combination of both medication and therapeutic services within the 30 days following an opioid-related hospitalization.[64] In addition, hospitalizations for diagnoses related to IV drug use (e.g., endocarditis and osteomyelitis) are often missed opportunities to start MAT. A *New England Journal of Medicine* article described a group of infectious disease specialists learning to prescribe buprenorphine to inpatients to treat addiction and prevent readmission due to recurring IV drug use.[65]

Some plans are making efforts to identify overdose events in the ED and follow up with patients to make sure they are linked to treatment, rather than simply restarted on the same dose of opioid, as is often the case.[66] Partnership HealthPlan of California launched a pilot to send information obtained from inpatient utilization management to the primary care provider. Since opioid overdose does not require public health reporting, and many hospitals do not have systems in place to notify prescribers, health plans can play an important role in ensuring overdoses do not recur by alerting prescribers after an overdose, and recommending either referring patients into treatment (if they have addiction) or tapering them to a safer dose (if taking opioids for chronic pain).

To overcome challenges with patient identification (since admission diagnoses often are inaccurate and may not include underlying addiction as the reason for admission), some plans are using real-time notification vendors to identify patients and connect them with case management, and then even enabling case management and providers to collaborate on shared plans of care. These tools create interfaces with electronic health records in all hospitals in a region, apply analytics, and then deploy alerts summarizing critical information and a care plan that can be used in real time by ED physicians, health plans, and primary care practices. Health plans can identify high-priority populations, such as patients seeking frequent or early opioid refills, or those using multiple pharmacies or providers, to help connect these patients with care management and steer them into addiction treatment.

"Lock-in" programs are increasingly used by Medicaid[67] and commercial health plans to identify patients using multiple providers and pharmacies, both to limit access to one provider and/or one pharmacy, and to refer to addiction treatment when appropriate.

Finally, some plans are actively providing case management for patients admitted to emergency departments or detox facilities. Blue Cross Blue Shield of Massachusetts hired social workers to contact plan members admitted

to detox facilities to help them figure out next steps for treatment.[68] Aetna launched a Behavioral Health Medication Assistance Program where nurses and psychologists worked with physicians to counsel and manage the care of patients with addiction. According to Aetna, this program resulted in a 30% increase in opioid abstinence rates, a 35% reduction in hospital admissions, and a 40% decrease in total medical costs.[69] Rhode Island launched a model where patients admitted to the ED with addiction or after an overdose are assigned to a recovery coach who meets with the patient over the next month and helps facilitate connections to treatment. While health plans have yet to cover these ED visits (paid from state and federal funding), they cover some of the ongoing counseling visits.[70] A New York commercial health plan (not named in the publication) assigned members using multiple pharmacies for opioids to a certified addiction counselor who contacted the prescribers to alert them about the issue, and contacted the members to screen them for addiction and discuss treatment options. As a result, the use of multiple prescribers and pharmacies dropped significantly.[71]

HEALTH PLAN STRATEGIES

- Contract with vendor to ensure notification of ED or hospital admissions for overdose; provide care management and treatment referral; notify prescribers.
- Start direct or delegated care management program for addiction; identify patients through pharmacy or utilization data, pharmacy benefits manager (PBM) analytic programs, or through lock-in programs.
- Work with hospitalists to start buprenorphine or methadone treatment with inpatients hospitalized with addiction-related diagnoses (e.g., endocarditis or osteomyelitis).
- Place peer coaches or care navigators in emergency departments to guide patients to treatment.
- Develop data dashboards to compare delegated medical groups and contracted providers on standardized measures of opioid prescribing and MAT utilization.
- Identify outlier and/or fraudulent prescribers; ensure patients are transferred to needed care if these practices close down.

Data Sources and Measuring Success

Health plans track MAT use and impact through pharmacy data (prescriptions filled) and utilization data (behavioral health visits, primary care visits, ED and hospital rates), although accurate inpatient data are elusive since the admission diagnoses may not mention SUD. Research studies tend to define MAT success as lack of illicit drug use in addition to retention and treatment, and avoidance of morbidity (HIV, hepatitis) and mortality (overdose). These outcomes can be difficult for health plans to measure. Therefore, plans often struggle to identify process and outcomes measures to define whether access to MAT is sufficient, and to know if new programs are meeting goals.

Multiple health plans promote clinical practice guidelines identified by the American Psychological Association and the American Society of Addiction Medicine (ASAM) as the standard for services and care delivery. Another leader described a study in progress, showing improved outcomes for patients using MAT: an increase in the number of people receiving MAT correlated with decreased ED admissions. The plan will soon publish an internal study that compared maintenance treatment with traditional treatment. The study found that "by increasing the coordination [between case managers, primary care providers, and the health plan] to offer comprehensive and evidence-based treatments, there are better outcomes." The same health plan leader reflected, "We have a task force that looks at MAT from a variety of angles. We have lots of resources pointing to MAT."

Interviewees noted that a lack of clear success metrics and data points for health plans makes comparison and outcome measure identification difficult between specific subsections of health plan membership.

"Where I work, clinicians from other specialties do not step forward and prescribe it due to perceived insurance problems."

— CSAM Member

HEALTH PLAN STRATEGIES

- Create dashboard to measure health plan success: opioid prescriptions and morphine milligram equivalents (MME) pmpm, multiple prescribers/pharmacies, high-dose use, buprenorphine prescriptions pmpm, members on MAT compared to members with SUD diagnoses.
- Promote clinical practice guidelines for safer prescribing and MAT.

Mitigating Buprenorphine Diversion

Health plan leaders are concerned about the risk of buprenorphine diversion (prescribed medications being sold or distributed to others) based on published reports, data from emergency departments, and information from law enforcement.[72] However, some leaders expressed that the risk of inadequate access to treatment outweighed the risk of inappropriate use, and that this calculation weighed into decisions to remove authorization requirements from buprenorphine and buprenorphine/naloxone products. One plan noted that 95% of buprenorphine authorization requests were approved, and most denied requests were due to lack of information, leading them to decide the authorization process was not adding value. Another plan leader stated that while authorization requirements were removed from buprenorphine products in general, these requirements will be kept in place for prescribers with outlier and unsubstantiated prescription patterns.

Alternate Views on Diversion

While minimizing diversion is a legitimate plan concern, some studies have shown that diverted buprenorphine is typically used for its intended purpose — reducing cravings and coping with withdrawal symptoms — as opposed to providing euphoria.[73] A study documented that people in treatment with historical illicit use of buprenorphine were twice as likely to stay in treatment as those with no prior experience.[74] In 1995, recognizing a spike in heroin deaths, the French government systematically removed all barriers to buprenorphine treatment by allowing all physicians to prescribe, maximizing reimbursements, and minimizing coverage barriers.[75] As a result, 20% of French general practitioners prescribe buprenorphine, overdose deaths have dropped by 79%, and diversion, while present, is described as minimal.

Return on Investment: The Financial Case for MAT

Cost factors in MAT were also examined as part of this research. Evidence summarized below shows that addiction treatment decreases health costs — largely due to avoided emergency department and inpatient stays. One study found that treating injection drug users lowers the incidence of expensive complications including endocarditis, abscesses, HIV, and hepatitis C. Treating addiction also lowers the ED and hospital costs associated with reversed opioid overdose events;[76] some of these studies are described below.

HEALTH PLAN STRATEGIES TO INCREASE NALOXONE DISTRIBUTION

- Offer or support training on naloxone co-prescribing (routine naloxone prescriptions with all — or high-risk — chronic opioid prescriptions).
- Incentivize or train local pharmacies to furnish naloxone without a prescription.
- Work with local coalitions to increase dispensing of naloxone in community settings (e.g., needle exchanges) under standing orders.

A 2014 study[77] looked at the costs of care in commercial integrated health systems and found that patients with buprenorphine plus counseling had less use of general medical services and lower total health care costs compared to those with little or no addiction treatment. Specifically, annual health care costs with buprenorphine treatment were $13,578, while average health care costs with no addiction treatment were $31,055. Other studies have shown that access to therapeutic doses of buprenorphine/naloxone are associated with a longer treatment period, with resources used and lower total medical costs despite higher pharmacy acquisition costs.[78]

A study looking at methadone maintenance and costs of care in a commercial plan demonstrated that costs were 50% lower compared to two or more drug-free treatment visits, and 62% lower when compared to one or zero

drug-free treatment visits.[79] A 2014 study on buprenorphine maintenance demonstrated higher pharmacy charges but lower outpatient, inpatient, ED, and total health care charges ($28,458 vs. $49,051) for patients adherent to buprenorphine.[80]

In another study of methadone treatment, a commercial health plan's costs for members receiving methadone maintenance were 50% lower ($7,163) than those with two or more outpatient addiction treatment visits without methadone ($14,157), and 62% lower than those with one or zero outpatient addiction treatment visits without methadone ($18,694).[81]

HEALTH PLAN STRATEGIES

- Work with addiction treatment and OB community to increase access to buprenorphine and methadone treatment for pregnant members.
- Work with hospitals to increase their capacity to manage neonatal abstinence syndrome and decrease the number of infants requiring NICU care, including promotion of evidence-based practices such as rooming in, breastfeeding, and use of buprenorphine in the treatment of infants.

MAT and Neonatal Abstinence Syndrome

Health plans are seeing increasingly long lengths of stay for neonatal abstinence syndrome (NAS).[82] The National Institute for Drug Abuse estimates the average cost of treatment for NAS as $66,700 per infant, compared to $3,500 without NAS.[83] While evidence supports minimizing stimulation by rooming-in (as opposed to a bright, overstimulating neonatal intensive care environment),[84] breastfeeding (in the absence of HIV), promotion of nonpharmacological soothing techniques,[85] and use of standardized scoring tools to assess when medication is needed, many hospitals feel ill-equipped to manage infants and thus transfer them to neonatal intensive care units, often leading to separation of mother and infant at a time when bonding is a critical motivating factor for women's retention in treatment.[86]

While MAT in pregnancy has been shown to increase retention in treatment and prevent relapse, many pregnant women, especially in rural areas, have no local access to care, and many fear seeking treatment due to the risk of losing custody. While attitudes are slowing changing, many child protection workers and judges continue to view MAT as a sign of continuing addiction and deny custody if women are taking methadone or buprenorphine. Buprenorphine in pregnancy can lower the risk of NAS and long lengths of stay compared to morphine treatment. One study showed the mean dose of morphine required for infants exposed to buprenorphine in utero was 1/10th the dose compared to methadone, with length of stay decreasing by 75%.[87] While neonatal outcomes improved, retention in treatment for buprenorphine was lower (67%) compared to methadone (88%), potentially due to the additional counseling and case management services offered in methadone maintenance. Studies have not found problems in childhood development due to treatment of addiction with buprenorphine or methadone in pregnancy.

While morphine has been considered the standard of care for NAS treatment, a 2017 *New England Journal of Medicine* randomized study showed treating neonatal abstinence syndrome with buprenorphine cut lengths of stay in half (15 vs. 28 days) compared to morphine, with no difference in the rate of adverse events.[88]

In summary, the opioid epidemic continues to drive up health care costs for plans, consumers, and the public, with costs of care due to opioid misuse and addiction rising to $31 billion for the insurance industry nationwide.[89] This creates a pressing business case for plans to work actively to prevent new cases of addiction through changing prescribing practices, and to ensure their networks have adequate treatment resources for people with addiction, including pregnant women, and for infants with NAS.

Legislation Related to Health Plans and MAT

Federal Parity Laws

The Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008 prohibits insurers from applying cost-sharing and benefit limits to treatments for SUD that are more restrictive than those placed on other medical services.[90] Prior to the ACA, MHPAEA did not apply to Medicaid beneficiaries or Medicare Advantage plans offered through group health plans, state and local government plans, Medicaid managed care plans, and state Children's Health Insurance Program plans. The ACA also

requires insurers to cover substance use and behavioral health treatment as an essential health benefit.

A 2016 federal parity task force issued a report[91,92] (see Appendix A) stating that a plan may not require prior authorization for buprenorphine based on safety risks associated with the drug if prior authorization is not required for prescription drugs with similar safety risks to treat medical or surgical conditions.[93] MHPAEA also prohibits fail-first requirements if such requirements are not equivalent to the medical benefit. Finally, 30-day limitations to buprenorphine could be inconsistent with authorization practices for chronic medical and surgical conditions, since authorization for prescription drugs used for chronic medical conditions is typically approved for 6 or 12 months. See Appendix A for federal questions and answers on these requirements.[94]

The *Centers for Medicare & Medicaid Services (CMS) Opioid Misuse Strategy Report 2016* recommended that health plans promote naloxone access and coverage among private payers, strengthen messaging, and accelerate widespread adoption of MAT by collaborating with SAMHSA and other Health and Human Services agencies.[95] The report includes plans for CMS to evaluate health plan coverage laws, including SUD treatment network adequacy, among other priorities.

It should be noted that federal negotiations on legislation to weaken the ACA continue at the time of this report's publication. Even without repeal, the essential health benefit definitions could be altered or eroded by administrative actions. In June 2017, the Robert Wood Johnson Foundation and Urban Institute released an analysis concluding that repealing and replacing the ACA could significantly reduce access to mental health and SUD treatment and parity protections.[96]

Actions in the States

At the state level, some policymakers are looking to legislative solutions to increase access to MAT. In 2014, Massachusetts enacted legislation to increase SUD treatment access by prohibiting prior authorization for substance use disorder and mandating coverage of 14 days of inpatient substance use treatment.[97] It also created a commission to look at the feasibility of requiring insurance providers to monitor and limit the use of opioids. The commission will also investigate models for limiting the overprescription of opioids without limiting patients' access to necessary pain medication.[98]

In Rhode Island, 2016 legislation required health insurers to provide SUD treatment to explicitly cover MAT services including buprenorphine, naltrexone, and other clinically appropriate medications.[99] Commercial health plans must provide coverage for at least one generic opioid antagonist and device approved to treat opioid overdose (e.g., naloxone). Health plans may require prior authorization for nongeneric versions. Coverage includes naloxone prescribed or dispensed via standing order or through a collaborative practice agreement, allowing it to be dispensed to family members or friends of people at risk of overdose.

In 2016, the New York Attorney General Eric Schneiderman initiated an investigation into Cigna and Anthem's MAT policies, alleging that authorization policies delayed treatment and unnecessarily put patients at risk. These investigations were part of a law that was passed in 2011 enabling doctors and pharmacists to report and track controlled opioids in real time. This law led to many prosecutions of health care providers who illegally prescribed and diverted opioids.[100]

In 2016, New York passed legislation limiting the use of prior authorizations for MAT, as well as limiting opioid prescriptions to seven days and requiring mandatory prescriber education on pain management.[101] This comprehensive legislation followed a final report and recommendations released by the Governor's Heroin and Opioid Task Force.[102] In February 2017, the American Medical Association sent a letter to the National Association of Attorneys General to raise awareness about the consequences of insurance plan requirements for prior authorization for MAT, urging "all attorneys general to carefully review and consider taking similar action to the policies of New York Attorney General Eric Schneiderman."[103] In 2017, Cigna, Aetna, and Anthem announced they would end prior authorization for MAT across the US.[104]

New York State's FY 2017 budget invested nearly $200 million to combat the heroin and opioid epidemic — an 82% increase in state spending since 2011. This figure included $38 million to fund MAT programs that serve approximately 12,000 clients in residential or outpatient settings.[105] Governor Cuomo states that he plans to eliminate prior authorization requirements and to increase access to buprenorphine by recruiting health care providers to become prescribers.[106]

Medicaid Managed Care and MAT in California

In 32 states including California, Medicaid pays for addiction treatment in a separately funded payment and delivery system, or "carve-out." Medicaid managed care plans cover medical care, counties cover care for serious mental illness, and addiction treatment is managed through a separate state program. As of 2016, 27 out of California's 58 counties did not have opioid treatment programs (OTPs), and few clinicians are stepping up to provide buprenorphine access in these counties. Only one Medicaid beneficiary receives buprenorphine for every four patients who receive methadone.[107]

In recent years, California has made a concerted effort to increase addiction treatment access in safety-net settings:

- In 2015, the California Department of Health Care Services (DHCS) removed the authorization requirement for buprenorphine in Medi-Cal (California's Medicaid); buprenorphine claims doubled between 2015 and 2016.[108]

- In 2016, DHCS received approval for a Medi-Cal waiver authorizing participating county governments to serve as managed care plans responsible for covering all SUD treatments for Medi-Cal enrollees. While most counties are participating, small rural counties do not have the resources to do so. In response, Partnership HealthPlan, a public Medi-Cal managed care plan, is planning to manage the addiction treatment network on behalf of eight of their counties, essentially "carving" SUD services back into managed care in their region.

- In 2017, DHCS received an $89 million SAMHSA grant[109] for a MAT expansion project, replicating a hub-and-spoke model proven successful in Vermont.[110] This model uses OTPs as specialty centers (hubs) where more complex patients can be managed, and primary care sites (spokes) where clinicians manage stable patients and milder addiction. While the grant will serve all of California, tribal and rural communities will receive special attention, since only 2.2% of American physicians have obtained the waivers required to prescribe buprenorphine to treat opioid use disorders, and 90.4% of these physicians are practicing in urban counties.

To address the "not in my backyard" challenges of local resistance to building addiction treatment resources, the state public health department partnered with the California Health Care Foundation (CHCF) to expand access to MAT by supporting locally-led community coalitions. Coalitions identify treatment gaps in their counties and work to increase access to MAT through provider trainings, launching induction clinics (allowing patients to be initiated in treatment and then transferred to primary care providers when stable), starting MAT telehealth programs, and integrating addiction treatment into community health centers. These coalitions also work actively to change opioid overprescribing practices and increase access to naloxone.[111] In related work, 25 community health centers across California joined a CHCF-funded learning collaborative to receive training and technical assistance to start MAT practices in their clinics,[112] and eight hospitals are participating in a related collaborative to start MAT-initiation programs in their emergency departments.[113]

While substance use treatment services are carved out of Medi-Cal managed care plan contracts, some local Medi-Cal managed care plans launched MAT expansion projects in their networks, recognizing that promotion of MAT is a way to improve health and safety in their membership while lowering ED and inpatient services associated with untreated addiction. Examples include sponsoring buprenorphine waiver trainings, pay-for-performance programs that incentivize physicians to become waivered and to accept new patients,[114] and fee-for-service payments on top of capitation.[115] Such incentives recognize the additional time required to start patients on treatment.

Conclusion: Next Steps for Health Plans

Health plans, as payers both for prescription opioids and the medical consequences of untreated OUD, are well-positioned to address the public health crisis through increasing access to addiction treatment and safer pain management options, and many are taking steps to do so. Health plan leaders interviewed for this research emphasized the importance of health plans taking a leading role in addressing both the roots of the crisis (through plan-wide efforts to ensure safer prescribing practices) and its consequences (by ensuring streamlined addiction treatment access, and safer management of opioid-dependent patients with chronic pain).

The literature review and interviews with health plan leaders indicate that plans are working to increase treatment access through multiple coordinated approaches:

- **Pharmacy benefit.** Changing formularies to promote safer opioid prescribing; eliminating prior authorization requirements and copays for MAT and naloxone; starting lock-in programs; incentivizing or training local pharmacies to furnish naloxone without a prescription.

- **Provider network.** Assessing OUD prevalence and ensuring sufficient MAT access in all regions; promoting new MAT access points in primary care, emergency departments, inpatient settings, and corrections by supporting trainings, increased reimbursement, P4P programs, or grants; contracting with telehealth providers; training providers to offer co-prescriptions of naloxone; incentivizing behavioral health integration through P4P or direct grants; working to increase access to MAT for pregnant women; and working with hospitals to ensure evidence-based treatment of neonatal abstinence syndrome.

- **Medical management.** Providing data analytics to identify patients at risk for addiction; training case managers to guide members to treatment; starting care management programs for addiction; notifying prescribers for ED and hospital overdose admissions; supporting peer navigators in emergency departments; and minimizing copays for addiction treatment (medications, prescriber visits, and behavioral health).

- **Data analytics.** Creating dashboards to measure progress on opioid prescribing and MAT access, and sharing them with providers and delegated medical groups; identifying outlier prescribers to provide education and (when appropriate) refer for fraud; identifying outlier members to refer to case management.

- **Community engagement.** Working with local opioid safety coalitions to adopt community prescribing guidelines and ensure adequate access to MAT and naloxone (for example, over 35 of California's 58 counties have active opioid safety coalitions; see www.chcf.org/oscn).

Both commercial and Medicaid health plan leaders focused on the need to counteract bias against medication-assisted addiction treatment by focusing on the evidence — lowered overdose rates and increased retention in treatment — and to directly address the stigma associated with MAT that still prevents many medical communities from stepping up to expand access. Some leaders called for aggressive action on network access for addiction similar to that used for any other specialty in high demand and low supply.

In terms of return on investment, the research shows that paying for OUD saves insurers costs in the long run.[116] MAT reduces expensive ED visits and hospitalizations due to overdose and other opioid-related morbidities.[117] Further, the costs associated with ineffective treatment go beyond relapse and can include higher risks for infectious disease due to IV drug use.

While plans have a clear business case for change, the health plan leaders stressed that their commitment went beyond return on investment. Plans are poised to play a critical role in a systemwide effort to turn the epidemic around: to prevent a new generation of people dependent on or addicted to opioids, to safely treat those with chronic pain at risk due to long-term opioid use, and to ensure that all members with addiction have easy access to effective treatment. Plans cannot do this alone, but the epidemic won't end unless they take action.

FOR MORE TOOLS, GO TO SMART CARE CALIFORNIA

Appendix A. FAQ on Implementation of ACA and Parity Act

A frequently asked questions document released to clarify the 2016 final report of the federal parity task force specifically addressing prior authorization for buprenorphine as a potential parity violation.[118]

Q. My plan requires prior authorization from the plan's utilization reviewer that buprenorphine is medically necessary for the treatment of my opioid use disorder. . . . Although there are prescription drugs to treat medical/surgical conditions that have similar safety risks, my plan does not impose similar prior authorization requirements on those drugs. Is this permissible?

A. *No. A plan may impose an NQTL [non-quantitative treatment limit], including a prior authorization requirement for buprenorphine, if, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its prior authorization requirement with respect to buprenorphine to treat an opioid use disorder are comparable to, and applied no more stringently than, those used in applying its prior authorization requirement with respect to medical/surgical benefits in the prescription drug classification under MHPAEA [Mental Health Parity and Addiction Equity Act].*

In this scenario, the plan imposes the prior authorization requirement due to stated safety concerns. However, the prior authorization requirement is applied more stringently to buprenorphine when used to treat opioid use disorder than it is applied to prescription drugs with similar safety risks to treat medical/surgical conditions. Accordingly, the plan's prior authorization requirement on buprenorphine does not comply with the MHPAEA.

Q. My plan requires that I meet specific nonpharmacological fail-first requirements (for example, that I have tried counseling alone, failed at recovery, and resumed substance use) before it will authorize coverage for buprenorphine to treat my opioid use disorder. While comparable evidentiary standards and other factors indicate that similar fail-first requirements could be imposed on certain prescription drugs covered by my plan for medical/surgical conditions, the plan does not impose fail-first requirements in these instances. Is this permissible?

A. *No. A fail-first requirement is an NQTL that must comply with the requirements of MHPAEA. A plan or issuer cannot impose a fail-first requirement on coverage for buprenorphine for opioid use disorder unless, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in designing and imposing this fail-first requirement are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying fail-first requirements to medical/surgical benefits in the prescription drug classification under MHPAEA.*

In this case, the plan is imposing a nonpharmacological requirement that the individual fail first at recovery with counseling alone before the plan will authorize coverage of benefits for buprenorphine. While comparable evidentiary standards and other factors indicate that similar fail-first requirements could be appropriate before authorizing coverage for certain other prescription drugs covered by the plan's first requirement that applies for medical/surgical conditions, the plan does not in fact impose fail-first requirements in any of these instances. Accordingly, the fail-first requirement imposed on buprenorphine is an NQTL that the plan applies more stringently to a substance use disorder condition than medical/surgical conditions. This disparity violates MHPAEA.

Q. My group health plan states that it follows nationally recogized treatment guidelines for setting prior authorization requirements for prescription drugs, but requires prior authorization for my buprenorphine/naloxone combination at each refill (every 30 days) for my opioid use disorder, which is not consistent with nationally-recognized treatment guidelines. Is this permissible?

*A. No. In setting the NQTL of prior authorization for the substance use disorder medication, buprenorphine/*naloxone*, a plan or issuer must apply comparable processes, strategies, evidentiary standards, and other factors no more stringently to buprenorphine/*naloxone *than those applied to medical/surgical medications. The plan states that it fellows nationally-recognized guidelines. However, these guidelines, such as the American Society of Addiction Medicine (ASAM) national practice guidelines, do not support 30-day authorization practices for buprenorphine/*naloxone*. Furthermore, the plan does not deviate from nationally-recognized treatment guidelines when establishing prior authorization requirements for any prescription drugs to treat medical/surgical conditions. Accordingly, although the plan asserts that its process of setting the NQTL of prior authorization — following nationally-recognized treatment guidelines — is comparable as written, in operation, the plan's process departs from and provides less coverage than recommended under nationally-recognized treatment guidelines for buprenorphine/*naloxone*, in violation of MHPAEA.*

However, as an alternative to simply mirroring nationally-recognized treatment guidelines, many plans and issuers use Pharmacy and Therapeutics (P&T) committees in deciding how to cover prescription drugs and evaluating whether to follow or deviate from nationally-recognized treatment guidelines for setting the prior authorization requirements. The Departments note that while the use of P&T committees to inform prior authorization requirements for prescription drugs in this manner may not violate MHPAEA ***per se****, these processes must also comply with MHPAEA's NQTL standard in operation. For example, if the plan deviates from nationally-recognized treatment guidelines for buprenorphine/*naloxone *based on P&T committee reports, then use of the P&T committee would be evaluated for compliance with MHPAEA's NQTL requirements (for example, by evaluating whether the P&T committee is comprised of comparable experts for MH/SUD conditions, as compared to the experts for medical/surgical conditions, and how such experts evaluated nationally-recognized treatment guidelines in setting prior authorization for medications for both MH/SUD and medical/surgical conditions).*

Appendix B. Alkermes Registry Data, VICTORY Trial

Most published studies reviewing the effectiveness of injectable naltrexone (Vivitrol) in opioid use disorder are short: two to six months in duration. The best available data on 12-month retention in treatment are from the Alkermes VICTORY (Vivitrol's Cost and Treatment Outcomes Registry) registry. While these data were not published, they were presented in a presentation at the American Society of Addiction Medicine Conference, April 13, 2014.

REASONS FOR DISCONTINUATION PRIOR TO 12 MONTHS	*n*	PERCENTAGE
Lost to follow up	199	49.4%
Withdrawal by patient	60	14.9%
Study terminated by sponsor	30	7.4%
Patient feels treatment goal met	22	5.5%
Other	21	5.2%
Physician intended planned course of treatment met	12	3.0%
Insurance loss or loss of coverage for Vivitrol™	11	2.7%
Lack of efficacy by patient	10	2.5%
Noncompliance	10	2.5%
Incarcerated	9	2.2%
Relocated	9	2.2%
Death	5	1.2%*
Time constraints	3	0.7%
Withdrawal symptoms or re-entered detox	2	0.5%

*Three ODs: 21, 55, and 115 days post last dose; one drowning: 28 days post last dose; one suicide: 34 days post last dose.

Source: Vocci, Frank, et al. "The Extended-Release Naltrexone (XR-NTX) Opioid Dependence Registry: Clinical and Functional Effectiveness." Paper presented at the American Society of Addiction Medicine conference, Orlando, FL, April 13, 2014, www.asam.org.

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