CENTER FOR HEALTH INFORMATION AND ANALYSIS

BENEFIT MANDATE REVIEW: MEDICATION-ASSISTED OPIOID TREATMENT

PROPOSED IN CHAPTER 258 OF THE ACTS OF 2014: AN ACT TO INCREASE OPPORTUNITIES FOR LONG-TERM SUBSTANCE ABUSE RECOVERY

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Benefit Mandate Review: Medication-Assisted Opioid Treatment

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Benefit Mandate Overview: Medication-Assisted Opioid Treatment

HISTORY OF THE PROPOSED MANDATE

Chapter 258 of the Acts of 2014 (Chapter 258) was signed by Governor Deval Patrick on August 6, 2014, enacting Senate Bill 2341. Section 32 of the law requires the Center for Health Information and Analysis (CHIA) to conduct a mandated benefit review – evaluating the legislation's potential impact on the health of the population and on insurance premiums – of two proposed mandated insurance benefits, consistent with its responsibilities under section 38C of chapter 3 of the Massachusetts General Laws.

WHAT DOES THE MANDATE PROPOSE?

Section 32 of Chapter 258 instructs CHIA to review a proposed mandate requiring health insurance plans to "reimburse providers for medication assisted opioid treatment, such as methadone, buprenorphine and extended-release naltrexone."

EFFICACY OF MEDICATION-ASSISTED OPIOID TREATMENT

Medication-assisted treatment (MAT) is "any treatment for opioid addiction that includes the use of a medication approved by the U.S. Food and Drug Administration (FDA) for opioid addiction detoxification or maintenance treatment." MAT is a broad term that generally encompasses several different approaches to treatment, including several forms of detoxification, medically-supervised withdrawal, and maintenance therapy. The three FDA approved medications for the treatment of opioid dependence are methadone, buprenorphine and naltrexone.

Medication-assisted treatment (MAT) is a recommended and effective treatment for opioid-addicted patients. In its 2005 report on MAT, the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) emphasized comprehensive care including a full continuum of services for treating patients with opioid addiction, including MAT within this spectrum. Overall, evidence has shown that MAT is effective in treating opioid addiction, when individualized based on each patient's conditions and needs.

CURRENT COVERAGE

In a recent survey of ten of the largest insurance carriers in Massachusetts, all reported coverage for medication-assisted opioid treatment. All carriers reported they cover buprenorphine/naloxone,

¹ Massachusetts Acts of 2014, Chapter 258, "An Act to Increase Opportunities for Long-Term Substance Abuse Recovery." Accessed 2 October 2014: https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter258.

[&]quot; U.S. Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (SAMHSA-CSAT). Treatment Improvement Protocol (TIP) Series, No. 43: Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs (TIP 43). Published 2005; accessed 15 October 2014: http://www.ncbi.nlm.nih.gov/books/NBK64168/.

iii Op. cit. SAMHSA-CSAT. TIP 43.



buprenorphine, and naltrexone. However, not all carriers cover methadone maintenance treatment; federal regulations require administration of methadone to occur at opioid treatment programs (OTPs, some of which may be referred to as "methadone clinics"). About 35 percent of the commercial fully-insured membership does not currently have methadone MAT coverage. The combination of buprenorphine and naloxone is by far the most commonly prescribed MAT.

COST OF IMPLEMENTING THE PROPOSED MANDATE

The likely impact of this proposed legislation on insurance premiums is immaterial and assumed to be zero. According to surveys of the largest insurers in Massachusetts, almost all cover all MAT products; two carriers, serving about one third of members, do not cover methadone. Therefore, any incremental impact on premiums of proposed legislation requiring coverage for MAT will stem from compelling methadone coverage by those two carriers. Whether or not this causes any shift to methadone from other MATs, per-user treatment costs for methadone are similar to those of the dominant MAT in the commercial population, buprenorphine, making any shift between the two products cost-neutral with no material effect on insurance premiums. In addition, while buprenorphine/naloxone is growing at a rapid rate in commercial claims, even among carriers that cover it, methadone claims are declining, possibly because current payment and other carrier policies lead individuals to get methadone treatment through programs funded by the Commonwealth's Department of Public Health.

PLANS AFFECTED BY THE PROPOSED BENEFIT MANDATE

Chapter 258 outlines the general terms of the proposed mandate but does not specify to which plans it would apply. This review assumes the proposed legislation, if enacted, would apply to the plans that most mandates do: individual and group accident and sickness insurance policies, corporate group insurance policies, and HMO policies issued pursuant to Massachusetts General Laws, as well as plans, self- and fully-insured, provided by the Group Insurance Commission (GIC) for public employees and their dependents. This review assumes the legislation requires coverage for members under the relevant plans, regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

PLANS NOT AFFECTED BY THE PROPOSED MANDATE

Self-insured plans (i.e., where the employer policyholder retains the risk for medical expenses and uses a carrier to provide administrative functions), except for those managed under the GIC, are not subject to state-level health insurance benefit mandates. State health benefit mandates do not apply to Medicare and Medicare Advantage plans whose benefits are qualified by Medicare; consequently this review excludes members of commercial fully-insured plans over 64 years of age. These mandates also do not apply to federally-funded plans including TRICARE (covering military personnel and dependents), the Veterans Administration, and the Federal Employee's Health Benefit Plan. Finally, this proposed mandate is assumed not to apply to Medicaid/MassHealth.



PRELIMINARY ESTIMATE OF POTENTIAL MASSACHUSETTS LIABILITY UNDER THE ACA

Analysis of the cost associated with proposed state benefit mandates is important in light of new requirements introduced by the Affordable Care Act (ACA). In accordance with the ACA, all states must set an Essential Health Benefits (EHB) benchmark that all qualified health plans (QHPs), and those plans sold in the individual and small-group markets, must cover, at a minimum. Section 1311(d)(3)(B) of the ACA, as codified in 45 C.F.R. § 155.170, explicitly permits a state to require QHPs to offer benefits in addition to EHB, provided that the state is liable to defray the cost of additional mandated benefits by making payments to or on behalf of individuals enrolled in QHPs. The requirement to make such payments applies to QHPs sold both on and off the Exchange, but not to non-QHP plans. The state is not financially responsible for the costs of state-required benefits that are considered part of the EHB benchmark plan. In Massachusetts, the Benchmark Plan is the Blue Cross and Blue Shield HMO Blue \$2000 Deductible (HMO Blue). State-required benefits enacted on or before December 31, 2011 (even if effective after that date) are not considered "in addition" to EHB and therefore will not be the financial obligation of the state, if such additional benefits are *not* already covered benefits under the State's EHB Benchmark Plan, HMO Blue. This ACA requirement is effective as of January 1, 2014 and is intended to apply for at least plan years 2014 and 2015.

CHIA's *preliminary* estimate of the proposed health benefit mandate is not intended to determine whether or not this mandate is subject to state liability under the ACA. CHIA generated this estimate to provide neutral, reliable information to stakeholders who make decisions that impact health care access and costs in the Commonwealth.

This review concludes the potential legislation has no material effect on premiums. An estimate and eventually a final determination of the Commonwealth's liability will require a detailed analysis by the appropriate state agencies, including an assessment of whether this mandate is subject to state liability under the ACA and the actual number of QHP enrollees. The federal government may remove or modify the obligation after 2015.

^{iv} The Health Connector, in consultation with the Massachusetts Division of Insurance, will need to be consulted to provide an analysis of estimated state liability associated with a given proposed mandated benefit bill.



Medical Efficacy Assessment: Medication-Assisted Opioid Treatment

Chapter 258 of the Massachusetts Acts of 2014¹ requires the Massachusetts Center for Health Information and Analysis (CHIA) to analyze potential legislation "mandating that insurance companies reimburse providers for medication assisted opioid treatment, such as methadone, buprenorphine and extended-release naltrexone...." M.G.L. c. 3 § 38C charges CHIA with reviewing the medical efficacy of proposed mandated health insurance benefits. Medical efficacy reviews summarize current literature on the effectiveness and use of the mandated treatment or service, and describe the potential impact of a mandated benefit on the quality of patient care and the health status of the population.

OPIOID USE, DEPENDENCE, ADDICTION, AND ABUSE

Opioids are drugs that reduce pain signals to the brain, decreasing one's perception of and reaction to pain, and increasing pain tolerance and feelings of pleasure.^{2,3} Opioids may be prescribed to alleviate pain from injuries, surgeries, dental procedures, and acute and chronic illnesses, as well as to treat addiction.⁴ Side effects of opioid use include drowsiness, constipation, nausea, and mental confusion; these drugs may also produce a euphoric reaction in some users.⁵ Opioid use can result in respiratory depression or death even in small doses for some users.⁶

Medications in the opioid class include morphine, codeine, oxycodone (including brand names OxyContin® and Percocet®), hydrocodone (including brand name Vicodin®), methadone, buprenorphine, and fentanyl, among others. In the United States, heroin is classified as an illicit opioid. When properly prescribed and used, opioids can be safe and effective tools to manage short-term and long-term pain. When used regularly or over a longer period of time opioids can lead to physical dependence, meaning the user's body develops a tolerance for the medication and needs an increased dose to achieve the same effect, and a gradual reduction in dosage is necessary to avoid withdrawal symptoms when stopping use. Withdrawal symptoms can include restlessness, sleeplessness, severe pain, diarrhea, and vomiting. It is important to note that physical dependence is "a normal adaptation to chronic exposure to a drug and is not the same as addiction."

Substance addiction is a chronic illness in which the use of drugs or alcohol physically changes the structure and function of the brain, affecting "multiple brain circuits, including those involved in reward and motivation, learning and memory, and inhibitory control over behavior." Addiction, which may or may not include dependence, "is distinguished by compulsive drug seeking and use despite sometimes devastating consequences." ¹²

Abuse occurs when individuals use opioids outside legitimate medical purposes to achieve the euphoric effect of the drug. According to the American Psychiatric Association, characteristics of abuse include failure to fulfill major role obligations, substance-related legal problems, recurrent use in situations that are physically hazardous, and continued use despite persistent social or interpersonal problems.¹³



When someone is prescribed an opioid for pain, close medical management is necessary to ensure the patient does not misuse or abuse the drug. This may include an initial assessment of risk factors associated with addiction prior to prescribing the opioid, medication counts, regularly scheduled office visits to monitor the effectiveness of the medication and the patient's compliance with prescribing guidelines, and physician monitoring of patient prescriptions across multiple providers.

IMPACT OF OPIOID ABUSE

In 2010, the leading cause of injury death in the United States was drug overdoses.¹⁴ In Massachusetts in 2011, general unintentional injury was the fifth leading cause of death, with over 33.6 deaths per 100,000 people, or approximately 2,200 deaths;¹⁵ of those, about one-third, or 9.5 to 12.3 deaths per 100,000 people, were related to drug overdoses.¹⁶

According to the CDC, "deaths from prescription painkillers have reached epidemic levels in the past decade," with the number of prescription overdose deaths surpassing those from heroin and cocaine combined. Of overdose deaths nationwide, 60 percent were related to pharmaceuticals, with over 70 percent of those stemming from misuse or abuse of opioids. Opioid abuse also burdens the health care system and the broader economy. In 2011, of the 1.4 million emergency department visits resulting from the non-medical use of pharmaceuticals, 30 percent were related to opioids. One study estimated the 2007 cost of prescription opioid abuse in the United States at \$55.7 billion, including workplace, healthcare, and criminal justice expenses. A similar study concluded that in one five-year period abusers of opioid medications cost insurers over \$14,000 more annually (over 8 times more) per patient than average patients due primarily to their high utilization of medical services and prescription drugs and their higher prevalence of other diseases or conditions.

Massachusetts residents have been prescribed the most-abused opioids at a disproportionately high rate. A recent report evaluated interstate prescription patterns for opioid pain relievers to identify variability in prescribing for drugs "prone to abuse." Selected statistics comparing the national average to prescriptions in Massachusetts are highlighted in Table 1.

Table 1: 2012 Opioid Prescriptions²⁴

	Prescriptions p	oer 100 persons	State
	U.S. (Average)	Massachusetts	Rank
Opioid pain relievers	82.5	70.8	41
Long-acting/extended release opioids	10.3	14.9	9
High-dose opioids	4.2	3.5	41

While Massachusetts ranks 41st in the nation in opioid pain relievers prescribed per 100 people, it ranks ninth in the number of long-acting or extended-release opioid prescriptions. According to the FDA, "extended-release (ER) and long-acting (LA) (ER/LA) opioids have clearly emerged as products with the highest potential for harm, misuse and abuse. These products contain large amounts of opioids in a single dosage form, sometimes in sufficient quantity to be lethal, especially in children, and they are a prime target of drug abusers."²⁵



MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION

Medication-assisted treatment (MAT) is "any treatment for opioid addiction that includes the use of a medication approved by the U.S. Food and Drug Administration (FDA) for opioid addiction detoxification or maintenance treatment." MAT is a broad term that generally encompasses several different approaches to treatment, including several forms of detoxification, medically-supervised withdrawal, and maintenance therapy. Major medications used when treating opioid addiction include:

- Methadone
- Buprenorphine
- Buprenorphine/Naloxone
- Naltrexone

Methadone and buprenorphine are synthetic opioids, while naloxone and naltrexone are antagonists that block the effects of opioids. Appendix A describes these medications and their use and efficacy in more detail.

EFFICACY OF MEDICATION-ASSISTED TREATMENT

Significant evidence exists for the efficacy of MAT when used in a manner appropriate for a patient's history and characteristics, though, in practice, barriers to its use are often present. The following paragraphs present evidence supporting the efficacy of MAT, along with findings about determinants of the most appropriate approach to MAT for specific patients and factors that create barriers to accessing MAT in practice.

MAT is a recommended and effective treatment for opioid-addicted patients. In its 2005 report on MAT, the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) emphasized comprehensive care including a full continuum of services for treating patients with opioid addiction, including MAT within this spectrum.²⁸ Opioids differ from other addictive drugs in that they "almost always produce significant physiological tolerance and a defined withdrawal syndrome."²⁹ Medications can help ease a patient's withdrawal symptoms and curb ongoing cravings. A report produced for the American Society for Addiction Medicine (ASAM) found that, as a chronic illness,

[M]any cases of opioid addiction cannot be cured – but <u>can</u> be treated and maintained.... [M]edications can be an important part of chronic, comprehensive care for opioid addiction [by interrupting] the cycle of addiction to allow patients to increase their functioning, gain some control over their addiction, and engage in therapeutic recovery.³⁰

Another report for ASAM and the National Institute of Drug Abuse (NIDA) concluded that:

[P]harmacotherapies [medications] have all shown clear clinical evidence of effectiveness in reducing opioid use and opioid use-related symptoms of withdrawal and craving as well as risk of infectious diseases and crime – when used as part of a comprehensive treatment approach and in appropriate doses. The effectiveness of these medications is true only when used in continuing care, maintenance regimens; there remains almost no evidence of enduring benefits from any of these medications when used only in detoxification regimens.³¹



Medication-assisted treatment for addiction, including both medication and psychosocial therapy, has proven effective in helping patients to stop using illicit opioids, remain in treatment, reduce criminal activity, and reduce risks of associated infectious diseases.³²

The most appropriate approach to MAT will vary by individual; no one therapy or treatment approach will be effective for all patients. Because the various FDA-approved treatment medications act differently at the brain's receptor level, they may result in "very different clinical effects during treatment." When comparing the available FDA-approved treatments, one study concluded that "[t]hese medications have very different pharmacological properties and clinical roles." Moreover, there are tradeoffs with different approaches that depend in part on patient characteristics, and these will be considered by the treating professional in determining an individual treatment plan. (See Appendix A for additional detail on the use of individual medications.)

For individuals with longer-term habits, maintenance treatment with drugs that mimic the effects of opioids (agonist treatment) coupled with psychosocial therapies has shown better outcomes – defined as retention in treatment and reduction of illicit drug use – than has short-term withdrawal therapy.³⁵ Methadone is especially effective for injection drug users when compared to therapy without maintenance medication.³⁶ And though it is associated with greater retention in treatment compared to buprenorphine maintenance, tight restrictions on the use and distribution of methadone, as well as social stigmas, may make it a less attractive treatment option for some patients compared to more widely available buprenorphine maintenance therapy.³⁷ Patients are also more likely to still be abstaining from illicit use at follow-up when treatment combines psychosocial and pharmacological detoxification treatments.³⁸

Some patients may respond well to withdrawal treatments that block the effect of opioids altogether (antagonist treatment), especially when they have "strong external motivation" such as through court-ordered or employer-stipulated treatment programs.³⁹ For the population of patients who have not been long addicted, who do not inject opioids, and who have a strong support system, withdrawal programs using naltrexone may be an effective treatment option.⁴⁰ However, this potential must be balanced against an increased risk of opioid overdose for relapsing patients using this type of treatment, possibly due to a decreased tolerance for opioids.⁴¹



Despite the evidence in support of MAT, access remains problematic for many patients. SAMHSA cautions that significant challenges remain to improving and expanding MAT access to opioid-addicted patients, including treating patients with more complex problems, promoting comprehensive and evidence-based treatments, expanding the overall treatment system, and combating social stigma associated with MAT.⁴² Moreover, patients seeking comprehensive treatment for opioid addiction that includes both pharmacotherapies and psychosocial support must "understand the intricacies of both pharmacy and medical [insurance] benefits" which may be a barrier to access for some addicted patients.⁴³ And strong federal regulations surrounding methadone and buprenorphine, further echoed by state regulation of methadone treatment, create additional barriers to its use. Another recent report summarized that:

[Strict licensing requirements and treatment protocols] isolate treatment from the rest of the health care system and serve as a barrier to entry for many patients and physicians....The highly restrictive treatment setting for patients with opioid dependence reinforces the stigma many people associate with treatment for substance abuse, and helps perpetuate the misconception that opioid dependence is a willful choice and not a long-term chronic medical disorder.⁴⁴

State discretion in changing some potential barriers to access is constrained by federal statutes and regulations. For example, as noted, federal regulations require administration of methadone used in treating addiction to occur at opioid treatment programs (OTPs), and to the extent that visiting such a clinic reinforces a stigma, patients might be reluctant to do so. States cannot change federal requirements for administering methadone, although it may be within their power to reduce stigma in other ways.

Overall, evidence has shown that MAT is effective in treating opioid addiction. As with all substance abuse treatment, to be most effective, medication-assisted treatment should be individualized based on the patient's conditions and needs, with no single approach or therapy appropriate for all patients.



APPENDIX A: MEDICATIONS FOR TREATING OPIOID ADDICTION

Current FDA-approved treatments for opioid addiction treatment include:

Methadone

A long-acting opioid agonist^v that activates the body's opioid receptors, methadone imitates the action of an opioid but not the euphoria of short-acting forms such as heroin.⁴⁵ Methadone is a Schedule II drug per the U.S. Drug Enforcement Administration (DEA), meaning that it is considered a "dangerous drug" with a high potential for abuse, with its "use potentially leading to severe psychological or physical dependence."^{46,47}

As treatment for opioid addiction, methadone is used to suppress cravings, reduce withdrawal symptoms as short-acting opioids are eliminated from the body, and block the effects of other illicit opioids. AB Properly dispensed for drug treatment, methadone is taken orally and in doses that stabilize patients, helping them to remain in treatment and reduce or eliminate non-medical opioid use and the associated risks from non-sterile injections (HIV, TB, hepatitis) and criminal activities related to drug acquisition. Further, treatment "has been shown to lead to improved overall adjustment, including reductions in psychiatric symptoms, unemployment, and family or social problems. Hethadone can be used as a detoxification medication, but is often used as a maintenance therapy. Use of methadone results in a tolerance in patients, and its discontinuation may produce significant withdrawal symptoms without proper medical management. According to the U.S. Centers for Disease Control, methadone maintenance treatment is "the most effective treatment for opioid addiction" among injection drug users.

As a potent opioid with a significant potential for abuse, prescribing of methadone is severely restricted, and regulation and oversight are significant and constrain the supply of providers. Unlike providers of any other medication in the U.S. healthcare system, methadone providers must be registered with the DEA.⁵⁶ Treatment is available only through opioid treatment programs (OTP) licensed by the state and certified by the federal Substance Abuse and Mental Health Services Agency.^{57,58,59}

Patients prescribed methadone are most often required to take a daily dose of the medication at the OTP under direct supervision; take home doses are tightly controlled by federal and state regulations.⁶⁰ These restrictions are problematic for patients whose schedule or access to these sites is restricted; moreover, patients are also concerned with an associated social stigma of this treatment.⁶¹ So while methadone has been shown to improve patient treatment retention when compared to other medication therapies such as buprenorphine (described in a subsequent section),^{62,63} these restrictions may create significant barriers to patients attempting this type of treatment.⁶⁴ Additionally, private insurer network, credentialing, and reimbursement rules further limit the number of OTPs that can provide services to commercially-insured patients.⁶⁵ However, OTPs may provide more comprehensive, individualized treatment integrated with behavioral, psychosocial, medical and other support services than treatment in other settings.⁶⁶

^v A chemical entity that binds to a receptor and activates it, mimicking the action of the natural (or abused) substance that binds there.





Buprenorphine

A partial opioid agonist, buprenorphine (including brand name Subutex®)^{67,68} can produce "typical" opioid effects such as euphoria and respiratory depression, but not to the same degree as heroin or methadone.⁶⁹ Buprenorphine is a DEA Schedule III drug, considered as having a lower potential for abuse than Schedule II drugs, described by the DEA as a drug with "moderate to low potential for physical and psychological dependence,"⁷⁰ "[a]Ithough the phenomenon of buprenorphine diversion is now well established."⁷¹

For the treatment of opioid addiction when properly prescribed at appropriate doses and taken sublingually (dissolved under the tongue), buprenorphine helps to suppress withdrawal symptoms of patients as they discontinue use of illicit opioids, and like methadone can be used either to detoxify patients or as maintenance therapy.^{72,73} However, unlike methadone, the effects of buprenorphine eventually plateau at increasing doses, producing the so-called "ceiling effect," and are less bioavailable, vi thereby reducing the potential risk of abuse and side effects of, or addiction to, the treatment itself.74 So while methadone has been shown to be more effective than buprenorphine for some patients, buprenorphine is "safer in overdose" than methadone.75 At high doses and in certain circumstances, buprenorphine can block the effect of other opioids and produce withdrawal symptoms "if administered to an opioid-addicted individual while a full agonist is in the bloodstream."76 The FDA first approved select buprenorphine products for opioid addiction treatment in October 2002.⁷⁷ Buprenorphine may be prescribed and dispensed by specially trained, SAMHSA-certified and DEA-registered physicians, significantly increasing provider supply and patient accessibility to this type of MAT (commonly referred to as Office-Based Opioid Treatment, or OBOT).78,79 These physicians must apply for a federal waiver to provide buprenorphine after meeting certain qualifying criteria and certifying their capacity to refer patients to appropriate counseling and other non-pharmacological therapies.^{80,81} In the first year of this waiver, physicians are restricted to treating 30 patients only, and can apply in their second year to increase treatment to 100 patients. 82 Most often, however, buprenorphine alone as a maintenance treatment is prescribed only to pregnant women or to those who are allergic to naloxone, for whom combination buprenorphine/naloxone therapy (described subsequently) may not be appropriate.

Buprenorphine/Naloxone

Buprenorphine is available with naloxone in a combination therapy (including brand names Suboxone®, Zubsolv®).83 As an individually-formulated drug, buprenorphine can be easily abused when crushed, mixed with water, and injected.84 To reduce the potential for this type of abuse, the FDA approved a formulation of buprenorphine combined with a short-acting antagonist, naloxone, intended for use as MAT maintenance therapy for opioid addiction.85 This formulation is also a DEA-Schedule III drug.86 When taken as a combination drug tablet sublingually as prescribed, the added naloxone produces no physiological effect.87 However, if the combination tablet is crushed and injected, the naloxone produces withdrawal symptoms in patients; this reaction is intended to deter abuse.88 Recently published research

vi Refers to the extent and rate at which the active drug enters systemic circulation, thereby accessing the site of action.



has concluded that buprenorphine/naloxone is best used as maintenance therapy when compared to tapering regimens, concluding that maintenance therapy patients were more likely to remain in treatment and to reduce their use of illicit opioids when compared to patients in withdrawal therapy programs.⁸⁹

Naltrexone

An antagonist pharmacotherapy approved in 2010 by the FDA as a long-acting injectable for the prevention of opioid dependence, naltrexone (brand name Vivitrol®)⁹⁰ can only be used as MAT after a patient successfully completes detoxification and are seven to ten days opioid-free, or the treatment will produce immediate withdrawal symptoms. Place Naltrexone is not a DEA-Scheduled drug. An oral form of the drug was first approved by the FDA in 1984 (Revia®). While still approved in this form, the drug's label no longer indicates or recommends its use for opioid dependence treatment due to significant patient compliance issues. However, it is possible that the oral form of naltrexone continues to be used off-label for maintenance therapy.

When used for MAT as a drug injected monthly, naltrexone does not carry the risk of abuse or overdose as with methadone or buprenorphine. Unlike the restrictions on providers and/or settings of methadone and buprenorphine therapies described previously, dispensing providers do not need additional training or certification to administer the drug. ⁹⁵ However, the injection form must be provided at the provider's treatment setting, creating barriers to treatment for some patients. Further, patients who subsequently may need pain management therapy while taking naltrexone require additional interventions to counteract the effect of this antagonist therapy.

As a maintenance medication, naltrexone "can essentially eliminate the rewarding effects of self-administered opioids, thereby dramatically reducing use." However, compared with maintenance therapies such as methadone or buprenorphine, patient adherence rates are "very poor," and patients are much less likely to remain in treatment using naltrexone except when "externally motivated" such as through court-ordered or employer-stipulated treatment programs, or a strong social support system. ⁹⁷ Moreover, there is an increased risk of overdose in patients who relapse while using naltrexone due to their reduced tolerance to opioids. ⁹⁸



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ENDNOTES

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 - 1. Malignant Neoplasms
 - 2. Heart Disease
 - 3. Chronic Low Respiratory Disease
 - 4. Cerebrovascular
 - 5. Unintentional Injury

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- ¹⁸ Op. cit. US-CDC: Prescription Drug Overdose in the United States Fact Sheet.
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 - 2. Medical maintenance: Provided to stabilize patients and may include long-term provision of [an addiction treatment medication] with a reduction in clinic attendance and other services. A patient can receive medical maintenance at an OTP [opioid treatment program], after he or she is stabilized fully. The patient usually must complete a comprehensive treatment program first.... To reduce clinic attendance—a key feature of medical maintenance—patients must qualify, subject to variations in State regulations (which may be more stringent than Federal regulations), to receive 7- to 14-day supplies of methadone for take-home dosing after 1 year of continuous treatment and 15- to 30-day supplies after 2 years of continuous treatment in an OTP (if additional criteria are satisfied [see chapter 5]) (42 CFR, Part 8 § 12(h); Federal Register 66:4079).
 - 3. <u>Interim maintenance:</u> Generally provided to patients awaiting admission to a comprehensive maintenance program.
 - 4. <u>Detoxification:</u> Involves medication and, perhaps, counseling or other assistance to stabilize patients who are opioid addicted by withdrawing them in a controlled manner from the illicit opioids.
 - 5. <u>Medically supervised withdrawal:</u> Involves the controlled tapering of treatment medication for patients who want to remain abstinent from opioids without the assistance of medication.
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 - 3. Promoting Evidence-Based Treatment Services
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Actuarial Assessment of the Mandate for Medication-Assisted Opioid Treatment Proposed in Chapter 258 of the Acts of 2014: "An Act to increase opportunities for long-term substance abuse recovery"

Prepared for Commonwealth of Massachusetts Center for Health Information and Analysis

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Prepared by Compass Health Analytics, Inc.



Actuarial Assessment of the Mandate for Medication-Assisted Opioid Treatment Proposed in Chapter 258 of the Acts of 2014

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Actuarial Assessment of the Mandate for Medication-Assisted Opioid Treatment Proposed in Chapter 258 of the Acts of 2014

Executive Summary

Section 32 of Chapter 258 of the Massachusetts Acts of 2014 (Chapter 258)¹ requires the Massachusetts Center for Health Information and Analysis (CHIA) to analyze potential legislation "mandating that insurance companies reimburse providers for medication assisted opioid treatment, such as methadone, buprenorphine and extended-release naltrexone." Massachusetts General Laws (M.G.L.) c.3 §38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by business and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect enactment of the proposed legislation would have on the cost of health care insurance in Massachusetts.

Chapter 258 outlines the general terms of the proposed mandate but does not specify to which insurance plans it would apply. This analysis will assume the proposed legislation, if enacted, will amend the statutes that regulate insurers providing health insurance in Massachusetts, applying the mandate to the full set of commercial insurance licenses, and to all plans offered by the Group Insurance Commission.

Background

Opioids are drugs that reduce pain signals to the brain,^{2,3} and may be prescribed to alleviate pain as well as to treat addiction.⁴ Medications in the opioid class include morphine, codeine, oxycodone (including brand names OxyContin® and Percocet®), hydrocodone (including brand name Vicodin®), methadone, buprenorphine, and fentanyl, among others.⁵ In the United States, heroin is classified as an illicit opioid.⁶ When properly prescribed and used, opioids can be safe and effective tools to manage pain. However, when used regularly or over a longer period of time they can lead to physical dependence. Abuse occurs when individuals use opioids outside of legitimate medical purposes to achieve the euphoric effect of the drug.

Substance addiction is a chronic illness in which the use of drugs or alcohol changes the structure and function of the brain,⁷ and "is distinguished by compulsive drug seeking and use despite sometimes devastating consequences." Medication-assisted treatment (MAT) is "any treatment for opioid addiction that includes the use of a medication approved by the U.S. Food and Drug Administration (FDA) for opioid addiction detoxification or maintenance treatment." MAT is a broad term that generally encompasses several different approaches to treatment, including detoxification, medically-supervised withdrawal, and maintenance therapy. The major medications used include: methadone, buprenorphine, buprenorphine/naloxone, and naltrexone. Significant evidence exists for the efficacy of MAT in treating opioid addiction, when used in a manner appropriate to a patient's individual history and needs.

Current coverage

In a recent survey of ten of the largest insurance carriers in Massachusetts, all reported coverage for medication-assisted opioid treatment. All carriers reported they cover buprenorphine/naloxone, buprenorphine, and naltrexone. However, not all carriers cover methadone maintenance treatment. Federal regulations require administration of methadone to occur at opioid treatment programs (OTPs, some of which may be commonly referred to as "methadone clinics"). One factor that may influence carrier decisions about whether to cover or how much to pay for methadone treatment is that the Department of Public Health may pay for methadone treatment at OTPs, including for patients with commercial coverage.

The language of Chapter 258's request to study the cost of requiring coverage for MAT, as written, requires coverage but does not explicitly address cost sharing for MAT, credentialing of OTPs in carrier networks, preauthorization requirements, or other standards an insurer might apply in deciding whether to approve MAT. Therefore this analysis assumes current cost-sharing, credentialing, and preauthorization rules will continue in effect, and any insurers responding to the mandate by adding methadone coverage can do so with similar conditions.

Analysis

As noted, all drugs commonly used for MAT are covered by all carriers with the exception of methadone, which is covered by some carriers, but not all. Therefore, any incremental impact on premiums of proposed legislation requiring coverage for MAT will stem from compelling methadone coverage by those carriers not currently covering it. This analysis assumes patients for whom methadone treatment might be appropriate but who have no methadone coverage either are receiving methadone treatment paid through a state-funded OTP, are paying out of pocket, or are receiving another treatment.

If a patient were receiving state-funded or self-funded methadone treatment through an OTP when his or her insurer began to cover methadone, that coverage would likely be subject to cost-sharing, credentialing, and preauthorization requirements generally similar to those currently in effect in policies offered by carriers who cover methadone. Commercial claim data from the Massachusetts All Payer Claim Database (APCD) show that, under these conditions, medical expense for methadone treatment for members who currently have methadone coverage (who represent approximately half of the membership of fully-insured plans) amounts to under a penny permember per-month (PMPM); furthermore, reimbursements insurers do make often cover only a quarter to a third of the cost of the service, with the rest borne by the patient or other sources, creating little incentive for even self-funded patients to access commercial coverage.

To the extent patients receiving another treatment would switch to methadone if their insurers added this coverage, any resulting increase in methadone treatment would be a substitute for other treatments and reduce utilization and associated costs of those other treatments.

ⁱ The great majority of carrier payments for MAT in the APCD are for buprenorphine/naloxone, which may be a substitute for methadone in some cases.

The analysis proceeded as follows:

- Summarize carriers' current MAT coverage
- Using the Massachusetts All Payer Claim Database (APCD), measure the per-user cost for methadone maintenance treatment for commercially-insured patients for carriers that cover this treatment
- Using the APCD, measure the cost for buprenorphine/naloxone on a per-user basis
- Compare the per-user cost of methadone treatment to the cost of buprenorphine/naloxone treatment
- Determine the change in claim expense if there is both (i) any material utilization shift from buprenorphine/naloxone to methadone, and (ii) any material change in cost per user for those carriers required to add methadone coverage

Any effect on incremental claim cost of the carriers adding methadone coverage would stem from the net effect of any increase in methadone treatment users, priced at the methadone average cost per user, minus any assumed related decrease in buprenorphine/naloxone users, priced at the buprenorphine/naloxone drug cost per user. Based on the 2009-2011 average cost per user measured in the APCD, a shift in use from buprenorphine/naloxone to methadone would have no material cost impact, as the cost per user for each product were very similar.

However, to the extent the costs of other related counseling services would add to the per-person cost of buprenorphine/naloxone treatment, that treatment would be more expensive than methadone. But since buprenorphine/naloxone is already covered by all carriers, if methadone treatment were indeed less expensive, carriers would almost certainly have voluntarily covered methadone; therefore mandated methadone coverage would not likely encourage more methadone utilization. The availability of public funding for methadone treatment for commercially-insured patients is a likely explanation for this apparent paradox, and suggests that requiring coverage alone is unlikely to increase paid claims by commercial insurers for methadone treatment since current policies related to credentialing, authorization, and cost sharing appear to restrain payments for larger carriers.

Recently, cost per user of methadone in the commercial population has dropped, but this appears to be at least in part related to a general reduction in claim payments for methadone treatment in the commercial population in recent years, which may be related to the availability of public funding. The sum total of all these considerations make it very unlikely that mandating MAT coverage alone will have a material impact on overall MAT spending in commercial insurance, and as a result, the outcome of the analysis for this proposed mandate is a zero dollar impact.

ⁱⁱ This is occurring despite reported large jumps in utilization of methadone treatment in publicly financed populations. It is possible that availability of payment from public sources has incentivized either lack of coverage or high levels of patient cost sharing for methadone treatment observed in the APCD for carriers covering methadone treatment.

Summary results

The analysis concluded that the incremental cost impact of the mandate for coverage of medication-assisted treatment for opioid addiction is immaterial and effectively zero over the time period 2015 to 2019. It will have no material effect on health insurance premiums over this five-year period. Carrier policies related to credentialing, authorization, and payment currently in place would not be affected, and continuation of these policies would be sufficient to maintain spending close to current levels even if coverage is mandated.

Executive Summary Endnotes

- 1. <u>Comprehensive maintenance</u>: Combines pharmacotherapy with a full program of assessment, psychosocial intervention, and support services; it is the approach with the greatest likelihood of long-term success for many patients.
- 2. Medical maintenance: Provided to stabilize patients and may include long-term provision of [an addiction treatment medication] with a reduction in clinic attendance and other services. A patient can receive medical maintenance at an OTP, after he or she is stabilized fully. The patient usually must complete a comprehensive treatment program first.... To reduce clinic attendance—a key feature of medical maintenance—patients must qualify, subject to variations in State regulations (which may be more stringent than Federal regulations), to receive 7- to 14-day supplies of methadone for take-home dosing after 1 year of continuous treatment and 15- to 30-day supplies after 2 years of continuous treatment in an OTP (if additional criteria are satisfied [see chapter 5]) (42 CFR, Part 8 § 12(h); Federal Register 66:4079).
- 3. <u>Interim maintenance</u>: Generally provided to patients awaiting admission to a comprehensive maintenance program.
- 4. <u>Detoxification</u>: Involves medication and, perhaps, counseling or other assistance to stabilize patients who are opioid addicted by withdrawing them in a controlled manner from the illicit opioids.
- 5. <u>Medically supervised withdrawal</u>: Involves the controlled tapering of treatment medication for patients who want to remain abstinent from opioids without the assistance of medication.

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⁴ Op. cit. NIH-NIDA: What are opioids?

⁵ Op. cit. NIH-NIDA: What are opioids?

⁶ U.S. Department of Justice, National Drug Intelligence Center. Heroin: Fast Facts. March 2013; accessed 21 November 2014: http://www.justice.gov/archive/ndic/pubs3/3843/#illegal.

⁷ National Institute of Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services (NIDA). Principles of Drug Addiction Treatment: A Research-Based Guide, Third Edition. NIH Publication No. 12–4180. Printed 1999, revised December 2012; accessed 29 August 2014: http://www.drugabuse.gov/sites/default/files/podat 1.pdf.

⁸ National Institutes of Health, National Institute on Drug Abuse (NIH-NIDA): How do opioids affect the brain and body? Accessed 19 December 2014: http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/how-do-opioids-affect-brain-body.

⁹ U.S. Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (SAMHSA-CSAT). Treatment Improvement Protocol (TIP) Series, No. 43: Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs (TIP 43). Published 2005; accessed 15 October 2014: http://www.ncbi.nlm.nih.gov/books/NBK64168/.

¹⁰ Op. cit. SAMHSA-CSAT. TIP 43.

Actuarial Assessment of the Mandate for Medication Assisted Opioid Treatment Proposed in Chapter 258 of the Acts of 2014

1. Introduction

Section 32 of Chapter 258 of the Massachusetts Acts of 2014 (Chapter 258)¹ requires the Massachusetts Center for Health Information and Analysis (CHIA) to analyze potential legislation "mandating that insurance companies reimburse providers for medication assisted opioid treatment, such as methadone, buprenorphine and extended-release naltrexone."

Massachusetts General Laws (M.G.L.) c.3 §38C charges the Massachusetts Center for Health Information and Analysis (CHIA) with reviewing the potential impact of proposed mandated health care insurance benefits on the premiums paid by business and consumers. CHIA has engaged Compass Health Analytics, Inc. to provide an actuarial estimate of the effect enactment of the proposed legislation would have on the cost of health care insurance in Massachusetts.

Assessing the impact of this potential legislation entails analyzing the incremental effect of the legislation on spending by insurance plans. This in turn requires comparing spending under the provisions of the proposed law to spending under current statutes and current benefit plans for the relevant services.

Section 2 of this analysis outlines the provisions of the proposed legislation. Section 3 summarizes the methodology used for the estimate. Section 4 discusses important considerations in translating the legislation's language into estimates of its incremental impact on health care costs and steps through the analysis of the calculations. Section 5 summarizes the results.

2. Interpretation of the Proposed Mandate

The following subsections describe the provisions of the proposed legislation.

2.1. Plans affected by the proposed mandate

Chapter 258 outlines the general terms of the proposed mandate but does not specify to which insurance plans it would apply. This analysis will assume the proposed legislation, if enacted, will amend the statutes that regulate insurers providing health insurance in Massachusetts, applying the mandate to the full set of commercial insurance licenses and all plans offered by the Group Insurance Commission, as listed below.

- Insurance for persons in service of the Commonwealth (amending M.G.L. c. 32A)
- Accident and sickness insurance policies (amending M.G.L. c. 175)
- Contracts with non-profit hospital service corporations (amending M.G.L. c. 176A)

- Certificates under medical service agreements (amending M.G.L. c. 176B)
- Health maintenance contracts (amending M.G.L. 176G)

The analysis assumes the proposed legislation requires coverage for members under the relevant plans regardless of whether they reside within the Commonwealth or merely have their principal place of employment in the Commonwealth.

Self-insured plans, except for those managed by the GIC, are not subject to state-level health insurance benefit mandates. State mandates do not apply to Medicare, and this analysis assumes this proposed mandate does not affect Medicare extension/supplement plans even to the extent they are regulated by state law. This analysis will not consider potential impact on Medicaid/MassHealth.

This analysis assumes the proposed legislation, if enacted, would be effective for policies issued or renewed on or after October 1, 2015, consistent with the effective date of mandate provisions already enacted in Chapter 258.

2.2. Opioid abuse and medication-assisted treatment

Opioid use, dependence, addiction, and abuse

Opioids are drugs that reduce pain signals to the brain,^{2,3} and may be prescribed to alleviate pain from injuries, surgeries, dental procedures, and acute and chronic illnesses as well as to treat addiction.⁴ Medications in the opioid class include morphine, codeine, oxycodone (including brand names OxyContin® and Percocet®), hydrocodone (including brand name Vicodin®), methadone, buprenorphine, and fentanyl, among others.⁵ In the United States, heroin is classified as an illicit opioid.⁶

When properly prescribed and used opioids can be safe and effective tools to manage pain. However, when used regularly or over a longer period of time they can lead to physical dependence. Abuse occurs when individuals use opioids outside of legitimate medical purposes to achieve the euphoric effect of the drug. Substance addiction is a chronic illness in which the use of drugs or alcohol changes the structure and function of the brain,⁷ and "is distinguished by compulsive drug seeking and use despite sometimes devastating consequences."

Medication-assisted treatment for opioid addiction

Medication-assisted treatment (MAT) is "any treatment for opioid addiction that includes the use of a medication approved by the U.S. Food and Drug Administration (FDA) for opioid addiction detoxification or maintenance treatment." MAT is a broad term that generally encompasses several different approaches to treatment, including detoxification, medically-supervised withdrawal, and maintenance therapy. Major medications used when treating opioid addiction include:

Methadone

- Buprenorphine
- Buprenorphine/Naloxone
- Naltrexone

Methadone and buprenorphine are synthetic opioids, while naloxone and naltrexone are antagonists that block the effects of opioids.

Significant evidence exists for the efficacy of MAT in treating opioid addiction, when used in a manner appropriate for a patient's individual history and needs. See the medical efficacy review of MAT for more detail on these drugs and their efficacy.

2.3. Current coverage

In a recent survey of ten of the largest insurance carriers in Massachusetts, all reported coverage for medication-assisted opioid treatment. All carriers reported they cover buprenorphine/naloxone (the most commonly prescribed MAT), buprenorphine, and naltrexone. However, not all carriers cover methadone maintenance treatment; about 35 percent of fully-insured membership has no coverage for methadone treatment. Federal regulations require administration of methadone to occur at opioid treatment programs (OTPs, some of which may be commonly referred to as "methadone clinics"). Some carriers may not cover methadone treatment because state agencies, notably the Department of Public Health, may pay for it, including for patients with commercial coverage.

The language of the proposed mandate, as written, does not explicitly address credentialing, authorization, or cost-sharing policies for MAT. Therefore this analysis assumes current credentialing, authorization, and cost-sharing rules will continue in effect, and any insurers responding to the mandate by adding methadone coverage can do so with similar conditions.

2.4. Other laws affecting medication-assisted opioid treatment

To the extent coverage for MAT is already required by federal or state law, it does not contribute to the incremental effect of this proposed legislation on premiums.

The Massachusetts mental health parity statutes

The Massachusetts mental health parity statutes¹¹ require insurers to cover biologically-based mental disorders, including substance abuse disorders. Subsection (g) of the relevant chapters specifies the range of inpatient, intermediate, and outpatient services for which coverage is required and the types of settings, including mental health or substance abuse clinics, in which they may be provided.

¹ The Bureau of Substance Abuse Services reports that some of its methadone expenditure is for persons with commercial coverage. Interview with H. Jacobs, Senior Policy Advisor, Commissioner's Office, Bureau of Substance Abuse Services. December 17, 2014.

The statutes further provide that "psychopharmacological services...shall be treated as a medical benefit and shall be covered in a manner identical to all other medical services." The statutes do not further define "psychopharmacological services" and whether those services include drugs themselves or simply medical management, nor do the statutes define whether the full set of agonist and antagonist drugs used in MAT are consider psycho-pharmaceuticals. As noted, not all insurers currently cover all drugs identified in the proposed legislation. This analysis assumes insurers are following current interpretation of the parity law and that it does not require coverage for all these drugs.

Provisions of Chapter 258 prohibiting preauthorization

Chapter 258 contains provisions, effective in October 2015, that will prohibit insurers from requiring preauthorization for services across the full spectrum of substance abuse treatment, defined to include "outpatient services including medically assisted therapies...." However, this analysis assumes the enacted preauthorization requirement only applies when coverage is provided, and that the preauthorization provision does not in itself require coverage for drugs used in MAT. The subject of the present analysis, per Chapter 258, is to assess the cost if such a provision requiring coverage were to be enacted. We note also that the scope of "medically-assisted therapies" in the preauthorization requirement does not explicitly include drugs, and in any case, based on a plain language interpretation, the equivalence of "medically assisted therapies" and "medication assisted treatment" is ambiguous at best.

3. Methodology

3.1. Overview

As noted, all drugs commonly used for MAT are covered by all carriers with the exception of methadone, which is covered by some carriers, but not all. Therefore, any incremental impact on premiums of proposed legislation requiring coverage for MAT will stem from compelling methadone coverage by those carriers not currently covering it. This analysis assumes patients for whom methadone treatment might be appropriate but who have no methadone coverage either are receiving methadone treatment paid through a state-funded OTP or self-paid, or are receiving another treatment.

If a patient were receiving state-funded or self-funded methadone treatment through an OTP when his or her insurer were to begin to cover methadone, coverage will be subject to credentialing, authorization, and payment policies generally similar to those currently in effect in policies from carriers who cover methadone. APCD data show that, under these conditions, medical expense for methadone treatment for members who currently have methadone coverage (who represent over 50 percent of the membership of full-insured plans) amounts to under a penny per-member per-

month (PMPM), and often has patient cost sharing of approximately three times the payment covered by insurance.ⁱⁱ

As noted, buprenorphine/naloxone is the most commonly used MAT in the fully-insured population, but were this proposed mandate to be enacted, requiring coverage for methadone, it would open up the possibility of some patients switching to methadone. Whether or not switching actually occurs, to the extent patients receiving another treatment switch, any resulting increase in methadone treatment would be a substitute for other treatments and reduce utilization and expense for those other treatments.

3.2. Steps in the analysis

The general approach outlined above was executed in the following steps.

- Summarize carriers' current MAT coverage
- Using the Massachusetts All Payer Claim Database (APCD), measure the cost for methadone maintenance treatment for commercially-insured patients on a per-user basis for carriers that cover this treatment
- Using the APCD, measure the cost for buprenorphine/naloxone on a per-user basis
- Compare the per-user cost of methadone treatment to the cost of buprenorphine/naloxone treatment
- Determine change in claim expense if there is any material utilization shift from buprenorphine/naloxone to methadone and any material change in cost per user for those carriers required to add methadone coverage

Section 4 describes these specific steps in more detail.

3.3. Data sources

The primary data sources used in the analysis were:

- Information from a survey of private health insurance carriers in Massachusetts
- Academic literature, published reports, and population data, cited as appropriate
- Massachusetts insurer claim data from the Massachusetts All Payer Claims Database (APCD) for calendar years 2009 to 2012, for plans covering the overwhelming majority of the under-65 fully-insured population subject to the proposed mandate¹³

ii APCD data show that for most members with methadone coverage who utilize covered methadone treatment, the carrier pays roughly one quarter to one third of the amount allowed under the payer's contract with the provider for the service, with the rest paid by other sources, including the member. This practice, presumably along with credentialing and preauthorization criteria that tend to support patients' utilization of other treatments, contributes to the low PMPM.

The more detailed step-by-step description of the estimation process described below addresses limitations in some of these sources and the uncertainties they contribute to the cost estimate.

3.4. Limitations

Available information on coverage from the carrier survey and multi-year detailed claim history provide a relatively clear picture of the current coverage and costs and the likely impact of requiring coverage. To the extent that carriers currently not covering methadone have average patient treatment profiles different than those covering methadone, the impact of the legislation may differ slightly from that presented in this analysis, but the difference is not likely to be material when viewed at the level of the overall fully-insured commercial market.

4. Analysis

This section describes in detail the calculations outlined in the previous section.

4.1. Current coverage of medication-assisted opioid treatment

Responses to the survey of carriers concerning Chapter 258 indicated that carriers cover MAT products. All carriers except two covered all products, with those two carriers covering all products except methadone. Therefore, the proposed mandate would add coverage for methadone for these two carriers, who together serve roughly one third of fully-insured members. For carriers that do cover methadone, there is significant variation around the average \$0.20 per-member permonth (PMPM) claim expenditure, ranging from \$0.001 to \$2.94. The low-end PMPM is from a large carrier that indicated in the survey that it covers methadone, but rarely pays for it as reflected in claim data. This may suggest the carrier uses preauthorization or other processes to support other products, notably buprenorphine/naloxone, or that the high cost sharing apparent in the claim data for methadone discourages using insurance coverage for treatment and makes accessing treatment provided through Department of Public Health funding more attractive. The methadone PMPM claim costs are higher among those plans whose commercial business is concentrated in Connector products, which might suggest differences in population attributes. As those plans are also more likely to have Medicaid managed care business, they may be more familiar with methadone treatment and methadone providers. It is not clear to what extent each of these, or other, factors may explain the variation in methadone PMPM expense among carriers.

4.2. Per-member and per-user costs for treatments

Table 1 displays the 2012 PMPM cost of MAT products for membership with methadone coverage (\$0.81 PMPM in total) and for the entire fully-insured market, with or without methadone coverage (\$0.74 PMPM).

Table 1 2012 PMPM Cost of MAT Products for Fully-Insured Commercial Population

	Covered Products		Total Market	
	% of Members	<u>PMPM</u>	% of Members	PMPM
Methadone	64.9%	\$0.20	100.0%	\$0.13
Buprenorphine	100.0%	\$0.01	100.0%	\$0.01
Naloxone	100.0%	\$0.00	100.0%	\$0.00
Buprenorphine/	100.0%	\$0.58	100.0%	\$0.58
Naloxone				
Naltrexone	100.0%	\$0.02	100.0%	\$0.02
Total		\$0.81		\$0.74

Over the period from 2009 to 2012, per-member spending on MATs increased at an average annual rate of 15.4 percent. However, the number of users of methadone reflected in commercial claims decreased by 26 percent over the same period (despite rapid increase in methadone use at provider sites), an annual rate of decrease of approximately 8 percent, while buprenorphine/naloxone users increased by 16 percent annually.

The effect on incremental claim cost of two carriers adding methadone coverage (which would affect approximately 35 percent of commercial fully-insured membership) would stem from the net effect of an increase in methadone treatment users, priced at the average cost per methadone patient, minus the assumed related decrease in buprenorphine/naloxone users, priced at the buprenorphine/naloxone cost per user. In analyzing the average cost per user, the APCD shows a 2012 average annual cost per user for buprenorphine/naloxone of \$2,357. The average cost per user for methadone has shifted over time, averaging \$2,435 for the period 2009 to 2011, but dropping in the 2012 APCD to \$1,704.

Based on the 2009-2011 average cost per user, a shift in use from buprenorphine/naloxone to methadone would have no material cost impact regardless of the number of users shifting to methadone. Based on the 2012 figure, the shift to methadone would save money rather than cost money. That is, the incremental impact of the mandate would be negative, saving carriers money.

To the extent that there are additional costs for buprenorphine/naloxone for other related counseling services this would make buprenorphine/naloxone more expensive than methadone. But since buprenorphine/naloxone is already covered by all carriers, if methadone treatment were indeed less expensive, carriers would almost certainly have voluntarily covered methadone; therefore mandated methadone coverage would not likely encourage more methadone utilization. The availability of public funding for methadone treatment for commercially insured patients is a likely explanation for this apparent paradox, and suggests that requiring coverage alone is unlikely to increase paid claims by commercial insurers for methadone treatment. Impacting expenditures would be more likely if additional provisions related to cost sharing, credentialing, and preauthorization were addressed.

In addition, evidence from existing spending discussed above indicates that carriers covering methadone approve it for use only rarely. As a result, it is not clear that methadone use would increase materially even if there were a cost differential between buprenorphine/naloxone and methadone.

The large majority of spending described by the proposed MAT mandate in Chapter 258 is already being provided by carriers. The relatively small portion not provided by carriers is for methadone coverage, but the costs per user of methadone treatment (including the required dispensing, testing, and counseling services accompanying it) and its primary alternative buprenorphine/naloxone are similar.ⁱⁱⁱ In this analysis there were some limitations in identifying within the APCD all the services related to managing buprenorphine/naloxone and providing associated counseling. To the extent costs associated with buprenorphine/naloxone are even higher than measured, a shift to methadone still does not contribute an incremental increase in medical expense, but in fact a decrease.^{iv} As noted, absent other changes, a more likely outcome is continued accessing of publicly-funded methadone treatment.

The sum total of all these considerations make it very unlikely that mandating MAT coverage alone will have a material impact on overall MAT spending in commercial insurance, and as a result, the outcome of this analysis is a zero dollar impact for this proposed mandate.

4.3. Incremental cost calculation

Based on the foregoing analysis, the estimate of the incremental effect of this mandate on average commercial fully-insured medical expense and premiums is zero.

5. Results

The estimated incremental cost impact of the mandate for coverage of medication assisted treatment for opioid addiction is immaterial and effectively zero over the time period 2015 to 2019. It will have no material effect on commercial fully-insured health insurance premiums over this five-year period. Note that while the effect on the average fully-insured member is immaterial, the impact of the proposed legislation on any one carrier may be sufficiently large as a proportion of that carrier's premiums to be noticeable, depending on its current benefit offering. In general, carrier policies related to credentialing, authorization, and payment currently in place would not be affected and continuation of these policies would be sufficient to maintain spending close to the current status quo even if coverage is mandated.

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iii The Massachusetts APCD in 2012 indicates that 94% of spending on MATs for commercial patients was for buprenorphine.

^{iv} And it is likely insurers would have already covered methadone and encouraged its use if they expected to save money by doing so.

Endnotes

¹ Massachusetts Acts of 2014, Chapter 258, Section 32 "An Act to Increase Opportunities for Long-Term Substance Abuse Recovery". Accessed 2 October 2014: https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter258.

- 1. <u>Comprehensive maintenance</u>: Combines pharmacotherapy with a full program of assessment, psychosocial intervention, and support services; it is the approach with the greatest likelihood of long-term success for many patients.
- 2. Medical maintenance: Provided to stabilize patients and may include long-term provision of [an addiction treatment medication] with a reduction in clinic attendance and other services. A patient can receive medical maintenance at an OTP, after he or she is stabilized fully. The patient usually must complete a comprehensive treatment program first.... To reduce clinic attendance—a key feature of medical maintenance—patients must qualify, subject to variations in State regulations (which may be more stringent than Federal regulations), to receive 7- to 14-day supplies of methadone for take-home dosing after 1 year of continuous treatment and 15- to 30-day supplies after 2 years of continuous treatment in an OTP (if additional criteria are satisfied [see chapter 5]) (42 CFR, Part 8 § 12(h); Federal Register 66:4079).
- 3. <u>Interim maintenance</u>: Generally provided to patients awaiting admission to a comprehensive maintenance program.
- 4. <u>Detoxification</u>: Involves medication and, perhaps, counseling or other assistance to stabilize patients who are opioid addicted by withdrawing them in a controlled manner from the illicit opioids.
- 5. <u>Medically supervised withdrawal</u>: Involves the controlled tapering of treatment medication for patients who want to remain abstinent from opioids without the assistance of medication.

² National Institutes of Health, National Institute on Drug Abuse (NIH-NIDA): Prescription Drug Abuse, What are opioids? Accessed 2 July 2014: http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/what-are-opioids.

³ NIH-NIDA: Prescription Drug Abuse, What are the possible consequences of opioid use and abuse? Accessed 24 October 2014: http://www.drugabuse.gov/publications/prescription-drugs-abuse-addiction/opioids/what-are-possible-consequences-opioid-use-abuse.

⁴ Op. cit. NIH-NIDA: What are opioids?

⁵ Op. cit. NIH-NIDA: What are opioids?

⁶ U.S. Department of Justice, National Drug Intelligence Center. Heroin: Fast Facts. March 2013; accessed 21 November 2014: http://www.justice.gov/archive/ndic/pubs3/3843/#illegal.

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⁸ National Institutes of Health, National Institute on Drug Abuse (NIH-NIDA): How do opioids affect the brain and body? Accessed 19 December 2014: http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/how-do-opioids-affect-brain-body.

⁹ U.S. Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment (SAMHSA-CSAT). Treatment Improvement Protocol (TIP) Series, No. 43: Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs (TIP 43). Published 2005; accessed 15 October 2014: http://www.ncbi.nlm.nih.gov/books/NBK64168/.

¹⁰ Op. cit. SAMHSA-CSAT. TIP 43.

¹¹ M.G.L. c.32A §22, c.175 §47B, c.176A §8A, c.176B §4A, c.176G §4M.

¹² Massachusetts Acts of 2014, Chapter 258, "An Act to Increase Opportunities for Long-Term Substance Abuse Recovery", Sections 9, 21, 23, 25, and 27. Accessed 2 October 2014: https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter258.

lore information can be found at http://www.mass.gov/chia/researcher/hcf-data-resources/apcd/.			

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