Office of the Inspector General
Commonwealth of Massachusetts

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MassHealth's Administration of Certain Medicaid and Health Safety Net Schedule II Drug Claims

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Executive Summary

At the direction of the Legislature, the Office of the Inspector General for the Commonwealth of Massachusetts ("Office") has studied the administration of the Massachusetts Medicaid ("Medicaid" or "MassHealth") and the Health Safety Net ("HSN") programs by MassHealth, the state entity that runs both programs. The Office examined how Medicaid and the HSN manage fee-for-service claims for certain drugs, with a focus on those drugs that have a high potential for abuse. These drugs include drug treatment agents such as buprenorphine and methadone, painkillers such as morphine and oxycodone, sedatives such as certain benzodiazepines, and stimulants such as amphetamines.

This review included over 800,000 paid prescription claims for MassHealth members and HSN users. Because MassHealth is responsible for processing both Medicaid and HSN prescription drug claims, the review looked at the combined utilization patterns for these two programs. The Office used data analytics to examine patterns relating to certain prescription drug claims to evaluate whether there are ways for MassHealth to detect fraud, waste, and abuse through robust claim analysis. The Office also noted what policies and practices the Medicaid and HSN programs have in place relating to the prescribing and dispensing of certain drugs, and compared these policies and practices with three other insurance programs (Connecticut Medicaid, Tufts Health Plan, and Medicare).

MassHealth has recently taken important steps by lowering the dose of opioids that will require prior authorization and by requiring prior authorization for new methadone prescriptions. However, the Office also found that MassHealth could better use claims data to target fraud, waste, and abuse relating to prescription drugs in both the Medicaid and HSN programs. Using data analytics is an effective way to focus on a particular subset of MassHealth members or HSN users who are, for example, using a particular drug or drug combination, and then to determine whether the treatment is clinically appropriate. Data analytics is also an effective tool for identifying patterns of prescribing and dispensing controlled substances that could indicate fraud or abuse.

Further, the Office found that MassHealth could take additional steps to more effectively manage claims for prescription drugs that have a high potential for abuse. Specifically, the Office recommends the following:

- MassHealth and the HSN should expand their use of the morphine equivalent dose ("MED") to identify possible opioid abuse. The MED allows for an "apples-to-apples" comparison of different kinds and amounts of opioids.
- MassHealth should require prior authorization for all prescriptions for 30 mg short-acting oxycodone tablets.
- MassHealth should require prior authorization for all methadone prescriptions for pain.
- MassHealth should put steps in place to reduce the number of members receiving prescriptions for methadone from a pharmacy after leaving a methadone treatment program.

- MassHealth should evaluate the efficacy of the Controlled Substance Management Program and either strengthen the program or consider an alternative.
- MassHealth should increase its use of the Department of Public Health's Prescription Drug Monitoring Program and should work with the Department to educate providers and pharmacies about how to use this program effectively.
- MassHealth should increase the number of members it refers to the Massachusetts Behavioral Health Partnership.

Background

I. The Office of the Inspector General

Created in 1981, the Office of the Inspector General for the Commonwealth of Massachusetts ("Office") was the first state inspector general's office in the country. The Legislature created the Office at the recommendation of the Special Commission on State and County Buildings, a legislative commission that spent two years probing corruption in the construction of public buildings in Massachusetts. The commission's findings helped shape the Office's broad statutory mandate, which is the prevention and detection of fraud, waste, and abuse in the expenditure of public funds and the use of public property. In keeping with this mandate, the Office investigates allegations of fraud, waste, and abuse at all levels of government; reviews programs and practices in state and local agencies to identify systemic vulnerabilities and opportunities for improvement; and provides assistance to the public and private sectors to help prevent fraud, waste, and abuse in government spending.

The Office has considerable experience reviewing healthcare programs that have eligibility, documentation, and verification components and has issued a number of analyses, reports, and recommendations regarding Medicaid, the HSN program, healthcare reform, and other healthcare topics. The Office also has expertise in developing fraud-control practices for state agencies and municipalities.

In July 2015, the Legislature enacted chapter 46 of the Acts of 2015. Section 146 of that law directed the Office to study and review the Massachusetts Medicaid ("Medicaid" or "MassHealth") and Health Safety Net ("HSN") programs:

> Notwithstanding any general or special law to the contrary, in hospital fiscal year 2016, the office of inspector general may expend a total of $1,000,000 from the Health Safety Net Trust Fund established in section 66 of chapter 118E of the General Laws for costs associated with maintaining a health safety net audit unit within the office. The unit shall continue to oversee and examine the practices in all hospitals including, but not limited to, the care of the uninsured and the resulting free charges. The unit shall also study and review the Medicaid program under said chapter 118E including, but not limited to, reviewing the program's eligibility requirements, utilization, claims administration and compliance with federal mandates. The inspector general shall submit a report to the house and senate committees on ways and means on the results of the audits and any other completed analyses on or before March 1, 2016.

Pursuant to this mandate, the Office conducted a review of MassHealth and HSN paid claims for certain drugs during fiscal year 2013 (July 1, 2012 through June 30, 2013). In particular, the Office studied approximately 800,000 fee-for-service paid prescription claims for Schedule II drugs along with several other types of drugs that are often used in conjunction with Schedule II drugs. The broad goals of this review were to use data analytics to understand patterns relating to certain prescription drug claims that could help detect fraud, waste, and abuse; to consider whether individuals were receiving certain drugs in a clinically appropriate

manner; and to compare the MassHealth and Health Safety Net programs with other payors. Because MassHealth is responsible for processing both Medicaid and HSN prescription drug claims, the review examined the combined utilization patterns for these two programs. For ease of reference, the Office will refer to people who utilize these programs as "MassHealth members" and "HSN users."

II. The Medicaid Program

The federal government created the Medicaid program in 1965 to provide medical assistance to low-income Americans, particularly children, through a shared state-federal commitment. Today, Medicaid pays for medical care, as well as long-term nursing and other care, for tens of millions of Americans. At the federal level, the Centers for Medicare & Medicaid Services ("CMS") administers the program. Each state administers its own version of Medicaid in accordance with a CMS-approved state plan. Although the states have considerable flexibility in designing and operating their Medicaid programs, they must comply with applicable federal and state laws and regulations. Accordingly, MassHealth must administer Medicaid in a manner that is consistent with federal guidelines that beneficiaries must meet and mandates with which the state must comply. The federal guidelines always take precedence over the state guidelines, as the federal guidelines set the minimum requirements that each state must follow. In Massachusetts, the Executive Office of Health and Human Services includes the Office of Medicaid ("MassHealth"), which oversees the Medicaid program.

A. MassHealth

1. Overview of MassHealth categories and coverage

Medicaid provides healthcare coverage for certain individuals who would not otherwise have access to such coverage. Although it is partially funded by the federal government, the Commonwealth is responsible for administering the program. As the administrator, MassHealth must ensure that the program meets both federal and state mandates. With permission from the federal government, the Commonwealth may create programs that broaden payment for healthcare services to include more residents who do not meet all the federal Medicaid standards. MassHealth currently administers seven different types of Medicaid programs and five additional non-Medicaid benefit programs. The MassHealth Medicaid programs are:

1. MassHealth Standard: for pregnant women, children, parents, caretaker relatives, young adults, disabled individuals, certain individuals who are HIV positive, individuals with breast or cervical cancer, independent foster care adolescents, Department of Mental Health members, and medically frail individuals;
2. CommonHealth: for disabled adults, disabled young adults, and disabled children who are not eligible for MassHealth Standard;
3. CarePlus: for adults 21 through 64 years of age who are not eligible for MassHealth Standard;

4. Family Assistance: for children, young adults, certain noncitizens, and individuals who are HIV positive who are not eligible for MassHealth Standard, CommonHealth, or CarePlus;

5. Small Business Employee Premium Assistance: for adults or young adults who work for small employers; are not eligible for MassHealth Standard, CommonHealth, Family Assistance, or CarePlus; do not have anyone in their family who is otherwise receiving a premium assistance benefit; and have been determined to be ineligible for a qualified health plan;

6. MassHealth Limited: for certain lawfully present immigrants, nonqualified persons residing under color of law, and certain other noncitizens; and

7. Senior Buy-In and Buy-In: for certain Medicare beneficiaries.[1]

The five additional non-Medicaid benefit programs are the Health Safety Net Program (for hospital and community health center expenses associated with providing care to underinsured and uninsured individuals), the Children's Medical Security Plan (provides certain uninsured children and adolescents with primary and preventive services), the Healthy Start Program (promotes early, comprehensive, and continuous prenatal care to low-income, uninsured pregnant women), the Insurance Partnership (makes health insurance more affordable for qualified small businesses and their employees), and the Special Kids/Special Care Pilot Program (provides coordinated medical care to children in foster care with special healthcare needs).

2. Prescription drug coverage[2]

MassHealth pays for prescription drugs, over-the-counter drugs, and other non-drug items (*e.g.*, blood testing supplies) for eligible MassHealth members, subject to certain restrictions depending on the program in which the member is enrolled.[3] MassHealth requires prescribers to issue prescriptions for a 30-day supply of drugs, unless the drug is available only in a larger package size or the prescriber determines that it would not be clinically appropriate to do so.[4] MassHealth will pay for a maximum of 11 monthly refills, except in specified circumstances. A pharmacy may not refill a prescription unless the MassHealth member requests the refill. MassHealth requires that its members obtain prior authorization for enumerated doses and formulations of certain drugs.

3. Controlled Substance Management Program

Many insurers use a "lock-in" program to combat potential abuse and misuse of controlled substances. A lock-in program can restrict a person to using only one designated

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[1] 130 CMR 505.001(A).

[2] 130 CMR 406.000 et seq.

[3] 130 CMR 450.105(A).

[4] There are limited additional exceptions to this rule.

prescriber or pharmacy as a way of reducing the use of multiple providers who may not know what other medications the person is taking. Medicaid lock-in programs currently operate in 46 states. MassHealth's lock-in program is called the Controlled Substance Management Program ("CSMP"). MassHealth may enroll a member in this program if the member is using an "excessive quantity" of prescribed drugs. MassHealth defines an "excessive quantity" as:

- 11 or more prescriptions, including the original fill and refills, of one or more controlled substances (including Schedule II drugs);
- during a three-month period; and
- obtained from four or more prescribers or filled by four or more pharmacies.

Before assigning a member to the CSMP, MassHealth reviews the member's claim history to determine whether there are legitimate, clinical reasons for the pattern of prescribing and dispensing.

For each person enrolled in the CSMP, MassHealth chooses one primary pharmacy. Once in the CSMP, the MassHealth member may only fill prescriptions at the primary pharmacy and only the primary pharmacy may receive payment from MassHealth for that member's prescriptions, with two exceptions. A pharmacy other than the primary pharmacy can dispense and receive payment for (1) a nonrefillable supply of a drug if the person's health or safety would be jeopardized without immediate access to the drug; or (2) a drug for family planning. MassHealth may also allow a non-designated pharmacy to fill a prescription in unique circumstances (*e.g.*, the designated pharmacy does not have a medication in stock or the member is receiving services far away from the designated pharmacy). MassHealth's claim processing system is designed to alert a pharmacy when a CSMP enrollee is trying to fill a prescription.

It is the primary pharmacy's responsibility to monitor the prescription utilization pattern of each person in the CSMP and to determine when a person is presenting a prescription that is appropriate for his medical condition. If the pharmacist at the primary pharmacy "reasonably believes" that the prescription is inappropriate for the person's medical condition, the pharmacist must contact the prescriber to verify the authenticity, accuracy, and appropriateness of the prescription. If a primary pharmacy is dispensing drugs in a manner that is inconsistent with professional standards, MassHealth may subject the pharmacy to administrative sanctions. The Office received the list of CSMP members for the time period under review from MassHealth and included those members in a separate part of this review.

III. The Health Safety Net

In 1985, the Legislature created the uncompensated care pool ("UCP") with the goal of "more equitably distributing the burden of financing uncompensated acute hospital services across all acute hospitals[.]" G.L. c. 6A, § 75 (repealed 1988). The purpose of the UCP was to pay for medically necessary services that acute care hospitals and community health centers provided to eligible low-income uninsured and underinsured patients. In addition, the UCP reimbursed hospitals for emergency services for uninsured patients for whom the hospitals were unable to collect payment. In 2006, the Legislature created the Health Safety Net ("HSN")

program, funded by the Health Safety Net Trust Fund, to replace the UCP. The stated purpose of the HSN program was to "maintain a healthcare safety net by reimbursing hospitals and community health centers for a portion of the cost of reimbursable health services provided to low-income, uninsured or underinsured residents of the commonwealth." Initially, the Division of Healthcare Finance and Policy managed the HSN program, but in 2012 the Legislature transferred that responsibility to the Office of Medicaid ("MassHealth") within the Executive Office of Health and Human Services. MassHealth in turn created the HSN Office to oversee the HSN program.

There are three categories of services for which the HSN program pays: (1) health services to low-income patients; (2) medical hardship for individuals whose medical expenses have so depleted their income that they are no longer able to pay for services; and (3) bad debt arising from accounts receivable that hospitals and community health centers have tried to collect without success. The HSN program pays only for services that are medically necessary and for which no other public or private payor is responsible. With regard to pharmaceuticals, the HSN pays for pharmacy services and MassHealth processes HSN pharmacy claims in the same way as it processes MassHealth pharmacy claims.

IV. The Office's Review of Certain Prescription Drug Claims

In light of the provisions of section 146 that directed the Office to study and review the Massachusetts Medicaid and HSN programs, the Office conducted a review to understand the programs' oversight of paid claims for Schedule II drugs, along with several other types of drugs that are often used in conjunction with Schedule II drugs.

A. Federal Drug Administration Drug Schedules

The Federal Drug Administration ("FDA") classifies drugs, substances, and certain chemicals used to make drugs into distinct categories, or schedules, depending on the drug's acceptable medical use and the drug's abuse or dependency potential. The FDA considers Schedule I drugs to be the most dangerous class of drugs with a high potential for abuse and potentially severe psychological or physical dependence. These drugs have no currently accepted medical use and include drugs such as heroin, LSD, ecstasy, and peyote. Schedule II drugs have a high potential for abuse, although less potential than Schedule I drugs, with misuse potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous and include cocaine, methamphetamine, methadone, oxycodone, Ritalin, and Adderall. Schedule III drugs have a moderate-to-low potential for physical and psychological dependence, and include such drugs as Tylenol with codeine, ketamine, anabolic steroids, and testosterone. Schedules IV and V include drugs with low potential for abuse or dependence and include drugs such as Xanax, Ambien, and Lyrica. Schedule VI drugs are prescription drugs that are not included in another schedule.

B. Paid Fee-for-Service Claims for Prescriptions

This review examined paid claims for 880,032 prescriptions for 176,763 individuals during fiscal year 2013. MassHealth and the HSN paid approximately $46 million for these claims. These paid prescription claims are a subset of all MassHealth and HSN prescription drug claims, with a focus on paid claims for Schedule II drugs and other drugs that are often used or abused in conjunction with Schedule II drugs. The review combined the utilization patterns for both MassHealth and HSN prescription drug claims because MassHealth processes the claims for both programs.

The average age of a person with a prescription drug claim in this review was 38 years old. There were 26,668 people (15%) under the age of 18 and the oldest person was 104 years old. The minimum number of paid prescription claims per person was 1; the maximum number for one person was 115. The following tables provide a summary of the drugs included in this review. There were 801,172 prescriptions for Schedule II drugs as well as 78,860 prescriptions for certain Schedule III and IV drugs, which were included because of their potential for abuse or potential interaction with Schedule II drugs.

Schedule II Opioids	
DRUG	**PRESCRIPTION COUNT**
OXYCODONE	336,458
HYDROCODONE	114,697
MORPHINE	40,560
CODEINE	36,444
METHADONE	20,598
HYDROMORPHONE	14,384
FENTANYL	8,286
TAPENTADOL	386
OXYMORPHONE	374
OPIUM	197
MEPERIDINE	172
LEVORPHANOL	50
TOTAL	**572,606**

Table 1: Schedule II Opioids

Schedule II Stimulants	
DRUG	**PRESCRIPTION COUNT**
MIXED AMPHETAMINE SALTS	125,573
METHYLPHENIDATE	100,572
DEXMETHYLPHENIDATE	21,851
LISDEXAMFETAMINE	16,631
DEXTROAMPHETAMINE	378
METHAMPHETAMINE	5
TOTAL	**265,010**

Table 2: Schedule II Stimulants

Schedule III & IV Drugs	
DRUG	**PRESCRIPTION COUNT**
BUPRENORPHINE	32,177
ANDROGEL GEL	3,651
BUTALBITAL COMBINATION TABLET	2,527
TESTOSTERONE INJECTABLE	1,817
TESTIM GEL	1,485
DRONABINOL	555
MISCELLANEOUS	204
TOTAL	**42,416**

Table 3: Schedule III & IV Drugs

For certain individuals whose paid claims indicated that they had used a large amount of Schedule II drugs, the review included a licensed pharmacist's examination of a detailed report from MassHealth – "All Services Report By Member" – that lists all of a person's paid claims over time. The All Services Report By Member includes the types of treatment a person has undergone, kinds of providers who have treated a person, and the diagnoses that a person has received, among other information. The purpose of this more intensive review was to better understand these individuals' healthcare treatment over the course of time to determine whether they had chronic illnesses, pain-related diagnoses, or substance use disorder diagnoses or treatment. This more intensive review also provided a general picture of each person's general well-being over time.

C. Morphine Equivalent Dose

Opioids are painkillers that cause a decreased perception of pain, decreased reaction to pain, and increased pain tolerance. Side effects of opioids include sedation, respiratory depression, constipation, and a strong sense of euphoria. Opioid toxicity and abuse is a public health concern in Massachusetts and the United States.[5]

The Center for Medicare and Medicaid Services ("CMS"), which administers the Medicaid program across the country, uses a daily morphine equivalent dose ("MED") to help identify potential adverse effects, inappropriate uses, or diversions of opioids. The MED allows for a uniform comparison of opioids of varying types and strengths by converting them to their equivalent dose of morphine. In other words, the MED allows for an "apples to apples" comparison of different kinds of opioids, such as oxycodone and methadone, by converting each to their equivalent dose of morphine.

CMS has set a daily threshold of 120 milligrams ("mg") for the MED for 90 consecutive days or more to help identify people who are at risk for potential adverse effects, inappropriate

[5] Memorandum from Paul L. Jeffrey, Directory of Pharmacy, MassHealth, to Prescribers (Jan. 2016), *available at* www.mass.gov/eohhs/docs/masshealth/pharmacy/opioid-letter-high-dose-limits.pdf.

use, or diversion of opioids from a legitimate use to an illegitimate one.[6] This review adopted the CMS threshold as a flag of potential adverse effects, inappropriate use, or diversion of opioids. Thus, throughout this report, a person with a "high MED" refers to someone with an MED of 120 mg per day for 90 or more consecutive days.

MassHealth sets an MED threshold for certain drugs. MassHealth then reviews pharmacy claims to determine whether a particular prescription will exceed the threshold. If the prescription claim exceeds the threshold, the MassHealth member must request and receive MassHealth's prior approval to fill that prescription.

D. Removal of Cancer Patients from Review

Pain associated with cancer can result in the high use of narcotics. Although there are other painful medical conditions, they generally do not require the level of opioid treatment that is required for cancer-related pain.[7] As a result, CMS typically excludes patients with a cancer-related diagnosis from its review of people who are potentially improperly using or diverting opioids. This review followed CMS's example and removed people whose paid claims included a cancer-related diagnosis during the time period under review. By way of example, one individual in this review had a maximum MED of 1,440 mg per day, which is more than 10 times the CMS daily threshold. This person's claim history indicated that he[8] received multiple combinations of short- and long-acting opioids which, along with his MED, would be an indicator of potential abuse or diversion of these drugs. However, his claim history indicated that he had malignant cancer that had spread to multiple organs. Thus, although his MED was extremely high and his prescription pattern would ordinarily raise questions regarding his opioid use, the review excluded him given his diagnosis of cancer.

E. The Department of Public Health's Prescription Drug Monitoring Program

The Department of Public Health's ("DPH") Prescription Drug Monitoring Program ("PMP") monitors the prescribing and dispensing of all Schedule II to V controlled substances ("controlled substance").[9] Each time a pharmacy fills a prescription for a controlled substance, it is required to report certain information to the PMP, including information about the pharmacy, the prescriber, the prescription, and the patient. The PMP also indicates whether a person used

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[6] The MassHealth and HSN data lacked the number of days' supply of the prescription. As a result, the review assumed a 30-day supply for prescriptions with 30 or more "units" billed; for those prescriptions with less than 30 units billed, the review assumed that the day supply was equal to the number of units billed. Generally speaking, a unit represents a pill, milliliter, or gram.

[7] "No randomized trials have shown long-term effectiveness of high dose opioids for chronic non-cancer pain." Memorandum from Paul L. Jeffrey, Directory of Pharmacy, MassHealth, to Prescribers (Jan. 2016), *available at* www.mass.gov/eohhs/docs/masshealth/pharmacy/opioid-letter-high-dose-limits.pdf.

[8] To avoid any risk of inadvertently identifying individuals in this review, the Office will use the pronoun "he" for all of the examples in this report regardless of whether the person is male or female.

[9] The PMP also monitors certain additional drugs that DPH has determined have the potential for abuse.

insurance to pay for a prescription or whether the person paid cash; when a person has, but is not using, insurance, paying cash can be an indicator of potential drug abuse or diversion.

F. Comparisons with Other Insurers

When appropriate, this review included comparisons with other insurers. The review used Connecticut's Medicaid program as a comparable public payor. Connecticut shares a similar geographic location with Massachusetts, and also has a similar population and percentage of people receiving Medicaid benefits. For a private payor, the review selected Tufts Health Plan, which has private plans available within Massachusetts. The review also used Medicare's prescription drug coverage, known as Part D. To participate in Part D, a Medicare beneficiary enrolls in one of dozens of plans, all of which must offer a minimum level of coverage. However, the choice of a Part D drug plan can have a large impact on a person's coverage because Medicare allows the plans to determine the range of available drugs, copayments, and pharmacies. In the discussion that follows, references to Connecticut Medicaid, Tufts Health Plan, and Medicare Part D provide context and points of comparison for the MassHealth and HSN programs.

G. Specific Drugs in This Review

1. Methadone

Methadone is a Schedule II drug. It is a synthetic opioid with two purposes: it can minimize the desire to use additional opioids or it can treat moderate-to-severe pain. It is the only Schedule II controlled substance that is indicated for the treatment of substance use disorders. A provider may prescribe methadone to treat opioid substance use disorders, but only if (a) the physician is registered with the DEA to run a narcotic treatment program; and (b) the physician is in compliance with DEA regulations regarding treatment.[10]

A pharmacy may dispense methadone, but only for pain; a pharmacy may not dispense methadone for the treatment of a substance use disorder.[11] The use of methadone to manage chronic pain has increased in recent years in part due to its lower cost compared to other long-acting opioids. However, methadone use for chronic pain is a concern as it disproportionately accounts for overdose deaths in patients receiving opioid treatment for chronic pain. Indeed, although there is a relatively low percentage of methadone prescriptions for pain, they account for one-third of opioid-related overdose deaths in the United States.

If a MassHealth provider prescribes methadone for pain, MassHealth requires prior authorization for more than a certain dose of methadone per day.[12] Tufts Health Plan has a

[10] In Massachusetts, DPH provides a separate license for substance abuse treatment programs. 105 CMR 164.000.

[11] In an emergency, a prescriber may dispense a single dose of methadone at a time, for a maximum of three days, while waiting to enroll a patient in an opioid treatment program.

[12] As of March 7, 2016, MassHealth will require prior authorization for all new methadone prescriptions, defined as prescriptions for people who have not filled a methadone prescription for 60 out of the last 90 days.

similar restriction. Currently, Medicare and Connecticut Medicaid do not restrict the use of methadone for pain management.

Receiving methadone treatment for a substance use disorder does not mean that a person cannot also receive opioids for the treatment of pain. MassHealth, Connecticut Medicaid, Medicare, and Tufts Health Plan all provide methadone replacement therapy to their eligible members and none of these payors restrict a person's ability to receive other opioids while also receiving treatment from a methadone clinic. However, simultaneous claims for methadone treatment and opioid prescriptions is an indicator of potential substance abuse or diversion.

2. Buprenorphine

Buprenorphine is a Schedule III drug that can treat both substance use disorders and moderate-to-severe pain. It is the only opioid replacement product that a pharmacy can dispense, which distinguishes it from methadone. Because people can misuse buprenorphine by crushing and then snorting or injecting it, however, it is often prescribed in combination with another drug, naloxone. Naloxone, commonly known as Narcan, blocks the effect of an opioid. Suboxone is one often-prescribed drug that contains both buprenorphine and naloxone. If a person misuses Suboxone, the naloxone component will block the effects of the buprenorphine so that the person will not feel any opiate effect and the person will begin to go into opioid withdrawal. Accordingly, healthcare providers choose Suboxone to treat substance use disorders because it provides an opiate effect but is less likely to be abused than other opioid replacement drugs.

MassHealth has placed some restrictions on the use of buprenorphine products, but does not require prior authorization for generic buprenorphine/naloxone tablets for less than or equal to 16 mg per day. MassHealth requires prior authorization for other forms and doses of buprenorphine/naloxone. For example, MassHealth requires prior authorization for all prescriptions for buprenorphine/naloxone greater than 32 mg per day and for all prescriptions for buprenorphine/naloxone:

- For between 24 mg and 32 mg per day, MassHealth requires prior authorization after three months of therapy; and
- For between 16 mg and 24 mg per day, MassHealth requires prior authorization after six months of therapy.

Unlike MassHealth, Connecticut Medicaid requires prior authorization for all buprenorphine-related products. Tufts Health Plan also requires prior authorization for all buprenorphine-related products, except for generic buprenorphine/naloxone tablets (which are subject to a limitation on the quantity prescribed). Medicare requires all Part D providers to cover drugs used to treat substance use disorders and to make the drugs available without prior approval.

3. Short-acting and long-acting opioids

Opioids are painkillers that cause a decreased perception of pain, decreased reaction to pain, and increased pain tolerance. Side effects of opioids include sedation, respiratory depression, constipation, and a strong sense of euphoria. Opioids can be divided into two groups based on their length of effect in the body: short-acting and long-acting. Short-acting opioids work for intermittent moderate-to-severe pain; long-acting opioids work for constant pain. Typically, prescribers will order one long-acting opioid and one short-acting opioid for the treatment of chronic pain. The long-acting opioid provides coverage throughout the day while the short-acting opioid is available for breakthrough pain, which is pain that surfaces in spite of the long-acting opioid. The patient should only have to use the short-acting opioid occasionally; if the patient requires consistent use of the short-acting opioid, the prescriber should increase the dose of the long-acting opioid to better manage the pain. Adding a different long-acting or short-acting opioid is generally not warranted as the prescriber could simply increase the dose of the original opioid. As a result, the use of multiple long-acting or multiple short-acting opioids is an indicator of potential drug abuse or diversion.

Moreover, use of the same amount of a high-dose, short-acting opioid every month in conjunction with a long-acting opioid is also an indicator of potential drug abuse or diversion. In this situation, the prescriber should increase the long-acting opioid rather than continue to prescribe the high-dose, short-acting opioid.

MassHealth currently requires prior authorization when a person is using two or more long-acting opioids or two or more short-acting opioids for more than two months.[13] Connecticut Medicaid does not explicitly require prior authorization in this situation, but does have an overutilization flag in its drug utilization review system. Tufts Health Plan does not have a specific limitation for dual long-acting or short-acting opioids, but these may fall under its general duplicate therapy policies. Medicare does not have any specific regulation on this issue.

[13] As of March 7, 2016, MassHealth will require prior authorization for doses of opioids that exceed an MED of 120 mg per day.

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Findings

The Office found the following regarding the paid drug claims for MassHealth members and HSN users:

I. 4,269 MassHealth Members and HSN Users Had High MEDs.

Data analytics is a powerful tool that can identify people who are potentially misusing prescription drugs. This review used data analytics to identify those MassHealth members and HSN users with a high MED, and specifically those people whose paid prescription claims exceeded 120 mg MED for 90 consecutive days or more. As indicated above, this is the threshold that CMS uses to help identify potentially inappropriate uses or diversions of opioids. Once the review identified individuals with a high MED, the Office then looked for additional indicators of potentially inappropriate uses or diversions of opioids. It was also possible to more closely review some of those individuals' claim records or All Services Report By Member.

The review identified paid claims for 4,465 people with a high MED, of whom 196 had paid claims that included a cancer diagnosis. The review excluded these individuals and as a result, this review included 4,269 people with paid claims for prescriptions that exceeded 120 mg MED for 90 consecutive days or more (2.4% of the people in this review).

The following examples illustrate the value of looking at paid claims through the lens of the MED. One person had paid claims indicating that he had a maximum MED of 1,710 mg per day, or more than 14 times higher than the screening threshold. His paid claims showed that he received only one long-acting and one short-acting opioid per month – methadone (long-acting) and oxycodone (short-acting). However, he received 1,350 tablets of methadone[14] every month and 240 tablets of oxycodone[15] every month, which means that he would have taken an average of 53 pills of opioids per day. Neither his paid claim history nor his All Services Report By Member contained a clinical indication that would support the use of this amount of these drugs. Further, the quantity of oxycodone is especially notable as they were 30 mg tablets, which are highly abused and sought after because they are easily crushed and then snorted or injected. The lack of clinical indication for these medications, combined with the extremely high quantities and presence of 30 mg tablets of oxycodone, suggest that his utilization may have been inappropriate. That is, these combined factors suggest that he may have a substance use disorder or that he may have been diverting the drugs (*i.e.*, selling them or giving them to others).

A second example of the benefit of using the MED as a screening tool involves a person with a maximum MED of 1,500 mg per day, or more than 12 times the screening threshold. His paid claims indicated that he had received only one long-acting medication, methadone. He received 1,500 tablets[16] of methadone every month, which means that he would have taken 50

[14] 10 mg each.

[15] 30 mg each.

[16] 10 mg each.

methadone pills per day. This person's claim history and All Services Report By Member did not contain an indication of pain that would explain this amount of methadone. The lack of clinical indication for, and the use of extremely high quantities of, methadone suggest that his utilization could have been inappropriate.

As a final example of the value of using the MED as a screening tool, one person had paid claims indicating that he had a maximum MED of 1,860 mg per day, more than 15 times the screening threshold. His paid claim history indicated that he received three different long-acting opioids (methadone, extended-release morphine, and OxyContin) at the same time on multiple occasions during the year. In addition to these three drugs, he also received a combination of drugs, which the federal government[17] considers to be one of its red flags for potential diversion and abuse. This combination consists of an opioid, a muscle relaxant, and a benzodiazepine (which has sedative, hypnotic, anti-anxiety, anticonvulsant, and muscle relaxant properties). This particular drug combination is widely abused for its euphoric effects. Both the muscle relaxant and benzodiazepine increase the intensity of the effects of opioids. Although there may be a short-term clinical use for this combination, review of this person's claim history and All Services Report By Member did not support the use of the combination of drugs or the simultaneous use of three long-acting opioids. This person's high MED, combined with the presence of three long-acting opioids and the use of the combination of drugs, suggest that his utilization was inappropriate.

In summary, using the CMS standard of 120 mg MED for 90 consecutive days or more as a benchmark for potential misuse, abuse, or diversion of drugs, the Office found 4,269 people whose paid prescription claims would warrant additional review to determine whether their drug use was clinically appropriate. As illustrated in these three examples and in many of the examples below, using the MED creates a starting point from which to conduct additional data analysis along with robust clinical analysis to determine whether MassHealth members and HSN users are receiving appropriate medical treatment or whether those individuals may be abusing or diverting drugs for which MassHealth and the HSN should not be paying.

Currently, MassHealth members can receive prescriptions for nine types of opioids that exceed 120 mg per day without prior authorization. However, in January 2016, MassHealth issued a memorandum to its providers implementing lower dose limits for opioids. Beginning on March 7, 2016, MassHealth will require prior authorization for doses of opioids exceeding a 120 mg daily MED. MassHealth's prescription processing system will check each opiate claim to be certain that the MED is not exceeded for a particular prescription. Specifically, the prescription processing system will perform a calculation using the drug, drug strength per tablet, quantity prescribed, and the number of days for which it was prescribed to calculate the MED. The Office recognizes this as an important development in how MassHealth monitors opioid prescriptions.

However, the Office also recommends that MassHealth take this process further and focus not only on individual prescriptions, but on all of a MassHealth member's current

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[17] The Office of the Inspector General of the United States Department of Health and Human Services.

prescription drug claims. As indicated in the examples above, one prescription alone may not exceed the MED, but the totality of a person's prescriptions could result in a high MED.

Given the presence of 30 mg tablets of oxycodone in this review, the Office also recommends that MassHealth require prior authorization for all 30 mg short-acting oxycodone tablets. These tablets of oxycodone are notable as they are highly abused and sought after because they are easily crushed and then snorted or injected. Adding this specific dose of oxycodone to the prior authorization list could help to reduce misuse.

II. MassHealth and the HSN Paid for a High Number of Methadone Prescriptions.

The Office's review found that MassHealth and the HSN paid for a large number of methadone prescriptions. When the Office more closely examined these prescriptions, there were a number of people who received prescriptions for methadone from pharmacies immediately after completing treatment for a substance use disorder at a methadone clinic, which could be an indicator of misuse.

As indicated above, pharmacies can only dispense methadone for the treatment of pain, not the treatment of a substance use disorder. If a provider does prescribe methadone for pain, MassHealth requires prior authorization for more than 60 mg of methadone per day.[18] In spite of this safeguard, there were a high number of paid pharmacy claims for methadone in this review. Specifically, 3.4% of the paid claims for opioid prescriptions in this review were for methadone. This number is notable because methadone made up 2% of opioid prescriptions across the United States in 2012. Thus, the utilization of prescription methadone by MassHealth members and HSN users was considerably higher than the rest of the nation around the same time period.

Furthermore, 40 people had paid claims for methadone prescriptions from a pharmacy immediately after they had paid claims for treatment at a methadone clinic. Keeping in mind that pharmacies can only dispense methadone for pain, this pattern of claims raised questions about the appropriateness of these prescriptions of methadone for pain. To further narrow this group, the review identified five people who had a high MED (between 165 mg and 338 mg). Over the course of the year under review, each of these people had paid claims for methadone clinics that ranged from two to 11 months. After these people stopped going to the methadone clinics, each had paid claims for methadone prescriptions from pharmacies for between five and 18 months. This pattern of use is suggestive of treatment for a substance use disorder with methadone outside of a narcotic treatment program, which would be illegal.

The Office recommends that MassHealth and the HSN proactively identify individuals with a high MED who are receiving prescriptions for methadone on the heels of claims for a methadone treatment program. MassHealth and the HSN would then be able to examine any patterns of methadone prescriptions, which could lead to uncovering inappropriate prescribing

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[18] As of March 7, 2016, MassHealth will require prior authorization for new prescriptions of methadone, defined as those for people who have not filled a methadone prescription in 60 out of the last 90 days.

practices, stopping the payment of claims for medically inappropriate prescriptions, and taking action against any prescribers who are prescribing methadone without a valid clinical reason.

With regard to methadone prescriptions for pain, the Office supports the change that MassHealth is making: as of March 7, 2016, MassHealth will require prior authorization for any of its members who will be receiving a new methadone prescription.[19] While recognizing the importance of this change, the Office also recommends that MassHealth require prior authorization for all methadone prescriptions as a way of reducing its potential misuse and abuse.

III. MassHealth and the HSN Paid Claims for Opioid Prescriptions for 345 People Undergoing Methadone Treatment.

MassHealth and the HSN paid claims for opioid prescriptions for people while they were undergoing methadone treatment. As part of its examination of these claims, the Office noted that claims for methadone treatment for a substance use disorder did not indicate the dose of methadone that a person receives, which is a missing link when calculating a person's MED. As stated earlier, the treatment of pain in patients with a history of a substance use disorder presents a challenge for providers who must balance the need to treat legitimate pain with potentially exacerbating the substance use disorder. The challenge intensifies when a provider is trying to treat pain in an individual who is undergoing treatment for a substance use disorder at a methadone clinic.

In this review, 345 people had paid claims for treatment at a methadone clinic while they were also receiving 30 or more units of short-acting or long-acting opioids. Of those 345 members, 20 had an MED of 120 mg per day or more. It is important to note that the MED calculation in this review takes into account only those opioids that the person received from a pharmacy; the paid claims in this review did not indicate the amount of methadone that people received from the clinic. At least seven of these people had high MEDs (ranging from 165 mg to 480 mg per day) and received opioids for which they had no clinical indication in their paid claim history or All Services Report By Member.

This pattern of paid claims may mean that a person is legitimately receiving treatment for both a substance use disorder and pain, but it could also be an indicator of abuse or diversion of prescription opioids. In short, the presence of paid claims for opioid prescriptions for people who are undergoing methadone treatment is another area in which data analysis could uncover inappropriate prescribing practices and payment of claims for opioids, as well as potentially lethal amounts of opioids. Further, MassHealth and the HSN would benefit from requiring additional information – the amount of methadone that each person receives at a treatment clinic – to inform the calculation of MEDs.

To that end, the Office recommends that MassHealth and the HSN programs slightly change how methadone clinics bill so that each claim includes the amount of methadone that a person receives. MassHealth and the HSN should also require methadone clinics to submit

[19] MassHealth is defining a "new" prescription as one for a person who has not filled a methadone prescription for 60 out of the last 90 days.

claims more quickly, which, combined with the dose of methadone that a person receives, would increase the effectiveness of any MED monitoring that MassHealth and the HSN perform. The Office also recommends that MassHealth and the HSN work with the Department of Public Health to determine whether there is a way for methadone clinics to submit information to the Prescription Monitoring Program ("PMP") for each person receiving methadone.[20] This would allow both prescribers and MassHealth to obtain a more accurate picture of a person's use of opioids.

IV. MassHealth and the HSN Paid Claims for Opioids While People Were Receiving Buprenorphine.

MassHealth and the HSN programs had a high number of prescriptions for Suboxone (a combination of buprenorphine and naloxone to treat a substance use disorder) and a high number of people receiving prescriptions for both Suboxone and opioids. This review also found a number of people who were receiving both Suboxone and prescriptions for other opioids. Some of these people had paid claim histories that contained an indicator of pain, but others did not.

By way of comparison, in 2012, Medicare paid more for Suboxone prescriptions in Massachusetts than for any other state in the United States:

2012 Medicare Part D Cost for Suboxone by State (Top 10 States)			
State	**Total Number Medicare Beneficiaries**	**Medicare Part D Prescriptions for Suboxone**	**Medicare Part D Cost**
Massachusetts	1,104,483	51,132	$15.00M
Pennsylvania	2,350,558	26,679	$9.16M
New York	3,093,591	24,069	$9.03M
Michigan	1,728,338	19,746	$7.72M
Florida	3,527,830	19,403	$7.59M
Ohio	1,971,260	18,201	$6.22M
Kentucky	793,271	17,427	$5.66M
Tennessee	1,109,791	16,108	$5.49M
California	5,000,198	15,232	$6.03M
Texas	3,187,332	14,800	$5.88M

Table 4: 2012 Medicare Part D cost for Suboxone by State (Top 10 States)

As previously discussed, Massachusetts has a high rate of methadone prescriptions. Similarly, 5.3% of the opioid prescriptions during fiscal year 2013 for MassHealth members and

[20] The current PMP statute provides that dispensing pharmacies may enter information into that system. Methadone clinics do not write or fill prescriptions, but rather order and administer methadone. As a result, this recommendation may require a change to the PMP statute.

HSN users were for buprenorphine products, whereas buprenorphine products accounted for 3.2% of opioid prescriptions dispensed by pharmacies across the country in 2012.

The review focused on paid prescription claims for buprenorphine products that people received at the same time they received other opioids. There were 79 people with both paid claims for Suboxone and prescriptions for other opioids.[21] Of these 79 people, 18 had a high MED. For instance, one person had a maximum MED of 332 mg per day. While he was receiving treatment with Suboxone, he also continually received prescriptions for oxycodone-based products even though neither his paid claim information nor his All Services Report By Member contained any clinical indication for ongoing pain relief. (He was also receiving prescription stimulants, again without an appropriate clinical indication for their use.)

Another individual had a maximum MED of 252 mg per day. While being treated with Suboxone, he continually received prescriptions for oxycodone and morphine-based products even though his paid claim information and All Services Report By Member did not contain any clinical indication for ongoing pain relief. These two people's opioid use appears to be indicative of drug abuse or diversion because there was no evidence of a clinical indication for the opioid prescriptions.

However, the review also identified paid claims for individuals whose use of Suboxone along with other opioids appeared to be appropriately managed. For example, the review included one person who had a maximum MED of 243 mg per day. He received prescriptions for Suboxone, as well as for immediate- and extended-release morphine. These prescriptions overlapped only at the beginning of his Suboxone treatment, after which time he did not receive any other opioid prescriptions. The short-term nature of the morphine prescriptions, along with the fact that they did not recur during the time under review, appears to indicate a clinically appropriate use. Another person had a maximum MED of 252 mg per day. He received Suboxone as well as prescriptions for hydrocodone-based products. However, he only received the hydrocodone for a brief period of time and there were clinical indications in his paid claim history that the use of hydrocodone appeared to be for pain relief.

MassHealth requires prior authorization for a person taking buprenorphine to fill a prescription for a long-acting opioid. However, MassHealth allows a person taking buprenorphine to receive up to a seven-day supply of a short-acting opioid to treat an acute episode of pain. Based on the examples noted above, it appears that additional clinical scrutiny would be appropriate in these circumstances.

In cases in which it is not clinically appropriate, receiving both Suboxone and other opioid prescriptions can be an indicator of drug abuse or diversion for which MassHealth and the HSN should not be paying. The Office recommends that MassHealth and the HSN use paid claims data to identify individuals with this pattern of prescription drug use. Once those individuals are identified, the Office recommends that MassHealth and the HSN look at the clinical need for pain relief. This second step is essential to determining whether the treatment

[21] These prescriptions were for 30 or more units of short-acting opioids, or any long-acting opioids.

for both a substance use disorder and pain was appropriate. The final step is to examine the providers involved and determine whether – and how – to intervene with the providers who have questionable prescription patterns.

V. MassHealth and the HSN Program Paid Claims for Two or More Long-Acting or Short-Acting Opioids at the Same Time.

The review found that MassHealth and the HSN paid claims for two or more long-acting or short-acting opioids at the same time. A number of these people did not appear to have any clinical indication for receiving more than one prescription for long-acting or short-acting opioids. As discussed above, the use of two or more long-acting or multiple short-acting opioids can indicate drug abuse or diversion. Therefore, this review identified people with paid prescription claims on the same day for two or more long-acting or two or more short-acting opioids. MassHealth requires prior approval for duplicate short-acting and long-acting opioid therapy, which it defines as prescriptions for two or more short-acting or long-acting opioids for more than two months. MassHealth permits this overlap to allow time for a person to transition off of one opioid and on to another.

Only a small percentage of people received two or more long-acting or short-acting opioids ("duplicate therapy"). However, of the people receiving duplicate therapy, a number of them had an MED that exceeded the 120 mg threshold. Specifically, 129 people had two or more long-acting prescriptions for opioids on the same day, of whom 29 people (22%) had a high MED. Also, 1,218 people had two or more short-acting prescriptions for opioids on the same day, of whom 127 (10%) had a high MED.

A. Two or More Long-Acting Opioid Prescriptions

Of the 29 people with two or more long-acting opioid prescriptions and a high MED, three had paid claims indicating that they received two specific long-acting opioids (methadone and morphine sulfate extended release) over time. One of these people received both long-acting opioids for two months, the second person received both for 10 months, and the third person had received both since March 2011. These people had a maximum MED ranging from 150 mg to 290 mg per day. It was unclear from the claim files and the All Services Reports By Member why any of these three individuals were receiving two long-acting opioids. Thus, two out of the three examples indicate that some people are receiving duplicate therapies for longer than a transition period. Combining these individuals' MED with information from their paid claims and All Services Reports By Member suggests possible opioid abuse or diversion.

A fourth person who received two long-acting opioids had a maximum MED of 405 mg per day. His diagnoses included lumbago (low back pain) and chronic pain syndrome. His claim data indicated that he had paid claims for methadone and OxyContin – two long-acting opioids. Rather than receive two different long-acting opioids for pain, he should have received an increase in the dose of one long-acting opioid. This person's claim history also indicated that he consistently received prescriptions for a short-acting medication (oxycodone) each month without a change in dosage of the long-acting drugs (methadone and OxyContin). This is an example of an inappropriate use of a short-acting medication because if he was consistently

using the short-acting opioid for breakthrough pain, his prescriber should have increased the long-acting opioid. This information suggests either that he was being treated inappropriately or that there was abuse or diversion of these medications.

Another person had a maximum MED of 285 mg per day. His claim data indicated that he received two long-acting opioids, methadone and morphine extended release, for four consecutive months. During these same four months, he also had paid claims for a methadone clinic where he presumably received methadone replacement therapy. Based on a review of his claims and All Services Report By Member, his utilization of pain medication does not appear to be clinically appropriate.

B. Two or More Short-Acting Opioids

Of the 127 people who received two or more short-acting opioids and had a high MED, one person had a maximum MED of 248 mg per day. He received four different short-acting medications during a time when he was recovering from a joint replacement. Ordinarily, this type of use for pain management would not raise any questions, as his prescriber may have been seeking the right drug to treat his pain. However, this person's paid claims and All Services Report By Member indicated that he was enrolled in a substance use disorder treatment program at the same time he received multiple opioid prescriptions. Thus, although his receipt of multiple short-acting opioids during his recovery from joint replacement may have been appropriate, his high MED and use of opioids while enrolled in a treatment program raises questions about the clinical appropriateness of his treatment.

Another person whose maximum MED was 180 mg per day received three different short-acting opioids over several months, during which time he also received two long-acting opioids. His claim history did not show any changes during this time that would require three different short-acting opioids. His claim history also indicates that he was consistently using the short-acting opioids without a change in the dosage of the long-acting opioids, which a prescriber could have done to reduce the need for the short-acting opioids. Based on his MED and claim history, it appears that either he was being treated inappropriately or there was diversion or abuse of these medications.

In sum, the Office recommends that MassHealth and the HSN identify individuals with high MEDs who are receiving prescriptions for two or more long-acting or short-acting opioids at the same time. MassHealth and the HSN could then evaluate the clinical appropriateness of those prescriptions and determine whether to intervene with those prescribers.

VI. MassHealth and the HSN Paid Claims for Opioids for People with a History of a Substance Use Disorder.

MassHealth and the HSN paid claims for opioid prescriptions for people with a history of a substance use disorder. Treating pain in patients with a history of a substance use disorder presents a challenge for providers who must balance the need to treat legitimate pain without potentially exacerbating the substance use disorder. In these situations, practitioners should keep the use of opioids for legitimate pain to the minimum dose and period of time necessary to treat

the condition.[22] If a person with a history of a substance use disorder has a chronic issue relating to pain, providers could prescribe a small amount of the opioid for pain relief and perform random blood or urine screenings to ensure the person is utilizing the medication appropriately.

None of the public or private health insurers included in this review differentiate how they treat pain in individuals with a history of a substance use disorder. Realistically, it would be difficult for an insurer to address this issue with a single rule because treatment decisions regarding pain must be tailored to an individual patient's clinical presentation. Furthermore, restricting access to medications based solely on a history of a substance use disorder would be unfair to this group of patients. However, it is possible for insurers to analyze claims to determine whether individuals with a history of a substance use disorder are receiving appropriate treatment for a clinical presentation that requires pain management.

In this review, 20,605 individuals had paid claims that included both a diagnosis of a substance use disorder and paid claims for opioids. Of these individuals, 651 had high MEDs. Some of these individuals had diagnoses that would support the use of opioids for pain. For example, one individual had a maximum MED of 224 mg per day and a history of opioid abuse. He was receiving Suboxone to treat the opioid abuse. He also received a short course of treatment with an opioid during the same time that he had surgery, which appeared to be an appropriate pain-related use.

However, some individuals with a history of a substance use disorder received opioid prescriptions that did not appear to be appropriate. For example, one individual was receiving Suboxone as opioid replacement therapy. While he was receiving Suboxone, he also received additional opioid prescriptions but there was no information in his claim history that would support these prescriptions. As such, the additional opioid prescriptions did not appear to be appropriate.

The Office recommends that once MassHealth and the HSN have identified people with high MEDs, they focus on people with a history of a substance use disorder as well as paid claims for opioids. MassHealth and the HSN could conduct a clinical analysis on these people in an effort to balance the need to treat people fairly with the possibility that a particular group of individuals may be more likely to misuse prescription opioids.

VII. MassHealth and the HSN Paid Claims for the Same Schedule II Drug on the Same Day for the Same Person.

This review identified people who had (a) more than one claim for the same Schedule II drug for the <u>same</u> dose on the same day; and (b) more than one claim for the same Schedule II drug for a <u>different</u> dose on the same day. Although these two situations appear to be similar, they arise from and create different issues.

[22] Daniel P. Alford et al., "Acute Pain Management for Patients Receiving Maintenance Methadone or Buprenorphine Therapy," *Annals of Internal Medicine* 144(2) (2006).

A. The Same Drug, Same Dose, Same Day

The same person receiving more than one prescription for the same drug and same dose on the same day would merit review to determine whether the prescriptions were for a legitimate purpose. Rather than issue multiple prescriptions for the same drug at the same dose, in most cases a prescriber could simply increase the quantity dispensed and modify the administration instructions. By contrast, obtaining multiple prescriptions for the same drug and dose is a tactic often used to bypass an insurer's quantity and dose limits. For example, MassHealth currently has dose and quantity limits to ensure that large doses of opioids are limited to those people with a legitimate medical need; in addition, people requiring large quantities or doses must receive prior authorization from MassHealth before the medication can be dispensed.

In this review, 48 people had two paid prescription claims for the same drug and the same dose on the same day. Two of these 48 people received the same drug at the same dose on the same day on more than one occasion. MassHealth and the HSN should examine this pattern of prescription drug use to determine whether the use is appropriate.

B. The Same Drug, Different Dose, Same Day

In contrast to the analysis above, there are legitimate reasons for a prescriber to order different strengths of the same drug on the same day. For example, morphine sulfate is not available in a 40 mg dose. As a result, a prescriber may issue two prescriptions, one for a 10 mg dose and another for a 30 mg dose, to obtain the desired 40 mg dose. Similarly, a person may need a different dose of the same drug at different times during the day, which would require separate prescriptions for the same drug at a different dose. In this review, 3,319 people had at least two paid prescription claims for the same drug with a different dose on the same day. This pattern is less concerning because there appeared to be a legitimate, clinical reason for these prescriptions. However, MassHealth and the HSN should consider whether to analyze the appropriateness of these prescriptions by, for example, determining whether the same prescribers wrote the prescriptions or whether the drugs are those that would require different doses.

VIII. MassHealth Uses a Controlled Substance Management Program for Members Who Use Excessive Quantities of Prescribed Drugs.

As indicated above, MassHealth has a Controlled Substance Management Program ("CSMP") for certain of its members. The purpose of the CSMP program is to restrict potential abuse or diversion of drugs by MassHealth members with a history of using excessive quantities of prescribed drugs.

MassHealth may enroll a member in this program if the member is using an "excessive quantity" of prescribed drugs. MassHealth defines an "excessive quantity" as:

- 11 or more prescriptions, including the original fill and refills, of one or more controlled substances (including Schedule II drugs),
- during a three-month period, and

- obtained from four or more prescribers or filled by four or more pharmacies.

Before assigning a member to the CSMP, MassHealth reviews the member's claim history to determine whether there are legitimate, clinical reasons for the pattern of prescribing and dispensing. For each person enrolled in the CSMP, MassHealth chooses one primary pharmacy. Once in the CSMP, the MassHealth member may only fill prescriptions at the primary pharmacy and only the primary pharmacy may receive payment from MassHealth for that member's prescriptions, with two exceptions.[23]

In fiscal year 2013, MassHealth had 184 people in its CSMP, or approximately 0.01% of its more than one million members. There were 128 women and 56 men in the CSMP. They came from 91 different cities and towns across Massachusetts, with nine from Quincy; seven each from Dorchester, Lynn, and Springfield; six from Brockton; and five from Attleboro, Fall River, Haverhill, Lowell, and Saugus. The oldest person was 70 years old; the youngest was 21 years old. There were two MassHealth members who had been in the CSMP since 2003; MassHealth added 24 members to the CSMP in fiscal year 2013. For each of the members in the CSMP, MassHealth designated one pharmacy where each person could fill his prescriptions. Pursuant to MassHealth regulations, only the designated pharmacy may receive payment from MassHealth for prescriptions filled for CSMP members. MassHealth spent $180,470 on 2,727 paid prescription claims included in this review for these CSMP members during fiscal year 2013.

There were 147 CSMP enrollees with paid claims in this review.[24] As illustrated below, the review found that of these 147 people, 92 always went to their designated pharmacy (62%), 16 went to a non-designated pharmacy on one occasion (10%), 24 used a number of different pharmacies including the designated pharmacy (16%), and 15 never went to the pharmacy designated by the CSMP (10%).

[23] A pharmacy other than the primary pharmacy can dispense and receive payment for (1) a nonrefillable supply of a drug if the person's health or safety would be jeopardized without immediate access to the drug; or (2) a drug for family planning. Also, MassHealth allows a skilled nursing facility ("SNF") that is providing care to a CSMP member to fill the member's prescriptions at the pharmacy that the SNF regularly uses.

[24] This is approximately 0.08% of the 176,763 people in this review.

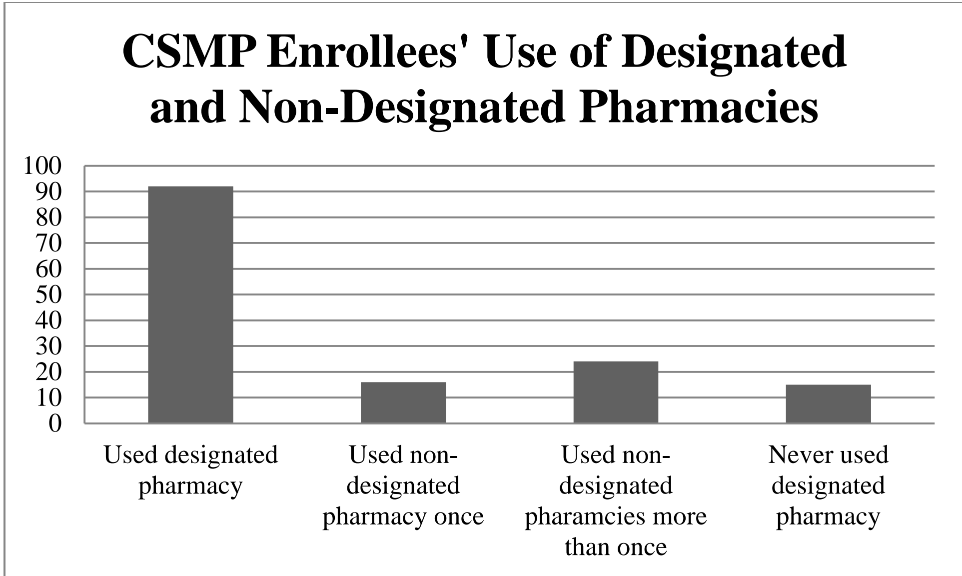

Table 5: CSMP enrollees' use of designated and non-designated pharmacies

MassHealth paid approximately $180,470 for prescription claims for all of its members in the CSMP, including $43,181 (23%) at non-designated pharmacies. In summary, 26% of the individuals in the CSMP in this review had prescriptions filled at non-designated pharmacies.

Consistent with its examination of paid prescription claims set forth above, the Office analyzed the paid claims for the 18 members of the CSMP who had a high MED. These individuals require additional focus because MassHealth determined that they have used excessive quantities of prescription drugs in the past <u>and</u> they had a high MED during the year of this review. Of these 18 people, 11 always went to their primary pharmacy (61%); one only used a non-designated pharmacy one time (5%); four used a number of different pharmacies including the designated pharmacy (22%); and two never went to the CSMP pharmacy (11%).

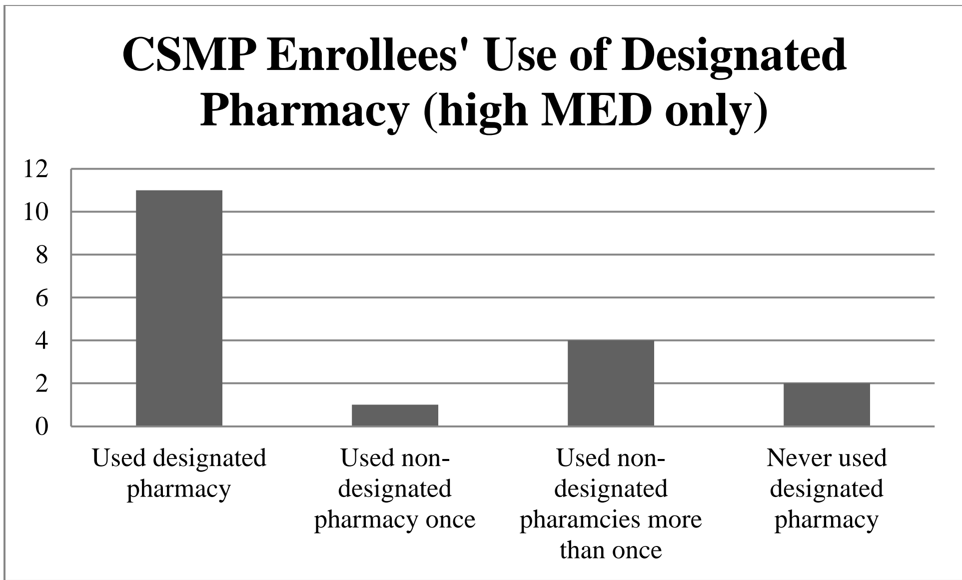

Table 6: CSMP enrollees' use of designated pharmacy (high MED only)

For these claims, MassHealth paid $69,424 (38% of the total payments for CSMP participants) with $18,237 (26%) going to non-designated pharmacies. Thus, 33% of the people with a high MED in the CSMP had prescriptions filled at a non-designated pharmacy.

In response to the Office's review, MassHealth examined the CSMP pharmacy claims for fiscal year 2013 (the same time period that the Office reviewed). MassHealth reported that there were 480 claims that CSMP members filled at non-designated pharmacies and that all of the claims were valid. MassHealth indicated that 279 of these prescriptions were filled at a long-term care pharmacy, a pharmacy that works with homeless shelters, or by a home infusion or specialty pharmacy. In each of these situations, MassHealth indicated that it believed that there was a valid, clinical reason for the member to have used a non-designated pharmacy. MassHealth also reported that 96 of these claims involved prescriptions that another insurer paid for, either in part or in full; seven involved an emergency; and 98 involved what MassHealth believed to be another valid reason (*e.g.*, the member was receiving services far from home or the designated pharmacy did not have necessary medication in stock).

The Office recommends that MassHealth study whether the CSMP does, in fact, have a positive impact on the potential abuse or diversion of drugs. If MassHealth determines that the CSMP is beneficial, the Office recommends that MassHealth increase its use of the CSMP and put additional controls in place to enforce compliance with the program. Specifically, the Office recommends that MassHealth use the current entry criteria to identify additional MassHealth members who should be included in the program. The Office encourages MassHealth to explore whether, among the more than one million MassHealth members, there are more than 184 people who would benefit from being included in the CSMP.

The Office also recommends that MassHealth augment the entry criteria for the CSMP to include people with a high MED even if they do not meet the current requirements (*i.e.*, have not filled 11 or more prescriptions for three or more months from four or more prescribers). MassHealth can accomplish this by including information from the PMP as part of its analysis of prescription utilization patterns. MassHealth could also strengthen its system that alerts a pharmacy if a CSMP member is trying to fill a prescription at an unauthorized pharmacy. The Office also recommends that MassHealth consider including people in the CSMP who are receiving methadone replacement therapy or buprenorphine for the treatment of a substance use disorder and who are receiving additional opioids to manage acute or chronic pain. This would create an additional level of supervision of individuals who are both receiving treatment for a substance use disorder while also taking opioids for clinically appropriate conditions.

Finally, if MassHealth determines that the CSMP does not reduce the abuse or diversion of drugs, then the Office recommends that MassHealth consider an alternative program. For example, MassHealth could explore the possibility of having a provider <u>and</u> pharmacy lock-in program for its members with a history of using excessive quantities of prescribed drugs. This would limit the number of prescribers as well as the number of pharmacies that these members could use, thereby increasing the consistency of care, which could reduce the number of prescriptions being issued.

IX. MassHealth and the HSN Did Not Appear to Regularly Use the Department of Public Health's Prescription Drug Monitoring Program.

MassHealth would benefit from increasing its use of the Department of Public Health's Prescription Drug Monitoring Program ("PMP") to evaluate specific MassHealth members' and HSN users' prescription drug claims. As described above, the PMP monitors the prescribing and dispensing of all Schedule II to V controlled substances ("controlled substance"). Each time a pharmacy fills a prescription for a controlled substance, it is required to report certain information to the PMP, including information about the pharmacy, the prescriber, the prescription, and the patient. By statute, this information is confidential and access is limited. However, an authorized prescriber can access a patient's prescription history over the past 12 months before issuing a prescription for a controlled substance. Law enforcement may also access information regarding a specific person – patient or prescriber – for the purpose of pursuing a drug-related investigation. EOHHS may also access this information when it is acting with regard to a MassHealth member.

MassHealth reported that four staff members from its pharmacy program have permission to access the PMP. An audit trail from the PMP indicates that only one of those staff members accessed the PMP during fiscal year 2013, and that person only accessed the PMP on 13 days during the year to check the prescription records of 46 people.

The Office recommends that MassHealth and the HSN program use the PMP more because it contains a wealth of information that would help uncover fraud, waste, and abuse in prescription drug claims. The PMP contains (i) the quantity and frequency of prescriptions that patients are filling; (ii) the patient's name and demographic information; (iii) whether a person used insurance[25] or paid cash for a prescription; (iv) the prescriber's information; and (v) information about the pharmacy. Using this information, it is possible to analyze, among other things, whether a person is paying cash to fill prescriptions at the same time he is using insurance to fill prescriptions, which could indicate that a person may be attempting to avoid an insurer's limit on the quantity or dose of a particular drug. It would also be possible to analyze the various kinds of drugs a person is receiving, how frequently a person is filling prescriptions, whether a person has more than one prescriber issuing prescriptions for the same drug at the same time, and whether a person is filling prescriptions at multiple pharmacies. All of these pieces of information may provide red flags about whether a person may be abusing or diverting drugs.

This review included a sample of records from the PMP for specific people with high MEDs who also had other indicators of drug abuse or diversion. The purpose of this evaluation was to determine whether information from the PMP might help MassHealth and the HSN determine whether a person is inappropriately using or diverting prescriptions for which it is paying. Information from the PMP would also be useful for MassHealth to determine whether to enroll people in its CSMP and whether to refer people to the Massachusetts Behavioral Health Partnership ("MBHP"), which is responsible for some of MassHealth's behavioral health

[25] The PMP data indicates only if a person used insurance or paid cash for a prescription. It does not include the name of the insurer.

services. MBHP could then engage in outreach efforts to try to engage the person in treatment (if appropriate).

For example, one person in the review had diagnoses during fiscal year 2013 that included a substance use disorder, depression, bipolar disorder, drug-induced mood disorder, and cannabis abuse.[26] During the year, his insurance paid for 50 prescriptions while he paid cash for 21 prescriptions; MassHealth would not know about these 21 prescriptions unless it reviewed his PMP records. His PMP records revealed that:

- He received prescriptions from six different providers and used 13 different pharmacies in 10 different cities and towns to fill his prescriptions.
- He paid cash for all of the 1 mg tablets of clonazepam[27] that he received during the year.
- He paid cash for some of the 2 mg tablets of clonazepam that he received and his insurance paid for some. On two different occasions in August 2012, he filled one prescription for clonazepam for which he paid cash and on the same day he filled a second prescription for Suboxone for which his insurance paid. Two different doctors issued these two prescriptions on each occasion.
- He paid cash for a total of 1,874 tablets of a stimulant that is typically prescribed for ADHD; his insurance paid for 1,672 tablets of the same dose of this stimulant and 975 tablets of this stimulant in a variety of other doses. There were six different prescribers for this stimulant.

In short, this individual presents an example in which MassHealth could combine its claims data, MED calculation, and PMP information to identify patterns of prescription drug use that could indicate fraud, waste, and abuse of the MassHealth or HSN programs.

A second individual paid cash for nine out of 43 prescriptions during the year under review.[28] His diagnoses during the year included a substance use disorder, hepatitis C, obesity, and joint pain. Although he used four different pharmacies in three different cities, he only paid cash at one pharmacy. His PMP information revealed that:

- All of his cash payments involved 2 mg tablets of clonazepam from one of his four prescribers; he paid cash for 810 tablets of clonazepam and his insurance paid for 1,080 tablets of the same dose of this same drug.
- His insurance also paid for prescriptions for methadone, oxycodone, and dilaudid (a Schedule II pain medication).

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[26] He was not in the CSMP.

[27] Clonazepam is a Schedule IV benzodiazepine that can enhance the effect of other drugs and is prone to being abused.

[28] He was also not in the CSMP.

Using the PMP information, MassHealth would be better able to identify patterns of his prescription drug use that could indicate fraud, waste, and abuse of the MassHealth or HSN programs.

A third example involves a person who used 10 different pharmacies in seven different cities and paid cash for eight out of 48 prescriptions. Specifically:

- He received prescriptions from five different prescribers.
- He paid cash for 108 tablets of clonazepam.
- His insurance also paid for approximately 600 tablets of the same dose of clonazepam, as well as prescriptions for buprenorphine/naloxone, buprenorphine, oxycodone, and Suboxone.
- His diagnoses during the year included a substance use disorder, anxiety, drug-induced sleep disorder, drug-induced mood disorder, and migraines.

Here again, the information from the PMP sheds considerable light on an individual's prescription drug use patterns that MassHealth could use to detect fraud, waste, and abuse.

DPH recently issued a $6.2 million contract to develop and implement a new PMP, which the agency anticipates will become operational in the summer of 2016.[29] The new PMP is expected to have a user-friendly interface, faster access to reports, the capability to exchange data with other states' PMP systems, the ability to link with Massachusetts health providers' electronic records, and efficient onboarding for new users. The Office recommends that MassHealth increase its use of the PMP to review specific controlled substances and in drug-related investigations, both now and when the new PMP becomes operational.

[29] *See* Department of Public Health, "State Hires Vendor to Revamp Prescription Monitoring Program" (Dec. 22, 2015), *available at* www.mass.gov/eohhs/gov/newsroom/press-releases/dph/state-hires-vendor-to-revamp-perscription-monitorint-program.html

Conclusion and Recommendations

The Office examined over 800,000 MassHealth and HSN paid fee-for-service claims for Schedule II drugs, which include drugs that have a high potential for abuse but also have accepted medical uses. The results of this review show the value of adopting a two-step strategy for identifying potential fraud, waste, and abuse: calculating individuals' MEDs and conducting clinical analyses of those individuals' healthcare data. The results of this review also demonstrate the value of using increasingly sophisticated data analytics on paid claims data to examine prescribing and dispensing patterns. MassHealth and the HSN have a wealth of claims data available and could use that data to identify patterns of prescribing and dispensing that raise questions regarding how medical providers are prescribing certain drugs. MassHealth and the HSN should have the resources available to it to leverage this data to identify fraud, waste, and abuse in the prescription drug program as well as to work towards improved health outcomes for their members and users.

Based upon the review, the Office also recommends the following:

I. MassHealth and the HSN Should Expand Their Use of the MED to Identify Possible Opioid Abuse.

Using the MED allows MassHealth to evaluate its members' and HSN users' opioid use by converting opioid prescriptions to their equivalent dose of morphine. CMS has set a daily threshold of 120 mg for the MED for 90 consecutive days or more as a flag for potential adverse effects, inappropriate use, or diversion of opioids ("high MED"). Beginning on March 7, 2016, MassHealth will require prior approval for certain opioid prescriptions that would result in a high MED, which the Office supports.

Based on its review of paid claims, the Office also recommends that MassHealth and the HSN expand their use of the MED. In addition to calculating a person's MED on a prescription-by-prescription basis, MassHealth and the HSN should use all of a person's prescriptions to calculate an individual's MED. If MassHealth or the HSN determines that a MassHealth member or HSN user has a high MED resulting from more than one prescription, it should review that member's claim history and evaluate the clinical necessity and appropriateness of the opioid prescriptions. MassHealth and the HSN should also consider whether to create an alert for pharmacies on a MassHealth member's or HSN user's files if they have a high MED. This would allow a pharmacy to determine whether to take steps to verify the authenticity, accuracy, and appropriateness of the prescription, as well as to ensure that the total amount of opioids that the person is receiving is not potentially toxic.

To increase the reliability of its MED calculation, MassHealth should consider creating additional billing codes that would require methadone clinics to indicate the specific dose of methadone that they administer to patients. Currently, the procedure code description for methadone treatment does not provide the specific dose of methadone. Requiring clinics to provide the dosage would allow MassHealth to include the amount of methadone that a member receives from a drug treatment program in that person's total MED.

Finally, the Office recommends that MassHealth and the HSN use the MED calculation as an alert to review claims data for a variety of people, including people with a high MED who, for example, (1) are filling opioid prescriptions while receiving treatment with buprenorphine; (2) have a substance use disorder and are filling opioid prescriptions; (3) have prescriptions for two or more long-acting or short-acting opioids at the same time; and (4) have prescriptions for the same drug and same dose or the same drug and a different dose.

II. MassHealth Should Require Prior Authorization for All 30 mg Short-Acting Oxycodone Tablets.

MassHealth requires prior authorization for some, but not all, prescriptions for oxycodone tablets. Oxycodone immediate release tablets come in different strengths, including in 30 mg tablets. Oxycodone 30 mg immediate release tablets are highly abused and sought after by people with a substance use disorder because they are easily crushed and then snorted or injected. Based on the results of this review, the Office recommends that MassHealth[30] require prior authorization on all oxycodone 30 mg immediate release tablets.

III. MassHealth Should Require Prior Authorization for All Methadone Prescriptions for Pain.

In Massachusetts, prescriptions for methadone for pain are high in comparison to national utilization. As of March 7, 2016, MassHealth will require prior approval for new methadone prescriptions (*i.e.*, for people who have not filled a methadone prescription for 60 out of the last 90 days). This is a positive step. However, MassHealth should require prior authorization before dispensing all forms and doses of this medication for pain. This would allow MassHealth to ensure that the medication is being utilized appropriately and that it does not contribute to prescription opioid overdoses.

IV. MassHealth Should Put Steps in Place to Reduce the Number of Members Receiving Prescriptions for Methadone From a Pharmacy After Leaving a Methadone Treatment Program.

The Office found that individuals in this review received prescriptions for methadone from a pharmacy right after they received methadone replacement therapy from a drug treatment program. This creates the appearance that prescribers and pharmacies are circumventing federal laws that prohibit the prescribing and dispensing of methadone for drug treatment outside of a licensed facility. There are two steps that MassHealth could take to reduce this pattern. First, MassHealth could require methadone clinics to submit their claims quickly so that it could determine whether the person receiving a methadone prescription had recently completed a methadone treatment program. If so, MassHealth could evaluate the clinical appropriateness of the prescription.

[30] Given the structure of the HSN program, some recommendations are only applicable to the MassHealth program.

Second, MassHealth could work with the Department of Public Health to determine whether methadone clinics could submit information to the PMP for each person receiving methadone.[31] This would allow MassHealth to check the PMP for individuals receiving methadone prescriptions to see whether they have received or are receiving methadone from a drug treatment clinic. This also would allow prescribers who check the PMP before issuing a prescription for opioids to see that a person has received or is receiving methadone treatment for a substance use disorder, which would inform their clinical judgment.

V. MassHealth Should Evaluate the Efficacy of the Controlled Substance Management Program and Either Strengthen the Program or Consider an Alternative.

Currently, for MassHealth, a member must meet one of two criteria for enrollment into the state's Controlled Substance Management Program ("CSMP"):

- Eleven or more prescriptions, including original fill and refills, of one or more controlled substances from Schedule II, III, or IV during a three-month period, obtained from four or more prescribers or filled by four or more pharmacies; or
- Members who were enrolled in the Controlled Substance Management Program of a MassHealth-contracted managed care organization ("MCO") at the time the member disenrolled from the MCO.

The Office recommends that MassHealth determine whether the CSMP does, in fact, have a positive impact on the MassHealth program and its members. If so, the Office recommends that MassHealth increase its use of the current entry criteria to identify additional MassHealth members who should be included in the program. The Office encourages MassHealth to explore whether, among the more than one million MassHealth members, there are more than 184 people who would benefit from being included in the CSMP.

The Office also recommends that MassHealth use two other entry criteria for enrollment in the CSMP. First, the Office recommends that MassHealth include people with a high MED, well above the 120 mg threshold, who may not meet the other prescription-related entrance criteria. For example, the review identified members with an extremely high MED (more than 1,000 mg per day) who did not obtain 11 or more controlled substance prescriptions in a three-month time frame. Second, the Office recommends that MassHealth consider including people in the CSMP who are receiving methadone replacement therapy or buprenorphine for the treatment of a substance use disorder and are also receiving additional opioids for the management of acute or chronic pain conditions.

In addition, the Office recommends that MassHealth use information from the Department of Public Health's Prescription Monitoring Program as part of its analysis of the prescription utilization patterns of MassHealth members and HSN users. MassHealth could also

[31] Currently, only pharmacies that "dispense" medications report information to the PMP. Methadone clinics "administer" methadone and, as a result, do not report to the PMP. Changing this could require a statutory amendment.

strengthen its system that alerts a pharmacy if a CSMP member is trying to fill a prescription at an unauthorized pharmacy.

If MassHealth determines that the CSMP does not have a positive impact on its program or members, then it should consider an alternative program such as a provider and pharmacy lock-in program.

VI. MassHealth and the HSN Should Increase Their Use of the Department of Public Health's Prescription Drug Monitoring Program and Should Work with the Department to Educate Providers and Pharmacies About Using This Program.

Determining whether a person is abusing or diverting drugs is not easy. However, the results of this review indicate that MassHealth and the HSN are not fully realizing the potential uses of the Department of Public Health's Prescription Drug Monitoring Program ("PMP").[32] The PMP is a valuable resource that contains a wealth of information that can shed light on a person's prescription utilization in a way that looking only at MassHealth and HSN claims cannot. Failing to make use of the PMP is a lost opportunity to reduce fraud and abuse. Finally, MassHealth and the HSN could work with the Department of Public Health to educate providers and pharmacies regarding how to use the PMP effectively.

VII. MassHealth Should Increase the Number of Members it Refers to the Massachusetts Behavioral Health Partnership

Recently, the MassHealth pharmacy program has started to refer members to the Massachusetts Behavioral Health Partnership ("MBHP"), which is responsible for some of MassHealth's behavioral health services. MBHP has then reached out to those members to offer support and services to address suspected substance use disorders. The Office recommends that MassHealth strengthen this aspect of its pharmacy program, put a standardized policy in place detailing the circumstances under which it will make such a referral, and strive to proactively identify and refer members to MBHP for outreach and possible treatment.

[32] Expanding its use of the PMP may require a statutory amendment.