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**Patterns of Suboxone Prescribing: An Analysis of Claims Data from Massachusetts**

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## Abstract

**Background:** Suboxone is an opioid medication that has been found to be effective for treating opioid dependence, but little research has examined the extent to which it is being prescribed and under what circumstances.

**Objective:** This study examined prescribing patterns for Suboxone in terms of volume and clinical indications.

**Methods.** The study was conducted using a statewide database comprising pharmacy and medical claims that were covered by commercial health insurance plans in Massachusetts between 2011 and 2015. Trends in prescribing volume for Suboxone were assessed based on the annual number of patients with a prescription for Suboxone. To examine clinical indications for Suboxone prescriptions, pharmacy claims were linked to patient's medical claims. For patients with common pain-related conditions, the odds they were prescribed Suboxone rather than oxycodone, a widely used opioid for pain management, were also examined.

**Results:** The number of patients with a Suboxone prescription increased substantially during the study period, from 6,581 in 2011 to 38,775 in 2015. The most common clinical indication for Suboxone prescriptions was opioid use disorder, but a substantial percentage of prescriptions were for pain alone. Results also suggest that clinicians may consider prescribing Suboxone rather than opioid agonists when a patient presents with non-opioid drug dependence or abuse.

**Conclusion:** Study results point to a substantial increase in the number of patients with prescriptions for Suboxone. While Suboxone is most frequently prescribed for opioid use disorder, clinicians also appear to prescribe it for pain alone, particularly for patients who may be at elevated risk for opioid use disorder.

**Key Words:** Opioids, Suboxone, Oxycodone

## **Introduction**

Approximately 50,000 individuals died from opioid-related overdoses in the United States in 2017, a nearly two-fold rise over the past decade (CDC Wonder, 2018). As the opioid addiction epidemic has been declared a national public health emergency, understanding the use of potential treatments for opioid dependence is of great importance. One drug that has been introduced to treat opioid dependence is Suboxone, which combines the opioid buprenorphine with naloxone (also known as Narcan®), an opioid antagonist used to counter the effects of opioid overdose (Velandar, 2018). Through the combination of buprenorphine, which has a reduced euphoric effect compared to full agonist opioids, and naloxone, which blocks receptors and accompanying euphoria, Suboxone helps addicts cope with the painful process of withdrawing from opioids.

While Suboxone has been found to be effective in treating opioid use disorder, substance abuse experts have expressed concerns that it is underutilized among clinicians due in part to a lack of education about and experience with the medication (Sittambalam, et al. 2014). Unlike methadone administered for substance abuse treatment in a clinic setting, as of 2002 qualified clinicians can prescribe Suboxone in office settings for the treatment of opioid dependence. However, to be qualified, clinicians must obtain a federal waiver that entails the completion of specific training for treating patients with opioid dependence (DHHS, 2018)

At the same time, although Suboxone is approved for the treatment of opioid use disorder, clinicians may also be prescribing it for chronic pain. Chronic pain and addiction are frequent comorbidities, potentially creating a therapeutic dilemma for physicians. A recent

small-scale trial indicated that approximately one-third of chronic pain patients may have an addictive disorder (Chelminski, 2005). While it is recommended that all pain patients be screened for psychological comorbidities before prescribing medical therapy, this can be difficult given that denial is a common attribute of addiction disorders (ASAM 2011). Given that the Suboxone is as effective for treating chronic pain with less risk of addiction, some physicians may view Suboxone as a first-line long-acting opioid for chronic pain for all patients, even those without a prior diagnosis for opioid use disorder. At present, however, relatively little information exists regarding the clinical circumstances under which Suboxone is being prescribed.

In this article, we report results from our analysis of prescribing patterns of Suboxone, including trends in prescription volume and clinical indications for prescriptions of this medication. Our investigation focused on Massachusetts, a state that has been impacted significantly by the opioid epidemic with nearly 2,000 confirmed opioid overdose deaths in 2017 alone; a 42 percent increase since 2014 (MDPH 2018). The opioid-related death rate in Massachusetts is now more than twice the national rate, making it a suitable case study (NIDA 2018). As policy makers and public health officials seek to address the opioid epidemic, understanding recent trends in how Suboxone is prescribed is of paramount importance to help inform clinical decision making regarding this medication.

### **Study Data and Methods**

The source of data for this study was the Massachusetts All-Payer Claims Database (APCD). These data are collected by the Center for Health Information and Analysis (CHIA). The APCD contains pharmacy, medical and dental claims, from private health insurers. For our analysis, we

used all commercially insured pharmacy and medical claims, which included Medicare Advantage and Medigap plans, for years 2011 to 2015. The pharmacy file contains information related to the date the prescription is filled, the drug name and quantity, information about the prescribing physician, patient, and pharmacy (HIPAA 2017). The medical claims file contains information regarding diagnosis, date of service, and location. There is also a member file that contains information for individuals who are commercially insured including gender, age, and type of insurance (e.g., HMO or PPO). We use these data to conduct three separate analyses of Suboxone prescribing.

First, we analyzed trends in the volume of Suboxone prescribing by aggregating data from the pharmacy file to the patient level. We identified all prescriptions for Suboxone and other commonly-prescribed opioids by using National Drug Codes (NDCs). Drugs classified as Suboxone were those containing any combination of buprenorphine and naloxone. For each year of the study period (2011-15) we counted the number of patients who had one or more claims for specific types of opioids including Suboxone. We only counted a patient once for each year even though he/she may have had multiple claims for refills and/or subsequent prescriptions for the same opioid. We counted patients rather than prescriptions because we were interested in counts of unique patient treatment claims rather than total prescription claims. As such, the patient rather than the prescription is the meaningful unit of analysis.

Second, we analyzed the clinical indications for prescribing Suboxone to patients by merging data from the pharmacy file with data from medical claims file. We used ICD-9 codes from the medical claims to classify diagnoses for opioid use disorder (where opioid use disorder includes clinical diagnoses of either opioid dependence or abuse, Sittambalam, et al. 2014), chronic pain, and non-opioid drug dependence or abuse during the three-month period prior to a

Suboxone prescription. These codes are presented in the Appendix. We chose a three-month window for two reasons. First, prescription claims include only the month in which they were incurred rather than a specific date. Second, physicians may try several medications for treatment purposes, as is common for substance dependence and chronic pain diagnoses. As such, prescriptions for Suboxone and relevant diagnoses may often not be perfectly contemporaneous. We linked the pharmacy claims for the first few months in 2011 to the medical records from the last three months of 2010, which were included in the study database.

We note that our analysis of clinical indications for Suboxone was confined to 2011 through 2013. Due to regulations issued by the U.S. Department of Health and Human Services regarding the privacy of patient records (HIPAA 2017), CHIA removed all medical claims for drug dependence from data sets containing patient information after 2013. As such, we were unable to identify clinical indications for Suboxone pertaining to opioid use disorder or drug dependence for the last two years of the study time frame, 2014 and 2015.

Third, we examined the likelihood that patients being treated for pain received Suboxone rather than oxycodone, the most frequently prescribed opioid for pain in Massachusetts in the commercial insurance market (based on investigators' analysis of member files). To be able to make appropriate comparisons, we confined the sample to patients who (1) had at least one claim in a given year during the study period for either Suboxone or oxycodone, and (2) had a medical claim in the three months prior to their prescription for one of the three most common pain-related conditions during the relevant time frame: 1) spinal disease, 2) general set of pain symptoms including fever, headache and cough, and 3) joint disease. We identified these conditions using 2-digit ICD-9 codes as specified in the Appendix.

To assess differences in prescribing patterns for Suboxone versus oxycodone, we conducted regression analyses for each one of the three pain-related conditions separately (e.g., spinal disease, general pain symptoms, and joint disease). For each regression model, the dependent variable was a binary indicator for the drug that was prescribed (i.e., a value of 1 if the patient was prescribed Suboxone, and 0 if the patient was prescribed oxycodone). There were two key independent variables. One was a binary indicator for whether there was a diagnosis of opioid use disorder in the 3 months prior to the prescription (as indicated by having a 4-digit ICD-9 diagnosis code of 304.0, 304.7, or 305.5). The other was a binary indicator for whether there was a diagnosis of non-opioid drug dependence or abuse in the 3—month window (as indicated by having a 4-digit ICD-9 diagnosis code starting with 304 or 305 other than 304.0, 304.7, or 305.5, covering, for example, addiction or abuse of cocaine, cannabis, and hallucinogens). As the dependent variables for these models were in binary form, we used logistic regression.

The regression models also included a set of control variables to account for patient characteristics that might affect prescribing patterns. These include gender, age, whether the individual's health plan was a health maintenance organization (HMO), and whether the individual was a Medicare beneficiary (i.e., enrolled in a Medicare Advantage or Medigap plan). We controlled for gender and age because drug dependence is often higher among males and younger patients. We controlled for membership in an HMO because this type of plan often has tighter controls for service and medication utilization than do other types of plans such as indemnity policies or preferred provider organizations. We controlled for Medicare status as these patients are generally older and are more likely to suffer from chronic pain. The regression models also included indicator variables for the month and year in which the prescription claim

was incurred to control for general trends in prescribing over time. County-specific indicators were also included to control for geographic variation in opioid prescribing given that such variation has been shown to be substantial, particularly across urban and rural counties (Prunuske, 2014).

### **Study Results**

Figure 1 presents data pertaining to the volume of Suboxone prescribing during the study period. Panel A of Figure 1 shows that the number of patients who had a prescription for Suboxone increased substantially during this time-period, from 6,581 in 2011 to 38,775 in 2015. During this period, the size of the commercially insured population was relatively stable at approximately 4.2 million individuals (based on authors' analysis of member files). Panel B shows the percentage change in numbers of patients with Suboxone prescriptions relative to the number of patients with prescriptions for other opioids during the same time period. While the number of patients with prescriptions for Suboxone increased by nearly 500 percent, the increase for other major opioids was much less, and even decreased in some cases.

Figure 2 presents results from our analysis of the clinical indications underlying Suboxone prescribing. We grouped pharmacy claims for Suboxone according to whether there were any medical claims in the prior three months for a diagnosis pertaining to only opioid use disorder, only chronic pain, some combination of both opioid use disorder and chronic pain, non-opioid drug dependence or abuse, or none of the above. The majority (53.4 percent) of patients had at least one medical claim related to opioid use disorder but no medical claims related to any pain diagnoses. Another 21.8 percent had medical claims related to both opioid use disorder and pain in the three months prior to being prescribed Suboxone. While less frequent, 11.6 percent of patients receiving a Suboxone prescription had at least one medical claim for a pain diagnosis

but, no claims for opioid use disorder. Finally, 3.8 percent of the patients with Suboxone prescriptions had a medical claim for non-opioid drug dependence or abuse. The remaining patients, less than 10 percent, had no recent medical claims for either drug dependence or pain.

Table 1 presents results from the analyses of the likelihood that patients treated for pain received Suboxone rather than oxycodone. Three sets of regression results are presented, one set for each type of pain-related condition: spinal disease, general pain symptoms, and joint disease. The coefficients listed in the table are the odds ratios of being prescribed Suboxone versus oxycodone. The first model in each set of results presents specifications including only the key independent and control variables; the second model presents specifications that include interaction terms for gender and age with our indicator for opioid use disorder.

For each of the three pain-related conditions, a diagnosis of opioid use disorder was associated with very high odds that a patient was prescribed Suboxone versus oxycodone. For example, relative to being prescribed oxycodone, the odds of being prescribed Suboxone for those with a diagnosis of opioid use disorder is approximately 49 to 1 for the sample with a diagnosis of spinal disease, 98 to 1 for the sample with a diagnosis of general pain symptoms, and nearly 70 to 1 for the sample with a diagnosis of joint disease. While of much smaller magnitude, a diagnosis of non-opioid drug dependence or abuse was also associated with a positive and significant increase in the odds of being prescribed Suboxone.

Other results from the regression analyses include statistically significant interactions for gender and age. For each of the three pain-related conditions, men with opioid use disorder had greater odds of being prescribed Suboxone than oxycodone, while for those over fifty years of age the reverse was true. In addition, Medicare patients with a diagnosis of spinal disease had greater odds of receiving Suboxone than Oxycodone, perhaps reflecting specific guidance or

established protocols. The indicator variables for 2012 and 2013 had statistically significant odds ratios exceeding 1.0, which is consistent with Figure 1 showing that Suboxone prescribing increased between 2011 and 2013.

## **Discussion**

As policy makers and public health officials search for ways to address the opioid epidemic, Suboxone has emerged as one potential medication that can help individuals reduce their dependence on opioids, either prescription or illicit, and reduce the risk of opioid-related overdose. It is also a medication that can be prescribed for chronic pain and is considered safer than other opioid medications. We examined the prescribing patterns for Suboxone in Massachusetts, revealing a large and statistically significant increase in the number of unique claims over a short time period (2011-2015). The percent increase in the number of Suboxone claims during this period (over 500 percent) far outpaced that of other commonly prescribed opioids. The rapid increase in Suboxone prescribing was likely attributable to two factors: 1) an increase in opioid use dependence among the general patient population in Massachusetts as the opioid epidemic took hold, and 2) an increase in the number of prescribers who were authorized to prescribe Suboxone (i.e., clinicians who obtained a waiver from the Substance Abuse and Mental Health Services Administration pursuant to the Drug Addiction Treatment Act of 2000 -- DATA Waiver). During the study period, the number of clinicians in Massachusetts who held a federal waiver to prescribe Suboxone reportedly more than doubled (personal communication with analysts at the Massachusetts Department of Public Health).

In terms of clinical indications for Suboxone use, we found, as expected, most prescribing was for opioid use disorder alone or in combination with a diagnosis for pain. For

patients with one of the three most common chronic pain conditions for which oxycodone is prescribed, the results of the logistic regression analyses indicate that a recent history of either opioid use disorder or non-opioid drug dependence or abuse is associated with significantly higher odds of having a prescription for Suboxone rather than oxycodone.

However, our results also indicate a small but notable amount of possible prescribing for pain alone. Moreover, the logistic regression results showed that a recent history of non-opioid drug dependence or abuse is also predictive of a patient receiving a Suboxone prescription rather than oxycodone for pain. These results are in line with what we heard anecdotally during interviews with a select group of substance abuse experts that were conducted prior to our claims analysis. Specifically, some physicians prescribe Suboxone for pain in the absence of opioid use disorder when a patient's general medical history suggests an elevated risk for opioid addiction. Furthermore, we also heard anecdotally that clinicians may choose to prescribe Suboxone over other opioids even without any indication of an elevated risk of addiction simply because it is as effective in treating pain but is far less addictive than most other alternatives. Additional work in this area is needed to better assess these differences in clinical indications pertaining to Suboxone prescribing.

Our study is limited in several ways. First, we examined data from Massachusetts, a state where the opioid epidemic has been particularly severe. It is possible that the severity of the opioid epidemic in Massachusetts has propelled the use of Suboxone at a rate that exceeds what has occurred in other states. Second, the use of claims data as the basis for our analysis has limitations due to documentation errors and omissions. We also limited our search for clinical indications for Suboxone prescriptions to a three-month window. It is possible that some patients had been diagnosed with opioid use disorder more than three months before they were

prescribed Suboxone and this would result in an overestimation of the amount of prescribing due to pain alone. Third, the study time frame lags some of the increased attention and related efforts of policy makers and public health officials to deal with the opioid epidemic, due to federal restrictions on reporting drug dependence in more recent years.

In conclusion, the study results do indicate that the medical community is beginning to embrace Suboxone as an important medication for combating opioid use disorder. Many physicians may still not be well informed about this medication and its uses creating a need for educational initiatives. At the same time, we need to be cautious about prescribing Suboxone only when it is clinically appropriate to do so as the medication is itself potentially addictive and can be abused. There exists the potential for people to combine Suboxone with other prescription medications (e.g., benzodiazepines or Gabapentin) for intentional abuse or misuse. Also, Suboxone is prescribed largely on an outpatient basis and may not be as strictly monitored as methadone treatment, which may be less suitable for patients who have a greater physical dependency and/or need to be monitored more closely. Accordingly, our findings suggest a need for ongoing efforts to monitor the prescribing patterns of Suboxone and its impact on opioid addiction. The study reported here is an initial effort toward this objective.

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11. Based on investigators' analysis of claims data. See Figure 1.member files.
12. Personal communication with analysts at the Massachusetts Department of Public Health.

Figure 1 (Panel A): Annual Number of Patients with a Suboxone Prescription for MA Commercial Health Insurance Plans, 2011-2015

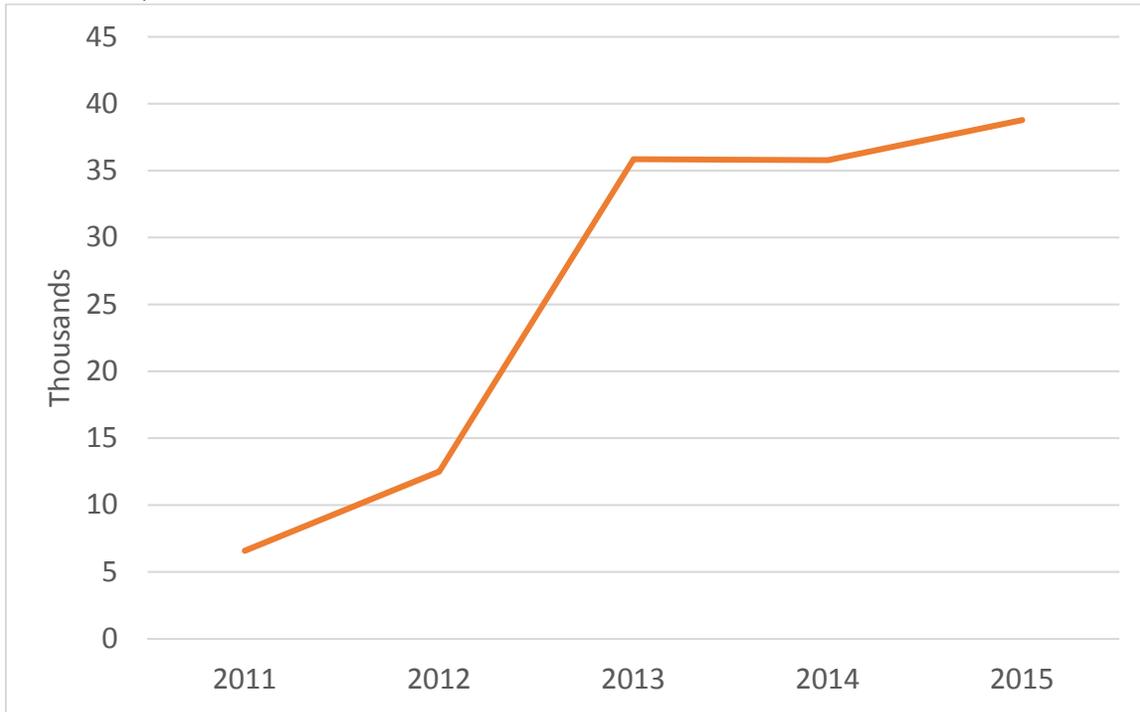


Figure 1 (Panel B): Percentage Change During Study Period in the Number of Patients with a Prescription for Suboxone and Other Major Opioids for MA Commercial Health Insurance Plans

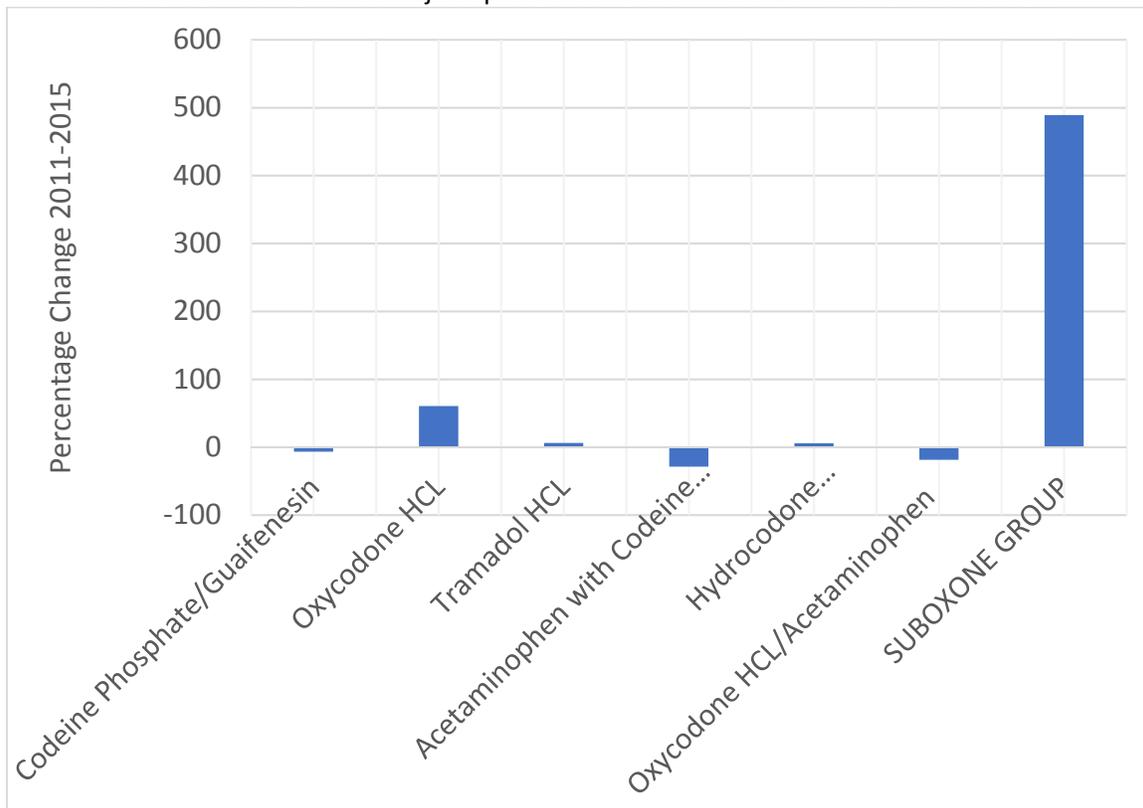
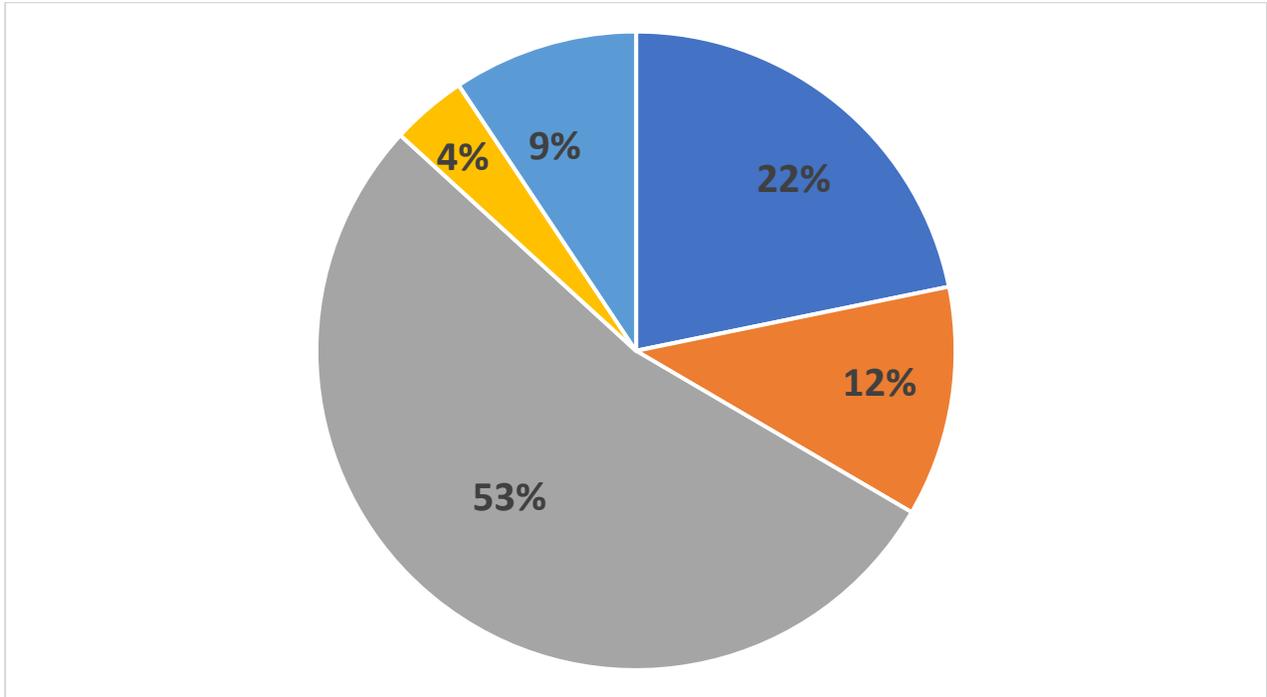


Figure 2: Distribution of Suboxone Prescriptions by Clinical Indication for MA Commercial Health Insurance Market, 2011-2013



■ Pain and Opioid ■ Pain Only ■ Opioid Only ■ Other Drug ■ Other

Table 1: Results of Regression Analyses for Clinical Indications Linked to Suboxone versus Oxycodone Prescribing

Variable	Major Pain Diagnosis Regression Results					
	Spinal Disease		General Pain Symptoms		Joint Disease	
	(1)	(2)	(3)	(4)	(5)	(6)
Opioid Use Disorder	49.22***	50.92***	98.20***	94.03***	70.72***	68.22***
Non-Opioid Drug Dependence/Abuse	3.01***	3.03***	3.38***	3.40***	3.00***	3.02***
Male	1.33***	1.24***	1.53***	1.45***	1.36***	1.21***
Age	0.97***	0.97***	0.96***	0.96***	0.98***	0.98***
HMO	1.02	1.02	1.01	1.01	1.07**	1.08**
Medicare	1.44***	1.39***	0.96	0.95	0.87	0.84
2012	1.52***	1.52***	1.57***	1.57***	1.33***	1.32***
2013	5.37***	5.41***	6.87***	6.89***	5.47***	5.45***
Male*Opioid Use Disorder		1.25***		1.26***		1.63***
Age>50*Opioid Use Disorder		0.64***		0.80***		0.55***
N	205,113	205,113	186,183	186,183	121,096	121,096
Pseudo R2	0.456	0.457	0.591	0.591	0.479	0.481

Notes: Coefficient estimates reported are odds ratios. Each regression contains month and county fixed-effects. The dependent variable takes on a value of 1 if the individual received Suboxone and 0 if the individual received Oxycodone. \*\*\* indicates  $p < 0.01$ , \*\* indicates  $p < 0.05$ , and \* indicates  $p < 0.1$ .

Appendix: ICD-9 Code Classifications for Drug and Pain

<b>ICD-9 Code</b>	<b>Description</b>	<b>Classification</b>
304.4 304.7 305.5	Opioid Use Disorder	ODU
304.1- 304.3 304.5- 305.4 305.6- 305.9	Non-Opioid Drug Dependence or Abuse	Other Drug
724	Other and unspecified disorders of the back	Pain
780	General Symptoms	Pain
789	Other symptoms involving abdomen or pelvis	Pain
786	Symptoms involving respiratory system and other chest symptoms	Pain
719	Other and unspecified disorders of joint	Pain
729	Other disorders of the soft tissues	Pain
722	Intervertebral disc disorders	Pain
723	Other disorders of cervical region	Pain
599	Other disorders of urethra and urinary tract	Pain
292	Drug psychoses	Other Drug
784	Symptoms involving head and neck	Pain
715	Osteoarthritis and allied disorders	Pain
739	Nonallopathic lesions, not elsewhere classified	Pain
726	Peripheral enthesopathies and allied syndromes	Pain
338	Pain, not elsewhere classified	Pain
847	Sprains and strains of other and unspecified parts of back	Pain
721	Spondylosis and allied disorders	Pain
959	Injury, other and unspecified	Pain
346	Migrane	Pain
592	Calculus of kidney and ureter	Pain
354	Mononeuritis of upper limb and mononeuritis multiplux	Pain
836	Dislocation of knee	Pain