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A case study of the regulations imposed upon
Massachusetts's prescription monitoring program

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Abstract

This case study focuses on the effectiveness of the recent regulations imposed upon Massachusetts's prescription monitoring program. Abuse and/or misuse of prescription opioids is becoming increasingly problematic within the United States and as a result many policy makers are looking for ways to combat the problem. In Massachusetts, the OxyContin and Heroin Commission was established to investigate the impact of both OxyContin and heroin on the state. The Commission delivered recommendations that eventually led the state legislature to make changes to Massachusetts's prescription monitoring program. This study targeted five major stakeholder groups and asked a series of questions through interviews and surveys. The research question was as follows: do major stakeholders see the recent regulations imposed upon the states prescription monitoring program as being effective in helping to combat abuse and misuse of prescription opioids in Massachusetts? Findings produced two main themes: 1) stakeholders believe prescription monitoring programs are successful in combating prescription drug abuse and/or misuse and, 2) there is an overwhelmingly negative attitude towards Massachusetts program design. Recommendations include determining how widespread the feelings of negativity and general lack of knowledge are felt across the Commonwealth, to educate users on the benefits of the program and encourage routine use, and to engage the state's licensing board.

Acknowledgements

I would like to thank all of those who agreed to participate in this study, my advisor Pamela Nadash for her thoughtful direction and my course advisor Hsin-Ching Wu for her patience and willingness to always answer my questions.

I would also like to acknowledge three very special people that made conducting this research, and completing the MSPA program possible: my mom, Bobbo, and my fiancé Mike. My mom and Bobbo consistently have provided me with guidance and support throughout the highs and the lows for the past two years. They also provided me with home cooked, hot meals every Monday and Wednesday night. Mike has grown with me throughout my graduate career, and always encouraged me when I was feeling down. He believed in my abilities and was a constant reminder of what I could achieve if I put my mind to it.

Last, but certainly not least, I would like to dedicate this research to my dad, Dana Rodman. I am proud to say that my dad is a recovering addict who has been clean for five years. His battle with prescription opioids influenced my research and through this case study I have gained a broader understanding for what happened to my family as a result of his addiction. My dad now spends his time helping other addicts find their way to sobriety and I can only hope that with continued research the Commonwealth can further help addicts and their families with their daily struggle.

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Introduction

Historically, drug addiction, abuse and misuse has been a sensitive subject that many people tend to shy away from acknowledging or even discussing in social settings. In reality, a large number of individuals, as well as their families, struggle with the horrors of drug addiction, abuse and/or misuse on a daily basis. According to the United States Food and Drug Administration (FDA) more than 16,000 lives are lost each year due to opioid-related overdoses (2014). In many cases addicts, abusers, misusers and their families struggle in silence because they fear how society will judge them. However, in recent years the misuse and abuse of prescription opioid drugs has become increasingly more prevalent and problematic within the United States (National Institute on Drug Abuse, 2011). The number of unintentional opioid related overdoses increased from approximately three thousand in 1999 to twelve thousand in 2008 (National Institute on Drug Abuse, 2011). As a result, the issue of prescription drug abuse and/or misuse is now affecting a significantly wider range of people than ever before. There are a number of reasons why the misuse and abuse of prescription opioid drugs has become problematic, including but not limited to the following: 1) these types of drugs are now more readily available than ever before, 2) many people do not realize how addictive the drugs can be, 3) there is a common misconception that they are “safer” than other drugs because a doctor prescribes them, and 4) they give the same recreational high as heroin yet come with less of a social stigma (National Institute on Drug Abuse, 2011).

OxyContin is one prescription opioid that has been receiving significant attention in recent years for being highly addictive and frequently abused and/or misused. Misuse is defined

as taking a prescription medication for a purpose or in a manner other than it was prescribed, or taking a prescription medication that was not prescribed to that particular person. In contrast, “abuse” of a prescription drug is when a person takes a prescription drug to achieve a euphoric high or for recreational purposes alone (Federal Drug Administration, 2010). OxyContin is a prescription pain pill that offers an extended release of oxycodone hydrochloride to help individuals with moderate to severe pain that requires relief for several days or more (Cicero, Inciardi and Munoz, 2005). Significant opioid misuse and abuse can be linked to the market introduction of OxyContin in 1996, mainly because of its addictive tendencies and availability. In fact, opioid addiction rates in Massachusetts increased by 950% between 1996 and 2006 (Massachusetts OxyContin and Heroin Commission, 2009).

As a result of prescription opioid misuse and abuse becoming increasingly problematic, many states have imposed regulations upon the prescription drug industry at large (Garcia, 2013). The majority of these regulations are intended to combat the misuse and abuse of such drugs by placing more accountability and obligation upon those who are not only prescribing the drugs, but also those who dispense them. In Massachusetts, the OxyContin and Heroin Commission was created under Chapter 302 Section 56 of the Acts of 2008 by the State Legislature to investigate the impact of both OxyContin and heroin on the state and in turn make policy recommendations to help combat the issue.

The recommendations made by the OxyContin and Heroin Commission aim to ensure that doctors and pharmacists are held to a higher standard, and require them to better manage and monitor the prescriptions they prescribe or dispense. The regulations that have been imposed are relatively recent and the long term effects have yet to be determined. Therefore, this study will focus on the short term effectiveness of the regulations pertaining to the states Prescription

Monitoring Program. Specifically, this case study will determine how the recent regulations are affecting several stakeholders and determine whether those stakeholders see the regulations as being effective and/or helpful in combating the misuse and abuse of prescription opioid drugs in Massachusetts.

The research question is as follows: do major stakeholders see the recent regulations imposed upon the states prescription monitoring program as being effective in helping to combat abuse and misuse of prescription opioids in Massachusetts? In addition, the larger question of how major stakeholders have been impacted as a result of the recent regulations will also be addressed.

This case study will provide information on how the industry in Massachusetts has changed as a result of the regulations. In addition, the case study will contribute to overall research on the topic by potentially uncovering adverse effects or unintended consequences of the regulations that should be considered when developing further policy recommendations. At this time there is a lack of research on how these regulations function in terms of success and/or failure and how they affect different stakeholders. This case study will examine best practice standards for prescription monitoring programs and help to determine if the recent regulations surrounding Massachusetts' state program are functioning as intended and in line with best practice standards.

History/Context

OxyContin is readily available for several reasons. In many cases the drug is legally distributed to pharmacies and then makes its way to the black market through diversion, fraud, false prescriptions, and doctor shopping (Massachusetts OxyContin and Heroin Commission, 2009). Diversion occurs when a prescription drug is dispensed or distributed in a manner other

than its intended purpose. Doctor shopping is when abusers target doctors that are known to be careless or sympathetic when prescribing or when a person visits multiple doctors and pharmacies in order to obtain multiples of the same prescription. In addition, some patients will sell their prescriptions for profit. The profitability is significant and serves as a motivator for diversion because OxyContin can be sold for up to \$100 per tablet on the black market. Abusers of OxyContin are known to crush the pill in order to destroy the time-release feature, and either snort, inject or chew the tablet in order to achieve a euphoric high (Massachusetts OxyContin and Heroin Commission, 2009). The high that is associated with destroying the time-release feature is comparable to the high that is associated with heroin, making these two drugs virtually interchangeable. Studies have shown that many OxyContin abusers will eventually turn to heroin because it is cheaper and even more readily available than OxyContin (Massachusetts OxyContin and Heroin Commission, 2009).

Accounts of prescription drug abuse leading to heroin use are becoming more and more prevalent in today's news stories. According to a Boston Globe article dated February 18, 2014, the City of Taunton witnessed 64 incidents related to heroin in a month and a half with 5 of those incidents resulting in death (Sampson and Anderson, 2014). The article also states that's advocates at the community meeting stressed that majority of users do not start off with heroin, but rather transition to the drug after first being prescribed opiates. In addition, a report on February 9, 2014 in the Vermont Valley News, law enforcement officials stated that they encounter heroin on a daily basis and most of it is reportedly coming from Massachusetts (Fleisher, 2014). As a result of such instances and the growing number of opiate related overdoses and deaths, Governor Deval Patrick recently declared a public health emergency in the state of Massachusetts (MacQuarrie, 2014).

Research shows that prescription drug abuse has increasingly become an issue for a wide range of people varying in age and background (Grau, et. al, 2007). Due to the fact that this issue is reaching a multitude of different people, prescription painkiller abuser is now considered to have reached epidemic proportions (Garcia, 2013). As a result, prescription drug abuse is no longer perceived as an individual struggle but rather a social issue that warrants public consideration. The Massachusetts OxyContin and Heroin Commission (2009) stated that opiate addiction within the Commonwealth has reached epidemic proportions larger than was seen with the flu pandemic, which constitutes this as a serious public health issue that warrants careful consideration and attention.

The Massachusetts OxyContin and Heroin Commission was established in the 2007-2008 legislative session to investigate the issues surrounding OxyContin, heroin and other opioid abuse and misuse within the Commonwealth. The Commission was comprised of legislative and gubernatorial appointments who examined various policies surrounding substance abuse, the total direct and indirect cost of said policies, how opioid drugs are making their way to the streets and how families across the Commonwealth are being impacted by the issue. In turn they were expected to make policy recommendations that would help combat the growing opioid epidemic. The Commission delivered recommendations relating to the following policy areas: 1) prevention and education, 2) distribution, dispensing and handling, 3) prescribing and monitoring, and 4) expansion of access to treatment services (Massachusetts OxyContin and Heroin Commission, 2009).

The Massachusetts OxyContin and Heroin Commission was established during a time when the Commonwealth was facing a serious problem. Not only had OxyContin abuse and/or misuse reached epidemic proportions but the state budget was also greatly impacted trying to

combat the issue. In 2005, the total cost of substance abuse and addiction to the Commonwealth amounted to 21.8% of the state's total budget. In addition, the state paid nearly \$200 million in emergency room costs related to opioid related overdoses (Massachusetts OxyContin and Heroin Commission, 2009). Furthermore, in 2002, Boston had the highest rate of OxyContin related emergency room visits in the country (Massachusetts OxyContin and Heroin Commission, 2009).

Despite the fact that over \$4.5 billion was spent on substance abuse and addiction, Massachusetts was ranked in the lower 50% of states in terms of total money spent on prevention, treatment and research (Massachusetts OxyContin and Heroin Commission, 2009). Only 2% of the \$4.5 billion, or \$66 million, was spent on prevention, treatment and research (Massachusetts OxyContin and Heroin Commission, 2009). The report presented to the legislative body of the Massachusetts State House in November of 2009 included 20 policy recommendations to update existing laws and create new laws pertaining to prescribing and dispensing substances that are controlled by the federal government and subject to regulation by the Drug Enforcement Agency (Massachusetts OxyContin and Heroin Commission, 2009).

The Commission revealed that the state's prescription monitoring program was failing to be an effective resource in combating the opiate epidemic. As a result, the commission made several recommendations to improve the state's prescription monitoring programs in hopes of it being used as an effective preventative tool. The Commission stated that although completely stopping misuse and/or abuse of prescription drugs is highly unlikely, reducing reckless or fraudulent distribution of the drugs is a realistic goal. Therefore, they concluded that one of the most efficient ways to stop fraud and limit the availability of opioid prescriptions is to have an active and useful prescription monitoring program.

As a result of the recommendations made by the Commission, the Massachusetts State Legislature eventually adopted legislation to reform state regulations. An Act Relative to Prescription Drug Diversion, Abuse and Addiction was adopted in August of 2012 and became Chapter 244 of the Acts of 2012. The legislation most notably made changes to Massachusetts' prescription monitoring program. Prescription monitoring programs maintain statewide databases that contain information regarding prescriptions that have been dispensed containing controlled substances. According to the Massachusetts Department of Public Health (2014) the goal of prescription monitoring programs are to promote safe prescribing and dispensing and to assist in addressing prescription drug misuse and abuse.

Under the new legislation, the Department of Public Health is charged with ensuring that all prescribers who are licensed to prescribe a controlled substance are automatically enrolled in the state's prescription monitoring program upon license renewal. In addition, it is now mandatory for prescribers to check the database for all new patients, which was not required in years past. In addition, the Act grants expanded database access to pharmacists within the Commonwealth. Practitioners and pharmacists in Massachusetts are required to fill out an enrollment form in order to be granted access, which can be viewed in Appendices A and B.

The Commission concluded that their recommendations surrounding prescription monitoring were the most promising of all the recommendations. They stated that resuscitating and improving the states program would help combat the opioid epidemic as well as save money for the Commonwealth. The recommendations surrounding the states prescription monitoring program were intended to make the program more accessible to non-governmental stakeholders such as pharmacists and prescribers and ensure that real time data is available and can flow in a non-restrictive and streamlined fashion.

Literature Review

Overview

Because prescription drug abuse and misuse has only been considered a social issue in the recent past, there has not been extensive research on the long term effects of regulating prescribing and dispensing of pharmaceuticals. However, significant research has focused on the regulations and how they affect different stakeholders in the short term. Policy makers have been charged with creating regulations that limit prescription drug diversion but at the same time do not interfere with adequate treatment of pain. In many cases, satisfying both objectives can be a challenge. According to Fishman et al. (2004), state and national organizations are considering under treatment of pain as a serious public health problem, underscoring the need for finding a balance between properly regulating prescribing and dispensing prescription drugs and proper treatment of pain. Many scholars believe that prescription monitoring programs promote more informed prescribing without deterring practitioners from prescribing controlled substances when needed (Perrone and Nelson, 2012). The National Alliance for Model State Drug Laws specifies that prescription monitoring programs are intended to do just that; support legitimate medical use of controlled substances while limiting diversion, misuse and abuse (Gugelmann and Perrone, 2011).

Many researchers support the use of prescription monitoring programs. Prescription monitoring programs were first established in 1989, with only 9 states participating in some capacity. By 2013, 49 out of 50 states had adopted some type of prescription monitoring program with the intention of better identifying inappropriate prescribers, their dispensing patterns, and to detect drug seekers and monitor behaviors (Garcia, 2013). Paulozzi et al. (2011) state that with proper program design, prescription monitoring programs have proven to be successful in

reducing misuse and abuse of prescription drugs. Garcia (2013) supports this claim and stresses the need for proper program design in order to reduce doctor shopping along with change prescribing behaviors. A survey of substantial literature regarding prescription monitoring programs produced two major themes relating to how an ideal program is run: 1) real time data and 2) access.

Real Time Data

In the pre-internet era, programs that required data input and sharing of data, such as prescription monitoring programs, were not very effective. According to Fishman et al. (2004), non-computerized monitoring programs actually had a negative impact on areas of legitimate medical care because pharmacists were prescribing based on outdated information. However, due to the development of the Internet, prescription monitoring programs are no longer facing limiting factors such as reporting with paper documentation, and the voluntary nature of reporting (Perrone and Nelson, 2012). Presently collecting and sharing real time data is not only a possibility, but it is easier than ever before with the help of electronic data transmission systems (Fishman et al., 2004). According to the Massachusetts Department of Public Health (2014) Massachusetts's prescription monitoring program is in fact a computer-based, Electronic Data Transfer system (EDT).

Clark et al. (2012) state that real time data that is constantly available is critical for the success of a prescription monitoring program, particularly in cases where dispensing occurs at 24 hour facilities. Therefore, it is critical to ensure that it is not burdensome or time consuming for pharmacists to upload information to the prescription monitoring program and encourage them to do so in a timely manner (Perrone and Nelson, 2012). Clark et al (2012) state that ideally, prescription monitoring programs should collect data within minutes of dispensing. According to

the Massachusetts Department of Public Health (2014) pharmacists are required to input data into the state's prescription monitoring program on a weekly basis but they are not mandated to consult the database before dispensing a prescription. In addition, the regulations encourage pharmacists to use professional judgment in deciding when to consult the database before dispensing (Ryle, 2013).

Gugelmann and Perrone (2011), discuss a study conducted in 2010 that supports the need for information that is updated in real time. The study looked at 179 clinical records that were reviewed by practitioners in Ohio's prescription monitoring program database. Having real time data available resulted in the practitioners changing their prescription practices in 41% of their interactions with patients.

Many believe that the quality of a patient's care can be significantly improved if those who are responsible for the patient have access to up-to-date, live information. According to Brushwood (2003), effective prescription monitoring programs provide feedback regarding a patient's history in a timely manner to physicians and pharmacists who are responsible for that patient. Perrone and Nelson (2012) argue that in order for a prescription monitoring program to be most valuable in clinical practice, it must be current. According to Clark et al. (2012), varying intervals of data collection compromise the utility of the data and significantly limits the success of the prescription drug monitoring program. In Massachusetts, practitioners are required to consult the database only when treating a new patient (Department of Public Health, 2014). This could potentially be problematic because physicians may have current patients that are abusers and or/misusers which would go undetected. Whereas, states such as Rhode Island and Connecticut require practitioners to consult the database every time they prescribe a controlled substance, in an attempt to avoid such misdetections (Rhode Island Department of Health, 2014;

Connecticut Department of Consumer Protection, 2014).

Furthermore, research shows that effective prescription monitoring programs must be comprehensive and accurate in data reporting. Brushwood (2003) describes a comprehensive program as one that requires the reporting and aggregation of data of all controlled substances that are dispensed versus only schedule II drugs. The United States Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five categories or schedules ranging from I-V based on the drug's acceptable medical use and the drug's abuse or dependency potential. Schedule I drugs have the highest potential for abuse and/or dependence whereas Schedule V drugs have the least potential for abuse and/or dependence (United States Drug Enforcement Administration, 2014). Brushwood (2003) goes on to state that not having a comprehensive program could result in not catching shifts in drug seeking behaviors. In Massachusetts, community pharmacies, hospital outpatient and clinical pharmacies as well as out of state mail order pharmacies that service patients in Massachusetts are required to report to the states prescription monitoring program (Massachusetts Department of Public Health, 2014). In addition, Massachusetts's prescription monitoring program reports on schedule II-V drugs and includes extensive information such as fill date, quantity, prescriber, dispensing pharmacy and insurance information (Ryle, 2013).

Research also shows that it is important to be comprehensive regarding the different types of pharmacies that are available (Brushwood, 2003). For example, mail order, internet pharmacies, hospital and retail pharmacies should all be required to report to the prescription monitoring program within their respective patient's state. Perrone and Nelson (2012) claim that in order to truly be effective all monitoring programs should have comprehensive information on the prescriber, the patient, the pharmacy, generic name of the drug, the dosage prescribed,

number of units dispensed, and the dates of both prescribing and dispensing. In addition, Brushwood (2003) argues that maintaining accuracy when inputting and using patient data is critical for a prescription monitoring program to be effective. If the data that is being reviewed is not accurate or even outdated then the purpose of the program is lost.

Access

The second major component to running a successful prescription monitoring program is allowing user-friendly and standardized access for a variety of stakeholders. Interstate access is a major hindrance for the effectiveness of prescription monitoring programs and failure to share data amongst states can lower the effectiveness of prescription monitoring programs. Since each state is charged with implementing and maintaining their own program, prescription monitoring programs vary greatly from state to state (Garcia, 2013). Such differences include the types of drugs that are reported, when prescribers are required to consult the database, how often dispensers must report data to the system, what stakeholders have access to the data, and whether the data can be shared with other states or not (Garcia, 2013). The chart below (figure 1) shows how the Massachusetts's prescription monitoring program compares to both Rhode Island and Connecticut's prescription monitoring programs in terms of who has access to the database, how often it is updated, when prescribers are required to consult the database, what drugs are monitored and whether or not the state shares information with other states.

	Who has access	How often is it updated	When are prescribers required to consult	What drugs are monitored	Types of Pharmacies required to consult
MA	Practitioners, Pharmacists, Delegates, Law Enforcement Officials	Weekly	New patients only	Schedule II-V	Community, hospital outpatient and clinical pharmacies, out of state mail order pharmacies
RI	Practitioners, Pharmacists, Law Enforcement Officials	Monthly	Each time a controlled substance is being prescribed	Schedule II-III	Retail, Institutional (outpatient) and Non-resident pharmacies (mail order)
CT	Practitioners, Pharmacists	Once a week, daily submissions are encouraged	Each time a controlled substance is being prescribed	Schedule II-V	Retail and hospital

(Figure 1 – MA prescription monitoring program compared to RI and CT)

According to Gugelmann and Perrone (2011) with no set standard for all prescription monitoring programs the result is inaccuracy and error within the systems. Perrone and Nelson (2012) go on to state that variations in data collection from state to state limits the effectiveness of the monitoring systems. Gugelmann and Perrone (2011) state that despite efforts from the United States Bureau of Justice to use federal funds to support interstate access, the success of prescription monitoring programs continues to be limited by variability in access across the states. Some states allow for prescribers, pharmacists and special law enforcement whereas other states only allow special law enforcement authorities to access the information in the database

(Gugelmann and Perrone, 2011). Brushwood (2003) claims that without a unified system it is impossible for prescription monitoring programs to function as intended. In addition, Clark et al. (2012) state that an ideal prescription drug monitoring program would have standardized, continuous access that meets the needs of the user.

Interstate collaboration and the creation of a national standard regarding information-sharing is essential. For example, Perrone and Nelson (2012) state that in urban areas that abut state borders, interstate access is crucial in reducing diversion. Reisman et al. (2009) support this claim by stating that interstate access allows for easier identification of doctor shoppers who cross state lines to fraudulently obtain controlled substances in two different states. Paulozzi et al. (2011), state that some prescription monitoring programs grant pharmacists the ability to capture a unique serial number that is associated with each prescription. The serial number can then be tracked to help identify duplicate prescriptions or stolen forms submitted at other pharmacies. If this type of access were granted to pharmacists nationwide, it would be much more difficult for drug seekers to doctor shop across state lines.

In addition to granting standardized, user-friendly access to pertinent stakeholders nationwide it is important that the application process is not cumbersome. According to Gugelmann and Perrone (2011) proper access to a patient's full prescription history allows for more informed prescribing on the part of the physician, and therefore less diversion and opioid abuse. Informed prescribing not only allows for less diversion and abuse, but it also promotes healthy and appropriate treatment of pain. Perrone and Nelson (2012) go on to state that in addition to granting access, states should focus their attention on making the log-in and application process simple and user-friendly. Having simple and user-friendly processes to gain

access to the database would allow for a less cumbersome and frustrating experience, and encourage more consistent usage.

Research Methodology

Overview

Drug abuse and misuse is a complex social issue that requires sensitivity within the research method in conjunction with in depth analysis. Overall, the goal of this study was to determine how different stakeholder groups feel regarding the effectiveness of the recent regulations imposed upon the state's prescription monitoring program. In particular this study examined how stakeholders feel regarding the overall success of prescription monitoring programs in general as well as gauge their perspectives on the effectiveness of the regulations in terms of helping to combat drug abuse and misuse within the Commonwealth.

For this case study two methods of qualitative data collection were utilized: 1) in depth interviews and 2) a survey. In addition the study targeted five key stakeholder groups including the following: 1) legislators who served on the OxyContin and Heroin Commission in Massachusetts, 2) both hospital and retail pharmacists who have experience with prescription monitoring programs, 3) doctors and organizational representatives who have experience and/or knowledge of opioid prescribing, 4) a sampling of recovering opioid addicts and, 5) substance abuse counselors. Perspectives from all five of these stakeholder groups helped to determine reoccurring themes in addition to any gaps in how different stakeholders view the effectiveness of the recent regulations. This study also provided insight as to how the stakeholders feel regarding the success of prescription monitoring programs in general.

Research Method

The research method was based on qualitative data that was generated through a single

case study approach consisting of five subjects of analysis within the state of Massachusetts. This study was based on a convenience sample and all subjects were contacted by email or via the phone. Participants from all five stakeholder groups were asked to contribute on a voluntary basis with no financial incentive. Data collection was conducted through a series of face-to-face or phone interviews and surveys. The subjects of the interviews and participants of the surveys were required to give informed consent prior to data collection. The letter of informed consent for all participants can be viewed in Appendix H. The identity of all research participants remained confidential throughout the entire process, and data will be destroyed when the study is complete. All interviews were recorded, and transcribed. The data was analyzed through a comparative process to determine any reoccurring themes or inconsistencies between the stakeholders.

Interviews

In depth interviews were conducted face to face or over the phone with subjects from four of the five stakeholder groups. One of the targeted groups consisted of a sample size of two members from the Massachusetts State Legislature who have experience with the subject matter. This particular study targeted legislators that served on the Massachusetts OxyContin and Heroin Commission. The OxyContin and Heroin Commission was established in the 2007-2008 Legislative Session to study the growing opioid abuse epidemic in Massachusetts. As stated earlier, the Commission released a report with findings on the subject and recommendations on how the state should proceed in handling the growing epidemic.

The legislators were asked a series of questions pertaining to their contributions to the Commission, their knowledge of opioid abuse and misuse prior to being on the Commission, the current regulations surrounding the states prescription monitoring program, the recommendations

that were made by the Commission and how they feel regarding the effectiveness of those recommendations at this time. The interview questions for legislators are outlined in Appendix C. Face to face or phone interviews were selected for this group because legislators may be able to offer additional information regarding their experience or knowledge of the subject outside of the interview questions that may add to the research. Subjects for this group will be recruited and contacted through their official capacity at the Massachusetts State House, or if they have since left the legislature through their current profession.

The second stakeholder group that was targeted is pharmacists. In order to gain a broad perspective both hospital and retail pharmacists were targeted. This study focused on a sample size of nine pharmacists that either had experience with prescription monitoring programs in Massachusetts, prescribing opioids themselves or were knowledgeable in prescribing opioids in general. The Prescription Monitoring Program used in Massachusetts is online and is a secure website that supports safe prescribing and dispensing. Massachusetts's regulations now require pharmacies to use the Online Prescription Monitoring Program, which exposes the majority of pharmacists in Massachusetts to the recent regulations.

The pharmacists were asked a series of questions regarding their experience using the prescription drug monitoring program, their views on the effectiveness of the recent regulations surrounding prescription monitoring programs, how they feel regarding the effectiveness of the regulations in terms of helping to combat drug misuse and abuse, and their views on over and under prescribing by doctors. The interview questions for pharmacists are outlined in Appendix D. Face to face and phone interviews were conducted with this group because as professionals they may be able to offer additional pertinent information relating to the subject matter that is not covered in the interview questions. Subjects for this group were recruited and contacted through

their official capacity at either local retail pharmacies or through local pharmaceutical hospital contacts.

The third stakeholder group that was targeted is doctors. In order to gain a broad perspective both physicians and organizational representatives were targeted. The sample of four doctors with experience prescribing pain medication brought a unique perspective due to the fact that the recent regulations have changed the way in which their industry operates. This study targeted physicians that treat chronic pain because they had experience prescribing opioids themselves. The doctors were asked a series of questions regarding how the regulations have affected their ability to do their job, their thoughts surrounding misuse and abuse of opioids in general, their views on under and over prescribing in general, and how they feel regarding the effectiveness of the regulations surrounding prescription monitoring programs in terms of helping to combat drug misuse and abuse. The interview questions for doctors are outlined in Appendix E. This stakeholder group was interviewed face to face or over the phone because the doctors may be able to offer additional information or insight not covered within the questions based on their personal and professional experience. Subjects for this group were recruited and contacted through the states medical association.

The fourth stakeholder group that was interviewed face to face or over the phone for data collection is substance abuse counselors. In addition to surveying recovering opioid addicts, substance abuse counselors were targeted in order to gain a broader perspective. The sample size of this group consisted of two people. The substance abuse counselors were asked a series of questions regarding how their patients are most commonly introduced to opioid drug, how they most commonly become addicted and how they most commonly obtain the drugs on a regular basis. This data provided insight on how and why prescription drugs are most frequently

misused, abused and/or making their way to street in Massachusetts. Lastly, they were asked a series of questions regarding the recent regulations surrounding prescription monitoring programs, and their views on the effectiveness of such regulations. The interview questions for recovering substance abuse counselors are outlined in Appendix F. For this stakeholder group face to face or over the phone interviews were conducted because they may be able to offer additional information or insight not covered within the questions based on their personal and professional experience. Subjects for this group will be recruited and contacted through their official capacity.

Surveys

The fifth stakeholder group that will be targeted for data collection is recovering opioid addicts. The sample size will be eight individuals and the identity of participants who fill out the surveys will be kept anonymous for confidentiality purposes. This stakeholder group will provide an important perspective because these are the people who have experience with addiction, and know how the drugs are commonly being misused and abused from personal experience. The survey will ask a series of questions regarding how the participant was introduced to the drug, how they became addicted and how they obtained the drugs on a regular basis. This data will provide insight on how and why prescription drugs are most frequently misused, abused and/or making their way to street in Massachusetts. Lastly, they will be asked a series of questions regarding recent regulations surrounding prescription monitoring programs, and their views on the effectiveness of such regulations. The survey questions for recovering addicts are outlined in Appendix G. For this stakeholder group a survey is being conducted because of the sensitive nature of the questions being asked. The participants may not feel comfortable sharing such personal details in a face to face setting. Subjects for this group will be

recruited and contacted through local substance abuse counselors.

Results/Findings

Overview

Significant data was collected from a variety of sources within all five stakeholder groups: 1) legislators, 2) both hospital and retail pharmacists who have experience with prescription monitoring programs, 3) doctors and organizational representatives who have experience and/or knowledge of opioid prescribing, 4) substance abuse counselors and 5) a sampling of recovering opioid addicts. Face to face or phone interviews as well as a series of surveys yielded data from two legislators, nine pharmacists, three doctors, one medical organizational representative, two substance abuse counselors and eight recovering addicts. Two main themes were established throughout the interviews and surveys which are as follows: 1) stakeholders in Massachusetts believe prescription monitoring programs are successful in combating prescription drug abuse and/or misuse and, 2) stakeholders in Massachusetts have an overwhelmingly negative attitude towards Massachusetts program design.

Prescription Monitoring Programs are Successful

A large number of the subjects believed that prescription monitoring programs are (or have the potential to be) successful in combating prescription drug abuse and/or misuse. Both legislators stated that they believe prescription monitoring programs are a successful way to combat prescription drug abuse and/or misuse. One in particular claimed that “Prescription monitoring programs are one of the ways we can help reduce prescription drug abuse. We all know that these drugs need to be prescribed by a licensed physician. Drug monitoring programs allows us to track who and more importantly how many prescriptions are being prescribed.” The other subject went on to state that “prescription monitoring programs can help us find legitimate

versus illegitimate prescribers.” That same subject then stressed the need for proper program design when developing a prescription monitoring program, “I believe prescription monitoring programs have the potential to be successful, if implemented properly.”

All of the pharmacists responded positively when asked if they believed prescription monitoring programs are successful in combating prescription drug abuse and/or misuse. One subject responded with “Yes!” while another stated “Yes, I believe prescription monitoring programs help reduce abuse and misuse of drugs.” Another subject went on to state “They are definitely helpful. I have seen it! I’ve had doctors call and tell us to cancel refills on a controlled substance since the patient was identified on PMP.” Lastly, one of the pharmacist subjects stated that “prescription monitoring programs are definitely helpful, but still relatively new. I think as more time passes and it becomes more used by RPh (Registered Pharmacist)/ MD (Doctor of Medicine) it will help to actually curb the misuse of prescription drugs.”

Half of the doctors that were interviewed felt as though prescription monitoring programs are successful in combating prescription drug abuse and/or misuse. One subject stated that “I think they can and potentially will be successful, baring implementation.” While another one of the doctors stated “Yes, they are successful. However, the way in which prescription monitoring programs are run could be improved. A centralized database that crossed state lines would be better.”

The substance abuse counselors that were interviewed vastly believed that prescription monitoring programs are successful in combating prescription drug abuse and/or misuse. One subject stated “Absolutely, I have already seen it in action. Patients in treatment who were receiving prescriptions that we weren’t aware of, we are now aware of. More importantly, it opens a discussion between patients and their physicians.” The other subject said “I love the

PMP. I see a lot of patients from New Hampshire that do not have one and there is a clear difference – it is scary. We should consider adding Suboxone and methadone to the database that would greatly benefit substance abuse counselors.”

The recovering addicts that were surveyed were not familiar with prescription monitoring programs.

Negative Attitude / Lack of Knowledge

Throughout the interviews and surveys an overwhelmingly negative attitude and general lack of knowledge surrounding Massachusetts’s prescription monitoring program emerged from many of the stakeholders, which was surprising given that most of the stakeholders felt as though prescription monitoring programs are successful. One of the legislators stated that “The recommendations of the commission for the states prescription monitoring program were positive, but Massachusetts is nowhere near meeting those goals.” That same subject went on to state the Department of Public Health needs to find more innovative ways to improve Massachusetts’ prescription monitoring program, “If the Department of Revenue can track parking tickets in real time, why can’t the Department of Public Health find a way to track this data real time.” The other legislator stated “More needs to be done in strengthening the states’ program. More collaboration needs to exist among federal and state officials.”

The pharmacists also portrayed a negative attitude and general lack of understanding. One subject stated “Massachusetts program could be effective if we put serious resources towards making it better.” Whereas another subject stated “I believe it has helped to some extent, but much more work needs to be done.” Another subject went on to say “I can check the prescription monitoring program, but what do you want me to do with that info? Electronic system is better than the old way; however, I have no idea who is even tracking the information.”

In addition, one subject stated “the database is not checked very often, there is a lag in real time information. Sometimes the information is not available when you need it, and then you find out later on that someone was doctor shopping when both pharmacies have a chance to upload the information.”

The doctors that were interviewed were extremely negative towards Massachusetts program design as a result of the regulations. One subject stated “The regulations were poorly drafted and would waste a lot of physicians time in looking up all new patients, regardless of any relationship to opioids much less a risk of abuse.” Another subject stated “Research should be done to pinpoint the connection between opioid abuse and prescribing. Research from the top down and interventions in identified areas of abuse will be more effective than mandating all practitioners to follow the dictates of the DPH.” Another subject stated “No, I don’t think the regulations will help in reducing abuse. Until doctors have more latitude to provide care to patients, have enough time to spend with them and are able to prescribe alternatives to narcotics it will be hard to do this justice.” In addition, one subject said “This is a multifactorial problem and like most things regulations look for easy unidirectional answers – those generally make things harder for the conscientious and don’t slow down the ones of concern. I wish they would talk to primary care doctors in practice and find out what the issues are and address those!”

One of the substance abuse counselors stated that “Massachusetts PMP can be cumbersome; having a delegate would be helpful.” In addition, one of the subjects was not familiar with the regulations at all “I am not familiar with the regulations, but all healthcare workers should know what other meds are being prescribed by other providers, and be vigilant about contradictions.”

Other

There were various findings throughout the case study that were not shared broadly across the group yet they were still noteworthy. One of the legislators stated “If the Commonwealth placed more resources in educating and rehabilitating those with drug issues, I truly believe there will be a reduction in overall crime and more importantly, a reduction in overdoses.” One of the pharmacists stated that “regulating the industry has potentially made it more dangerous for patients. Prescription opioids are a gateway to addiction and when patients are addicted and cannot access these medications (or don’t have the support to break their addiction) they turn to more dangerous street drugs like heroin.” However, one of the doctors stated “Prescriptions are issued for the primary purpose of treating patients appropriately; we must not lose sight of this in a rush to respond to the established addiction and overdose problems in our society. Licensing boards have the clinical expertise to balance patient needs with proper practitioner standards of care. The DPH does not have broad based expertise in this area.”

Both the substance abuse counselors and the recovering opioid addicts felt as though people will continue to find the drugs no matter what types of regulations are put into place. One of the substance abuse counselors stated “As long as drugs are good and kill pain, people will want them. There are so many levels of issues to cover that I don’t know that any amount of legislation can cover them all and actually be effective.” In addition, when asked whether they believed regulating the prescription drug industry has helped to combat drug abuse all of the recovering addicts said no. One subject in particular stated “I don’t think it has had any effect. Making them harder to get doesn’t mean they cannot be found.” Another subject stated “I think they ought to help the addict, not make him/her turn to crime to get the drugs.” The perspectives of the recovering addicts is important and will be discussed in the paragraphs below.

Discussion

The findings of this case study yielded very positive results in terms of how the stakeholders view the effectiveness of prescription monitoring programs in general. Majority of the stakeholders displayed positive feelings regarding the usefulness of prescription monitoring programs in conjunction with stressing the need for proper program design. However, there was an overwhelmingly negative attitude towards Massachusetts program design and a general lack of knowledge surrounding the prescription monitoring program itself. Subjects raised concerns ranging from real time data issues, the need for federal and state collaboration, interstate access and cumbersome and time consuming processes.

The findings of this study are interesting because with the help of recent regulations, the Massachusetts's prescription monitoring program design meets most of the technical components of an ideal prescription monitoring program. The program uses an electronic data transmission system, it has real time data capabilities and it is comprehensive and accurate. However, Massachusetts does not share data across state lines and there are no nationwide standards for who has access to the database.

Many complaints were lodged regarding real time data. One legislator questioned why the Department of Public Health has not come up with a way to track this information live. However, the capability to access real time information is there. It is not an issue regarding the technical components but rather an issue of physical resources. In order to have the information readily available pharmacists would have to be updating the database simultaneously as they were dispensing the drugs. A disadvantage to placing a requirement such as this on the pharmacists is that it would be extremely time consuming and an unrealistic expectation. In addition, some may argue that this type of pressure and added responsibility could potentially

affect the quality of service provided by the pharmacists.

Many of the stakeholders also claimed that more federal and state collaboration is needed. Federal and state collaboration would allow for interstate sharing and push the federal government to set a national standard for who has access to the database. Standardized access would allow for more comprehensive interstate sharing and increase the amount of information available to those who have access to the database. One may conclude that interstate sharing would be particularly beneficial to those practicing close to the border of neighboring states. Interstate sharing in Massachusetts would close the gap in terms of what Massachusetts's prescription monitoring program design is lacking.

Several of the stakeholders, including those who are expected to use the program on a regular basis, displayed a general lack of knowledge regarding the state's prescription monitoring program and the recent regulations surrounding the program. Many of the stakeholders were simply unaware of how the program was designed and how it is intended to function. The recent regulations allow for the creation of delegates to act on behalf of registered participants, and the OxyContin and Heroin Commission did consult with primary care physicians across the Commonwealth when drafting recommendations. The fact that some of the stakeholders were unaware of the provisions surrounding delegates and did not realize that the commission consulted with primary care physicians prior to making recommendations shows a lack of communication between the stakeholders and the policy makers. In addition, the fact that some of the pharmacists were unclear as to what happens with the information once they report it is an area that needs improvement.

It is important to note that a few of the stakeholders provided insight that was not consistent amongst all stakeholders, but was still pertinent to the overall discussion. One of the

legislators very adamantly stated that the opioid epidemic is a multilateral issue which warrants a comprehensive approach in terms of combating the overall problem. This statement was corroborated by one of the doctors who claimed that regulating the industry could potentially make it more dangerous for addicts or push them to turn to street drugs such as heroin. In addition, one of the recovering opioid addicts stated that policy makers should be helping the addict instead of forcing him or her to crime. All of these statements warrant the consideration of policy makers regarding how the state is investing in rehabilitation services and what kind of access is available to those who are in need. This case study suggests that in addition to maintaining a fully functional prescription monitoring program a deeper look at the overall services available to addicts is necessary in order to truly combat opioid abuse and/or misuse within the Commonwealth.

Recommendations

Definitive statements regarding further policy recommendations cannot be made at the conclusion of this case study. However, the research does suggest that further study is warranted and a different approach in terms of program design is desired. The first recommendation is to determine how widespread the negative attitude and general lack of knowledge regarding the states prescription monitoring program truly is. Policy makers should be charged with organizing a commission, much like the OxyContin and Heroin Commission, to investigate and determine the attitudes and knowledge of stakeholders across the Commonwealth. This Commission should hold forums across the Commonwealth in order to gain insight as to how widespread the negative feelings and lack of knowledge is felt amongst stakeholders in Massachusetts. Insight from a larger sample of stakeholders will help to determine if further study and recommendations are needed.

The second recommendation is for policy makers and the Department of Public Health to develop a campaign to educate users on the benefits of the program, how the program is intended to function and to encourage routine use. For example, doctors should be encouraged to consult the database every time they prescribe a controlled substance, not just for new patients. In addition, pharmacists should be encouraged to update the database in a timely manner in order to help curb doctor shopping and diversion. If policy makers and the Department of Public Health want to restore faith in the Massachusetts's prescription monitoring program they must educate the primary users on the benefits of such behaviors. In addition, it would be helpful to outline how Massachusetts program compares to other programs nationwide to give stakeholders a better sense of how Massachusetts is performing on a larger scale.

The third recommendation is for policy makers and the Department of Public Health to engage the state's licensing board. It is imperative that the pharmacists and physicians understand how the licensing board fits within the overall process and are educated on their procedures. These particular stakeholders should feel confident that any pertinent information that is funneled into the database is making its way to the licensing board when necessary. According to this case study, many stakeholders do not feel confident that the information they are submitting is making its way to the correct authorities. If the primary users of the system do not have faith in the overall purpose of the program it is inevitable that they will not regularly use the program.

Limitations

There were a few limitations encountered throughout this case study. The main limitation was a condensed amount of time for research, in addition to the scope of research evolving over time. There were only two months in between IRB approval and the date of completion. This

time frame limited the amount of data collection for such a complex and wide ranging issue. In addition, it was somewhat difficult to get professionals to agree to be interviewed because of the sensitive nature of the topic and the fact that opioid abuse is an emerging issue in the Commonwealth at this time. Many potential participants were hesitant to open up about the issue in fear of jeopardizing their career by providing information they were not authorized to provide. In addition, the Department of Public Health was unwilling to communicate or give any perspective on the issue stating that the regulations were still a work in progress and they were not at liberty to discuss them.

Conclusion

After extensive research and literature review, this case study revealed that further study and action on behalf of the policy makers and Department of Public Health is needed at this time. The research question was proposed as follows: do major stakeholders see the recent regulations imposed upon the states prescription monitoring program as being effective in helping to combat abuse and misuse of prescription opioids in Massachusetts? According to this case study the answer is inconclusive at this time. However, despite the fact that definitive statements regarding the larger population of stakeholders cannot be made, the study does suggest that although stakeholders in Massachusetts believe prescription monitoring programs are successful in combating prescription abuse and/or misuse they have a predominantly negative outlook regarding the program design of Massachusetts program in particular with regards to the recent regulations imposed upon the program. Although Massachusetts's prescription monitoring program appears to meet the technical components of a successful prescription monitoring program many of the pertinent stakeholders lack general knowledge on how the program is intended to function, are frustrated with the usability of the program and do not have faith in the

overall outcome.

Due to the fact that prescription monitoring programs are still relatively new, additional research and assessment of different programs across the country is necessary in order to truly define the ideal prescription monitoring program. However, Massachusetts can make more of an impact in terms of combating prescription opioid abuse and misuse by encouraging routine use and educating users in order to garner additional support of the program. In addition to maintaining a useful prescription monitoring program policy makers and other governmental authorities must commit to supporting other initiatives surrounding substance abuse in order to achieve the overall goal of decelerating the opioid epidemic in Massachusetts. On March 27 of this year Governor Deval Patrick stated that he would commit \$20 million in additional funds to increase drug treatment and recovery services (State House News Service, 2014). This is a step in the right direction, however, a more detailed and extensive plan is needed in the near future. The legislature must act, and they must act fast in order to truly have an impact in terms of combating the overarching issue.

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Appendix A



Commonwealth of Massachusetts, Department of Public Health, Drug Control Program
99 Chauncy Street, Boston, MA 02111
Telephone 617 983-6700

Massachusetts Online PMP Enrollment Form for Prescriber

- All boxes below are required to be filled in unless otherwise indicated. Incomplete forms will be returned.
 - Read the Terms and Conditions for Prescriber and Dispenser Use of the MA Online PMP.
 - Sign and date the form.
 - Mail, do not fax, the completed form to the address above, and retain a copy for your records. No fee is required.
- For MCSR Amended Application forms and other DCP information visit DCP's Web site at <http://www.mass.gov/dph/dcp>
For MA Online PMP information visit <http://www.mass.gov/dph/dcp/onlinepmp>

In the boxes below enter the requested information.			
1) Degree: (Select one)			
<input type="checkbox"/> MD	<input type="checkbox"/> DMD	<input type="checkbox"/> DDS	<input type="checkbox"/> DO
<input type="checkbox"/> RPh (CDTM only)	<input type="checkbox"/> DPM	<input type="checkbox"/> RN/NP	<input type="checkbox"/> RN/NM
<input type="checkbox"/> RN/PC	<input type="checkbox"/> RN/NA	<input type="checkbox"/> PA	
2) Massachusetts Controlled Substance Registration Number (MCSR):			
3) Massachusetts Board of Registration License No.:			
4) DEA Controlled Substance Registration No. (If possessed):			
5) List additional DEA numbers and DEA "X" numbers used on prescriptions that might be dispensed in MA pharmacies.			
6) Name:			
First:	Middle:	Last:	
Suffix: (e.g. Jr., Sr., II, III)			
7) Business Address: Applications that include a P.O. Box number without a street address cannot be processed. Out-of-state addresses require a letter of explanation.			
Facility Name and Department (if applicable):			
Street:			
City:	State:	ZIP:	
8) Mailing Address: <input type="checkbox"/> Check here if same as above			
Street:			
City:	State:	ZIP:	
9) Business Telephone No.: ()			
10) Individual e-mail Address:			
11) Specialty (Enter up to 3 codes from the Specialty Code List):			
12) Virtual Gateway Username (If possessed, see instructions):			
13) Birth Month and Day [MMDD] (Do not include year):			
14) Compose a four digit PIN for MA Online PMP (No letters or other non-numeric characters):			

TERMS AND CONDITIONS FOR PRESCRIBER AND DISPENSER USE OF THE MASSACHUSETTS ONLINE PRESCRIPTION MONITORING PROGRAM

By logging in to and using the Massachusetts Online Prescription Monitoring Program ("MA Online PMP"), you agree to abide by the requirements governing the Prescription Monitoring Program at 105 CMR 700.012 and any other applicable requirements, including, but not necessarily limited to:

- 1) You attest to the following:
 - i. You are a duly licensed practitioner, pharmacist or other licensed health care professional authorized to prescribe or dispense controlled substances in the Commonwealth of Massachusetts;
 - ii. You are duly registered, or in the process of registering, with the Massachusetts Department of Public Health, Drug Control Program, to prescribe controlled substances. You also agree to promptly notify the Department of any change or proposed change in licensure or registration status;
 - iii. You are duly enrolled to use the MA Online PMP and that you have not provided nor will provide your login credentials (i.e., username, password, Personal Identification Number or any other security information) to anyone else. You are responsible for promptly notifying the Drug Control Program of any compromise of your login credentials or changes to your enrollment information (e.g., changes to name, business or email address, license or registration number) or prescriptive privileges; and
 - iv. Your use of the MA Online PMP is for the purpose of preventing the prescribing and/or dispensing of controlled substances to the same individual from multiple sources or the unlawful diversion of controlled substances. You may not request the prescription history for anyone other than your patient or for a patient encounter.
- 2) You acknowledge that you understand the following:
 - i. The Department of Public Health does not guarantee the accuracy or completeness of the information contained in the database. There may be multiple persons with the same name in the database, so you should use other information, such as date of birth and address, to distinguish your patient from others with the same name;
 - ii. You may use or disclose information obtained from the MA Online PMP, including reports generated from the database, only as permitted by applicable state and federal laws governing confidentiality and security of personal/patient information, including, if applicable, the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA);
 - iii. You must promptly notify the Department of any potential violation of confidentiality or use of the data in a manner contrary to the regulations or applicable professional standards;
 - iv. Usage of the MA Online PMP is recorded and monitored and that your right to use the system may be revoked at any time at the discretion of the Department.
 - v. Your controlled substances registration may be suspended or terminated in accordance with 105 CMR 700.004(L)(1), and that a referral may be made for criminal prosecution or disciplinary action by your licensing board, for the following:
 1. a request, use or disclosure of data that involves a willful failure to comply with the standards in 105 CMR 700.012 for request, transmission or disclosure of data;
 2. a failure to reasonably protect data in accordance with the requirements of 105 CMR 700.012 or other applicable state or federal law; or
 3. an attempt to obtain data through fraud or deceit;
 - vi. Data is being provided for the purpose of safe prescribing and dispensing, including assessing or preventing the possibility of drug abuse or diversion, but does not require you to take action that you believe to be contrary to the best interests of your patient; and
 - vii. The Department may revise these Terms and Conditions from time to time. You will be notified of any change and your continued use of the MA Online PMP after such notice shall constitute your acceptance of the new Terms and Conditions.

Applicant please sign and date below

I hereby certify that the information on this form is true to the best of my knowledge and I hereby agree to the *Terms and Conditions for Prescriber and Dispenser use of the Massachusetts Online Prescription Monitoring Program* ("MA Online PMP"). I understand that the Terms and Conditions may be revised from time to time, that I will be notified of any change and that my continued use of the MA Online PMP after such notice shall constitute my acceptance of the new Terms and Conditions.

Signature of enrollee applicant (no initials) _____ Date_____

MA Online PMP Enrollment Form Instructions

Allow two to three weeks after the enrollment form is received by the Drug Control Program (DCP) until you receive authorization and credentials to login to the Massachusetts Online Prescription Monitoring Program (MA Online PMP).

The most common reasons for return of enrollment forms are:

- Failure to fill in a PIN composed of four numerals.
- Discrepancies between information provided on the enrollment form and the corresponding information previously provided for the enrollee's Massachusetts Controlled Substances Registration (MCSR). MCSR registrants are required to submit an MCSR Amended Application form if there is a change in name, business address, DEA number, or Board of Registration number.

These instructions follow the enrollment form sequentially. If you need additional guidance contact the Drug Control Program at 617 983-6700.

Questions:

- 1) Select your professional degree.
- 2) Fill in your current MCSR number.
- 3) Fill in your the Board of Registration number.
- 4) Fill in your personal DEA number.
- 5) If you issue prescriptions using multiple DEA numbers or DEA "X" numbers at different times and locations, providing those to DCP will help ensure that you retrieve more complete prescription history reports listings from the MA Online PMP.
- 6) Include your complete middle name (no initials), and a suffix, if applicable.
- 7) Fill in your business address.
- 8) Fill in your mailing address. If you do provide a mailing address, all correspondence will be sent to your business address.
- 9) Fill in the phone number at which you can be reached. Please be mindful that this phone number would be used should DCP need to contact you or should prescribers or pharmacists need to consult with you regarding MA Online PMP prescription histories.
- 10) Please provide an email address that you monitor frequently. You will receive status updates and instructions on using the MA Online PMP will be sent to the email address you provide on the enrollment form. The email address will also be used to send updates regarding the MA Online PMP Terms and Conditions, alerts and MA Online PMP enrollment renewal notices.
- 11) Enter the relevant Specialty Code(s) found on the Specialty Code List. If you do not see a code that closely identifies your specialty, you may write in your specialty.
- 12) If you are not already an end user of the Virtual Gateway (VG), leave this box blank. The MA Online PMP is hosted in the VG, which is an internet portal operated by the Massachusetts' Executive Office of Health and Human Services (EOHHS) to provide the general public, medical providers, community-based organizations and EOHHS staff with a single resource for health and human services' applications. If you are already an end user of the VG because of another application, please provide your VG username. A preexisting VG end user will continue to use the same username and password.
- 13) Enter your birth month and day. You may omit the year. This information is required by the VG.
- 14) The four-digit PIN you create is a necessary identifier should you need to have your password reset for the MA Online PMP. If you do not provide a four digit PIN, DCP will create a PIN for you and will email the PIN to you along with your MA Online PMP user instructions. Please be sure to save the number in a location that you can easily retrieve it if needed.

Specialty Code List

Specialty	Specialty Code	Specialty	Specialty Code
Addiction Medicine	ADXN	Orthopedics	ORTH
Allergy	ALGY	Osteopathic Medicine	OSTM
Anesthesiology	ANTH	Otolaryngology	OTOL
Bariatrics - Weight Control	BAWT	Pain Medicine	PAIN
Cardiology	CDGY	Psychiatry - Adult	PCAD
Dermatology	DERM	Psychiatry - Child & Adolescent	PCCA
Dental - General Practice	DNAA	Psychiatry - Geriatric	PCGR
Dental - Oral and Facial Surgery	DNOF	Pediatrics	PEAA
Dental - Orthodontics	DNOR	Pediatrics - Palliative Care	PEHP
Dental - Periodontics	DNPR	Pediatrics - Surgery	PESG
Emergency Medicine	EMRG	Podiatry - Diabetics	PGDB
Endocrinology	ENDM	Podiatry - Surgery	PGSR
Family Medicine	FAMM	Physical Med & Rehab	PHYM
Gastroenterology	GAST	Pulmonology	PLDS
Geriatrics	GRTC	Podiatry - General Practice	PRAA
Hematology	HEMT	Psychopharmacology	PSPM
Hospice - Palliative Care	HSPC	Radiology	RDOL
Immunology	IMMN	Rheumatology	RHMA
Infectious Disease	INFD	Surgery - General	SGAA
Hospitalist	INTH	Surgery - Orthopedic	SGOR
Internal Medicine	INTM	Surgery - Plastic	SGPL
Neurology	NRAA	Sports Medicine	SPMD
Neurology - Pediatric	NRCH	Toxicology	TXGY
Obstetrics & Gynecology	OBGN	Urology	URGY
Oncology	ONCG	Vascular Disease	VSDS
Ophthalmology	OPHY		

Appendix B



Commonwealth of Massachusetts, Department of Public Health, Drug Control Program
99 Chauncy Street, Boston, MA 02111
Telephone 617 983-6700

Massachusetts Online PMP Enrollment Form for Dispensers

- All boxes below are required to be filled in unless otherwise indicated. Incomplete forms will be returned.
 - Read the Terms and Conditions for Prescriber and Dispenser Use of the MA Online PMP.
 - Enclose a photocopy of your current Board of Registration license (wallet-size). Originals will not be returned.
 - Sign and date the form.
 - Mail, do not fax, the completed form to the address above, and retain a copy for your records. No fee is required.
- For MCSR Amended Application forms and other DCP information visit DCP's Web site at <http://www.mass.gov/dph/dcp>
For MA Online PMP information visit <http://www.mass.gov/dph/dcp/onlinepmp>

In the boxes below enter the requested information.			
1) Massachusetts Pharmacy Board of Registration Pharmacist License No. (Begins with "PH"):			
2) Pharmacy DEA Number:			
3) Name:			
First:	Middle:	Last:	
Suffix: (e.g. Jr., Sr., II, III)			
4) Business Name and Address: Applications that include a P.O. Box number without a street address cannot be processed. Out-of-state addresses require a letter of explanation.			
Business Name:			
Department (if applicable):			
Street:			
City:	State:	ZIP:	
5) Mailing Address: <input type="checkbox"/> Check here if same as above			
Street:			
City:	State:	ZIP:	
6) Business Telephone No.: ()			
7) Individual e-mail Address:			
8) Virtual Gateway Username (If possessed, see instructions):			
9) Birth Month and Day [MMDD] (Do not include year):			
10) Compose a four digit PIN for MA Online PMP (No letters or other non-numeric characters):			

TERMS AND CONDITIONS FOR PRESCRIBER AND DISPENSER USE OF THE MASSACHUSETTS ONLINE PRESCRIPTION MONITORING PROGRAM

By logging in to and using the Massachusetts Online Prescription Monitoring Program ("MA Online PMP"), you agree to abide by the requirements governing the Prescription Monitoring Program at 105 CMR 700.012 and any other applicable requirements, including, but not necessarily limited to:

- 1) You attest to the following:
 - i. You are a duly licensed practitioner, pharmacist or other licensed health care professional authorized to prescribe or dispense controlled substances in the Commonwealth of Massachusetts;
 - ii. You are duly registered, or in the process of registering, with the Massachusetts Department of Public Health, Drug Control Program, to prescribe controlled substances. You also agree to promptly notify the Department of any change or proposed change in licensure or registration status;
 - iii. You are duly enrolled to use the MA Online PMP and that you have not provided nor will provide your login credentials (i.e., username, password, Personal Identification Number or any other security information) to anyone else. You are responsible for promptly notifying the Drug Control Program of any compromise of your login credentials or changes to your enrollment information (e.g., changes to name, business or email address, license or registration number) or prescriptive privileges; and
 - iv. Your use of the MA Online PMP is for the purpose of preventing the prescribing and/or dispensing of controlled substances to the same individual from multiple sources or the unlawful diversion of controlled substances. You may not request the prescription history for anyone other than your patient or for a patient encounter.
- 2) You acknowledge that you understand the following:
 - i. The Department of Public Health does not guarantee the accuracy or completeness of the information contained in the database. There may be multiple persons with the same name in the database, so you should use other information, such as date of birth and address, to distinguish your patient from others with the same name;
 - ii. You may use or disclose information obtained from the MA Online PMP, including reports generated from the database, only as permitted by applicable state and federal laws governing confidentiality and security of personal/patient information, including, if applicable, the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA);
 - iii. You must promptly notify the Department of any potential violation of confidentiality or use of the data in a manner contrary to the regulations or applicable professional standards;
 - iv. Usage of the MA Online PMP is recorded and monitored and that your right to use the system may be revoked at any time at the discretion of the Department.
 - v. Your controlled substances registration may be suspended or terminated in accordance with 105 CMR 700.004(L)(1), and that a referral may be made for criminal prosecution or disciplinary action by your licensing board, for the following:
 1. a request, use or disclosure of data that involves a willful failure to comply with the standards in 105 CMR 700.012 for request, transmission or disclosure of data;
 2. a failure to reasonably protect data in accordance with the requirements of 105 CMR 700.012 or other applicable state or federal law; or
 3. an attempt to obtain data through fraud or deceit;
 - vi. Data is being provided for the purpose of safe prescribing and dispensing, including assessing or preventing the possibility of drug abuse or diversion, but does not require you to take action that you believe to be contrary to the best interests of your patient; and
 - vii. The Department may revise these Terms and Conditions from time to time. You will be notified of any change and your continued use of the MA Online PMP after such notice shall constitute your acceptance of the new Terms and Conditions.

Applicant please sign and date below

I hereby certify that the information on this form is true to the best of my knowledge and I hereby agree to the *Terms and Conditions for Prescriber and Dispenser use of the Massachusetts Online Prescription Monitoring Program* ("MA Online PMP"). I understand that the Terms and Conditions may be revised from time to time, that I will be notified of any change and that my continued use of the MA Online PMP after such notice shall constitute my acceptance of the new Terms and Conditions.

Signature of enrollee applicant (no initials) _____ Date _____

MA Online PMP Enrollment Form Instructions

Allow two to three weeks after the enrollment form is received by the Drug Control Program (DCP) until you receive authorization and credentials to login to the Massachusetts Online Prescription Monitoring Program (MA Online PMP).

The most common reasons for return of enrollment forms are:

- Failure to fill in a PIN composed of four numerals.
- Discrepancies between information provided on the enrollment form and the corresponding information previously provided for the enrollee's Massachusetts Controlled Substances Registration (MCSR). MCSR registrants are required to submit an MCSR Amended Application form if there is a change in name, business address, DEA number, or Board of Registration number.

These instructions follow the enrollment form sequentially. If you need additional guidance contact the Drug Control Program at 617 983-6700.

Questions:

- 1) The license number you provide must match, or be reconciled with the number on file with Board of Registration in Pharmacy.
- 2) Fill in the DEA number of the main pharmacy at which you practice. Please be mindful that, although you are providing the pharmacy's DEA number, you will receive a personal login credential which is not to be shared.
- 3) Include your complete middle name (no initials), and a suffix, if applicable.
- 4) Fill in your business address.
- 5) Fill in your mailing address. If you do not provide a mailing address, all correspondence will go to your business address.
- 6) Fill in the phone number at which you can be reached by DCP, or by prescribers or pharmacists who need to consult with you regarding MA Online PMP prescription histories.
- 7) Please provide an email address that you monitor frequently. You will receive status updates and instructions on using the MA Online PMP via the email address you provide on the enrollment form. The email address will also be used to send updates regarding the MA Online PMP Terms and Conditions, alerts and MA Online PMP enrollment renewal notices.
- 8) If you are not already an end-user of the Virtual Gateway (VG), leave this box blank. The MA Online PMP is hosted in the VG, which is an internet portal operated by the Massachusetts' Executive Office of Health and Human Services (EOHHS) to provide the general public, medical providers, community-based organizations and EOHHS staff with a single resource for health and human services' applications. If you are already an end-user of the VG because you are already using one or more other applications in the portal, please provide your VG username. A preexisting VG end-user will continue to use the same username and password.
- 9) Enter your birth month and day. You may omit the year. This information is required by the VG.
- 10) The four-digit PIN you create is a necessary identifier should you need to have your password reset for the MA Online PMP. Please be sure to save the number in a location that you can easily retrieve it if needed.

Appendix C

- 1) How long have you been a member of the Massachusetts state legislature?
- 2) How did you become a member of the OxyContin and Heroin Commission?
- 3) Prior to being on the Commission what were your thoughts on prescription opioid abuse being a problem in MA? Did that change throughout the process of being on the Commission? How so?
- 4) Are you familiar with how prescription monitoring programs? If yes, can you elaborate on how they are intended to function as a result of the recommendations of the commission?
- 5) Do you feel that prescription monitoring programs are successful in combating prescription drug abuse?
- 6) Do you personally believe that over-prescribing and/or under-prescribing is an issue in MA? If yes to either, can you elaborate on how so?
- 7) Is there anything you think the Commonwealth should be doing in order to combat prescription drug abuse that we are not doing?

Appendix D

- 1) How long have you been working within the pharmaceutical industry?
- 2) Are you licensed to dispense drugs containing opioids?
- 3) Are you familiar with the recent regulations imposed upon the states prescription drug monitoring program? If yes, can you elaborate on them?
- 4) Can you explain how prescription monitoring programs work?
- 5) In your professional opinion, do you believe prescription monitoring programs are successful in reducing abuse and misuse of prescription drugs?
- 6) Do you believe that a doctor over-prescribing and/or under-prescribing is an issue in MA? If yes to either, can you elaborate on how so?
- 7) In your opinion, do you believe that regulating the states prescription drug monitoring program has helped combat drug abuse in MA?

Appendix E

- 1) How long have you been working within the medical industry?
- 2) Are you licensed to prescribe drugs containing opioids?
- 3) How effective do you think opioids are in terms of treating pain? Do you believe they are highly addictive? If so, does that affect your willingness to prescribe them?
- 4) Are you familiar with the recent regulations imposed upon the states prescription monitoring program?
- 5) If yes, can you describe how the regulations have affected you doing your job?
- 6) In your professional opinion, do you believe that prescription monitoring programs are successful in reducing abuse and misuse of prescription drugs?
- 7) Do you believe that a doctor over-prescribing and/or under-prescribing is an issue in MA? If yes to either, can you elaborate on how so?
- 8) In your opinion, do you believe that regulating the states prescription drug monitoring program has helped combat drug abuse in MA?

Appendix F

- 1) How long have you been working as a substance abuse counselor?
- 2) Do you treat patients who are abusing and/or misusing drugs containing opioids?
- 3) How effective do you think opioids are in terms of treating pain? Do you believe they are highly addictive?
- 4) Where do majority of the patients you see obtain the opioids they abuse and/or misuse?
- 5) Do you believe that a doctor over-prescribing and/or under-prescribing is an issue in MA? If yes to either, can you elaborate on how so?
- 6) Are you familiar with the recent regulations imposed upon the states prescription monitoring program?
- 7) Do you believe that prescription monitoring programs are successful in reducing abuse and misuse of prescription drugs?
- 8) In your opinion, do you believe that regulating states prescription monitoring programs has helped to combat drug abuse in MA?

Appendix G

1) How long has it been since you stopped using prescription drugs?

___0-12 months

___Between 1 and 4 years

___Between 4 years and 5 years

___More than 5 years

2) How did you become addicted to narcotics? (short answer below)

3) Are you familiar with the regulations imposed upon the prescription drug industry?

___yes ___no ___not sure

4) When you were using where did you most often get the narcotics?

___a friend

___prescription from my doctor

___prescription drug dealer

___other

5) Have you ever relapsed?

___yes ___no

6) If yes, why triggered the relapse? (short answer below)

7) In your experience, where do you feel most addicts get their narcotics? (short answer below)

8) Do you believe that regulating the prescription drug industry (ie. instituting stricter laws for prescription monitoring programs, and harsher penalties for doctors that over-prescribe) has helped combat drug abuse? Please explain.

Appendix H

XXXX, 2014

Dear Prospective Participant,

My name is Meredith Rodman and I am a graduate student at the University of Massachusetts Boston in the Department of Public Policy and Public Affairs. I am conducting a research project examining the regulations imposed upon the prescription drug industry within Massachusetts as they relate to prescription monitoring programs. As a scholar in this field, I am hoping to interview you in person or over the phone, for about 30 to 60 minutes.

After I complete all of my interviews, I plan to write up the results of my study. Any information I use from the interviews would be presented in such a way as to ensure confidentiality. You could end the interview or not answer questions at any point for any reason. While I cannot promise any direct benefit from your participation in this study, I hope that it will provide systematically collected data on what scholars in the field of prescription drug regulations see as emerging issues. I would be pleased to provide you with a copy of what I write.

University research procedures govern this project and I would be pleased to answer questions about these procedures at any time. This project has been reviewed by the Institutional Review Board at the University of Massachusetts Boston. Approval of this project only signifies that the procedures adequately protect the rights and welfare of participants. Should you have any questions or concerns for the Institutional Review Board (IRB), you may contact IRB directly at the Office of Research Compliance at (617) 287-5374 or at human.subjects@umb.edu. I hope to speak with you about emerging issues in the field of prescription drug regulations. If you are willing to talk with me, just let me know and I will contact you to set up a time.

Thank you,
Meredith Rodman

Meredith Rodman
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