Executive Summary

This legislative report presents information and data relevant to the operation of the Prescription Monitoring Program (PMP), and recommendations that are necessary for pharmacists and practitioners to achieve one hundred per cent compliance with the electronic prescription drug monitoring program.

Statistical Summary of Current (2018) Compliance:

PA 15-198 mandated that practitioners review patient controlled substance prescription history prior to prescribing controlled substances, and that pharmacists report controlled substance dispensing on a daily basis.

- 31,124 Controlled Substance Registrations (CSPs) - some practitioners hold more than one;
- 28,304 CSP registrants are registered with the Connecticut Prescription Monitoring and Reporting System (CPMRS);
- 18,027 CSP registrants have issued a controlled substance prescription;
- 1,237,933 CSP registrants or their delegates performed a CPMRS lookup; and
- 695 of 695 pharmacies are confirmed to be compliant with daily uploading.

Overview of Recommendations for Improved Compliance:

- Increased outreach and educational opportunities to help maximize participation in the PMP and ensure proper use of the CPMRS;
- Improvements to the prescription monitoring software, including
    - ease of access
    - enhanced analytics
    - availability of interstate data
    - enhanced software to assist in the identification of practitioners that are not conducting data reviews in accordance with CT laws
- Increased investigations of prescribers for failing to register or conduct review of patient medical records prior to prescribing controlled substances;
- Increased enforcement actions against prescribers for failing to register or conduct review of patient medical records prior to prescribing controlled substances; and
- Delegate accounts, properly supervised and maintained, provide a secure and effective means to increase CPMRS utilization.

Introduction

The Commissioners of Public Health and Consumer Protection submit this joint report, in accordance with Public Act 18-100 and CGS Sec. 11-4a of the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to public health and consumer protection, regarding recommendations that they agree are necessary for pharmacists and practitioners to achieve the goal of one hundred per cent compliance with the Electronic Prescription Drug Monitoring Program.

Background of the Prescription Drug Monitoring Program

The laws and regulations governing the distribution and handling of controlled substances in Connecticut set standards for the safe dispensing and use of controlled substances for practitioners and patients while also preventing illegal and harmful activities.

Connecticut General Statutes (CGS) Sec. 21a-254 (formerly Sec. 19-461) established a controlled substance prescription database that operates as the Connecticut Prescription Monitoring and Reporting System (CPMRS) in the Department of Consumer Protection, within the Drug Control Division's Prescription Monitoring Program (PMP).[1] The PMP collects and stores prescription data for Schedule II through Schedule V drugs within a centralized database, the CPMRS. It is used by healthcare providers and pharmacists in the active treatment of their patients to help achieve a balance between abuse prevention and safe use of controlled substances. The PMP became fully operational in February 2008, and the CPMRS went "live" for prescribers and pharmacists to use on July 1, 2008.

Since 2008, multiple statutory changes have been made to the PMP and CPMRS:

- Public Act 13-172 required all prescribers in possession of a Connecticut Controlled Substance Registration (CSP) to register with the CPMRS. The Act also increased the pharmacy uploading requirement from twice a month to once a week, and required out-of-state pharmacies that dispense in Connecticut and prescribers who dispense controlled substances to upload dispensing information into the CPMRS.
- Public Act 15-198 and Public Act 15-5 (June Spec. Sess.) mandated practitioners to review, prior to prescribing greater than a 72-hour supply of any controlled substance, the patient's records in the CPMRS. These Public Acts also required prescribers who prescribe controlled substances for continuous or prolonged treatment to review the patient's records in the CPMRS at least once every 90 days. The pharmacy and dispensing practitioner mandated upload frequency was also increased from weekly to daily.
- Public Act 16-43 allowed veterinarians who dispense controlled substances to continue to upload the dispensing information on a weekly, rather than daily basis. This Public Act also:

[1] The database name, CPMRS, and the program name, PMP, are often used interchangeably.

exempted a prescribing practitioner who prescribes greater than a 72-hour supply of any Schedule V controlled substance from the mandated 90 day review of patient's records in the CPMRS, instead making that an annual requirement; and allowed for prescribers to designate unlicensed and licensed delegates to have user accounts to review a patient's controlled substance prescription information in the CPMRS on behalf of the prescribing practitioner.

Prior to the initial launch of the CPMRS, it was extremely difficult for practitioners and pharmacists to identify drug-seeking behavior because a patient's complete prescription dispensing history was neither centralized nor current. As a result, many drug-seeking patients weren't referred to a medical practitioner for help, or to law enforcement for an investigation. When such a patient was detected by a healthcare professional, most were dismissed from the medical practice or refused service, forcing the patient to move on to a different unsuspecting prescriber or pharmacy, or worse, to seek medication from illicit sources. The CPMRS presents a complete picture of a patient's prescribed controlled substance use history by providing a single point of collection and access to controlled substance prescriptions that have been dispensed to an individual patient. As a healthcare tool, the CPMRS is used to improve quality of patient care and to reduce prescription abuse, addiction, and overdose. It allows providers the opportunity to properly manage the patient's care, including the referral of a patient to services offering treatment for drug abuse or addiction when appropriate. The CPMRS also provides the opportunity for practitioners to review their own prescribing history to identify forgeries, data integrity issues or dispensing errors.

The CPMRS is multifaceted:

- Collects data regarding every controlled substance prescription for Schedule II through V as defined under the state's Controlled Substance Act;
- Improves patient care by providing prescribers and pharmacists with their patient's controlled substance history report;
- Assists practitioners in identifying possible drug therapy complications;
- Improves communication with pharmacists and other prescribers to help prevent drug misuse, addiction and overdose;
- Provides automated clinical notifications to prescribers and pharmacists
    - Prescriber/Dispenser Threshold
    - Concurrent Opioid & Benzodiazepine
    - Morphine Milligram Equivalent (MME);
- Reduces drug diversion;
- Assists law enforcement personnel in prescription drug investigations; and
- Allows the following registered users access to data

- *Dentists, physicians, nurse practitioners, optometrists, veterinarians, other healthcare professionals and their delegates, pharmacists, and law enforcement.*

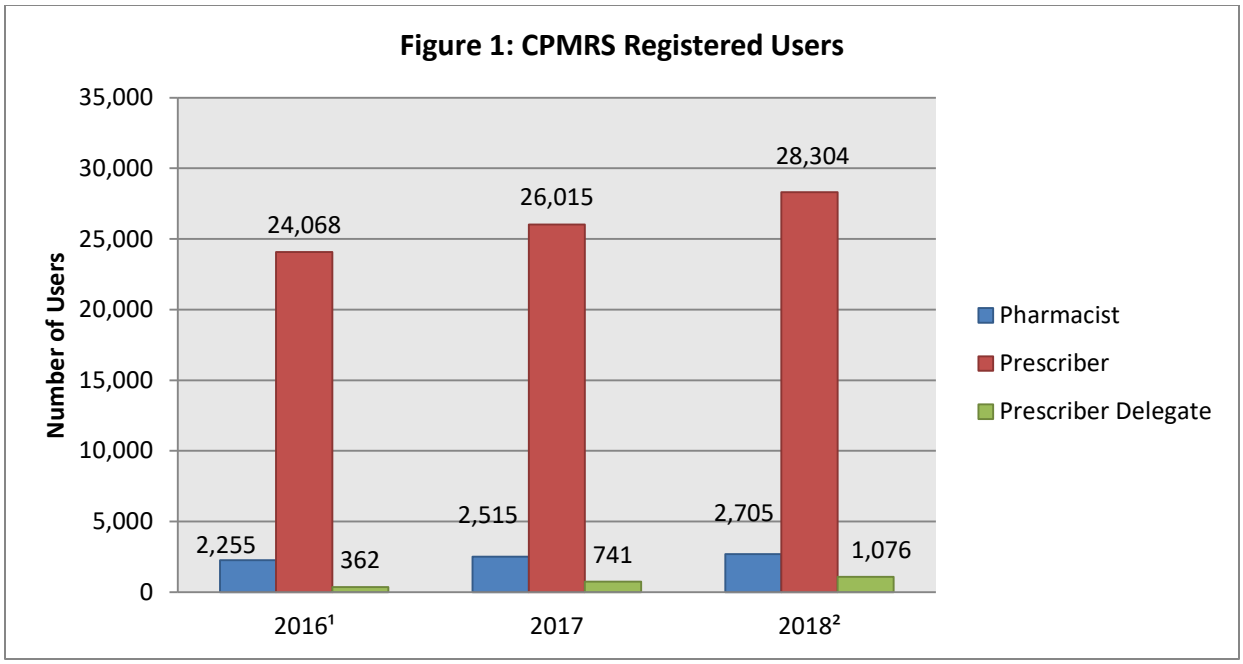
Software Vendor for the Prescription Drug Monitoring Program

Appriss Health is the current contractor providing prescription drug monitoring database services (CPMRS) for the PMP. Appriss Health uses the prescription drug monitoring interface, AWARxE, which provides PMP staff the following capabilities:

- Authorize practitioners, their delegates and pharmacists registering for CPMRS access;
- Manage CPMRS accounts;
- Maintain a list of data submitters, from pharmacies and licensed practitioners, who dispense schedule II, III, IV or V controlled substances;
- Approve data submissions from pharmacies and licensed practitioners who dispense Schedule II, III, IV or V controlled substances under federal and state law;
- Conduct analysis of pharmacies that have not reported or are delayed in reporting.
- Create dashboard announcements accessible to registered users;
- Consolidate patient information for patients reported to the database with differences in name, date of birth, or gender;
- Generate patient prescription history reports;
- Generate dispensary activity reports; and
- Generate alerts for practitioners and pharmacists based on thresholds for high doses, high-risk drug combinations, and potentially risky patient behavior.

CPMRS Registration

Practitioners and their delegates, along with pharmacists, are the two user groups that access the CPMRS most regularly. Their registration numbers can be found in Figure 1**.**



1) 2016 data does not reflect a full calendar year; 2) 2018 data reflects numbers as of November 5, 2018

Due to the transition to a newer CPMRS platform in 2016, only six months of data available in that year.

Practitioners with a CSP are mandated to register and use the CPMRS. Previously reported data in the CPRMS shows that in 2014 there were approximately 8,434 practitioners registered, rising to approximately 13,553 registered practitioners in 2016. At the time of this analysis, there were 31,124 CSP registrations in the state; a total of 28,304 of whom were registered in the CPMRS. A practitioner can have multiple CSP registrations based on practice location but is only required to register with the CPMRS once. This issue may artificially increase the total number of CSP registrations. Steady increases in the number of registrations have occurred over the past three years.

Enforcing the mandatory registration with the CPMRS for all CSP registrants was challenging until 2016 when the PMP transitioned to a new, more robust CPMRS platform that provides a better range of analytical tools for all users. Education, outreach and enforcement are necessary to achieve and maintain the goal of 100% compliance with the CPMRS. These activities require significant staff hours from the PMP team as well as from the Department of Consumer Protection (DCP) legal department. Activities include: trainings, seminars, educational sessions, marketing campaigns, data analysis, investigations, warning letters, compliance meeting notifications and compliance meetings. Accordingly, appropriate funding and staffing levels are necessary to support a continued increase and maintenance in prescriber registration and usage of the CPMRS, which will help achieve a significant change in the

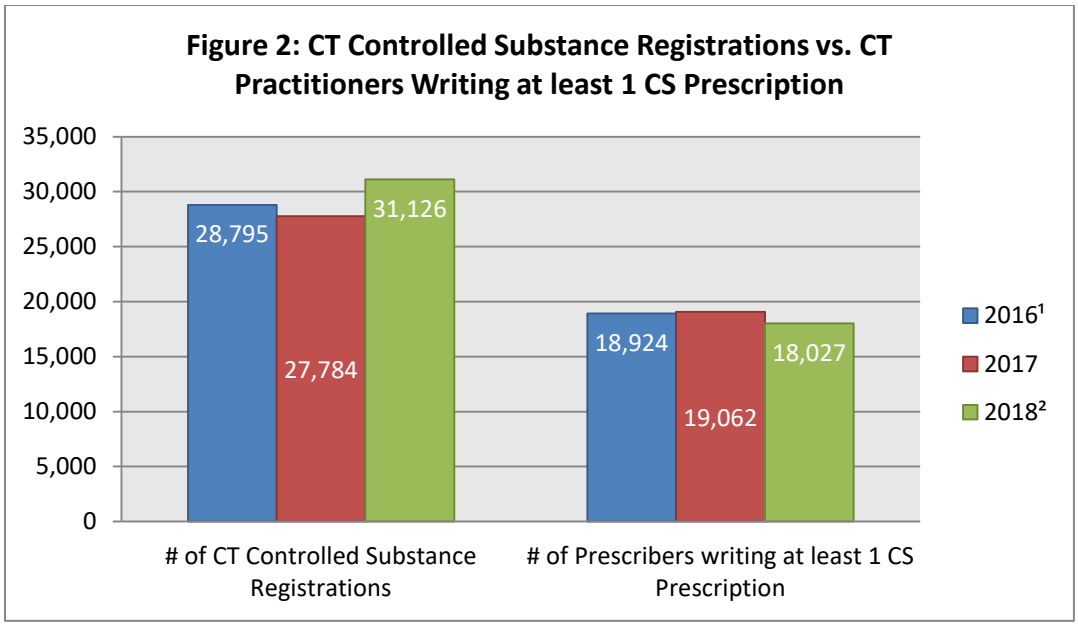
prescribing and dispensing of controlled substances. The CPMRS is only an effective tool when practitioners and pharmacies are compliant with mandated registration, upload and usage laws, however a CPMRS with full capabilities and mandated usage will not reduce prescription drug misuse alone.

CPMRS User Compliance Rates

The CPMRS is continuously registering new users and encouraging the use of CPMRS data by all appropriate end users, which maximizes prescription monitoring utilization and impact. Users of the CPMRS are provided accurate, real-time prescription data, compliant with state regulations, which allows the prescribers and dispensers to make better informed patient prescribing decisions at the point of care, and intervene earlier if there are medical contraindications or potential prescription drug abuse.

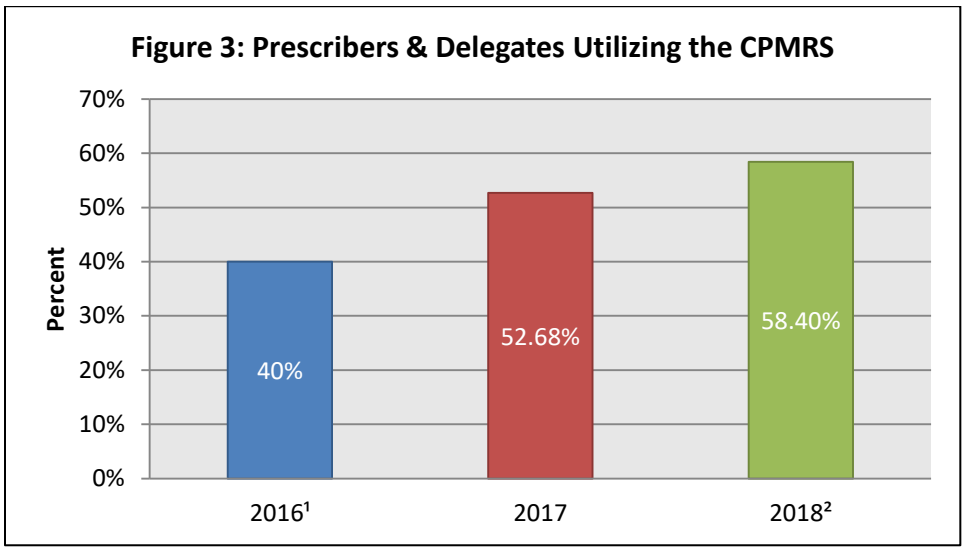
The PMP consistently emphasizes to prescribers that they need to consult the CPMRS when prescribing more than a 72-hour supply of a controlled substance. It also emphasizes that patients should not be dismissed from care based solely on CPMRS information. Using the CPMRS as designed by regulatory compliance policy is an opportunity for prescribers and pharmacists to provide potentially life-saving information and interventions for their patients. Prescribers can easily confirm that the information in the CPMRS is correct by contacting the pharmacy where the data originated. They can also check for: potential data entry errors; use of a nickname or maiden name; possible identity forgery or theft to obtain prescriptions; and easily assess a patient's prescription history for possible misuse or abuse.

Importantly, not all prescribers with a CSP prescribe controlled substances. Additionally, prescribers may have multiple CSPs (only one log-in is required). Also, not all prescribers who prescribe a controlled substance(s) will meet the lookup mandate (prescribing more than a 72-hour supply of a controlled substance) for that prescription(s). Therefore, the number of registered users actually using the CPMRS **will never** be 100% of all CSPs in the state. Figure 2 illustrates the total number of CSPs in the state versus those who wrote at least one controlled substance prescription during 2016, 2017 and 2018. While the data for 2016 and 2018 is not complete, in 2017, over 30 percent of prescribers who had an active CSP did not prescribe any controlled substances.



1) 2016 data does not reflect a full calendar year;
2) 2018 data is as of November 5, 2018

Figure 3 illustrates the percentage of prescribers, or authorized delegates, who looked up a patient that received at least one controlled substance prescription in 2016, 2017 and 2018. Although Figure 3 provides a valuable statistic, it should be noted that controlled substance prescriptions for less than 72 hours do not require a CPMRS check. Future analytical tool purchases may allow for the ability to expand and improve the usefulness of this data.



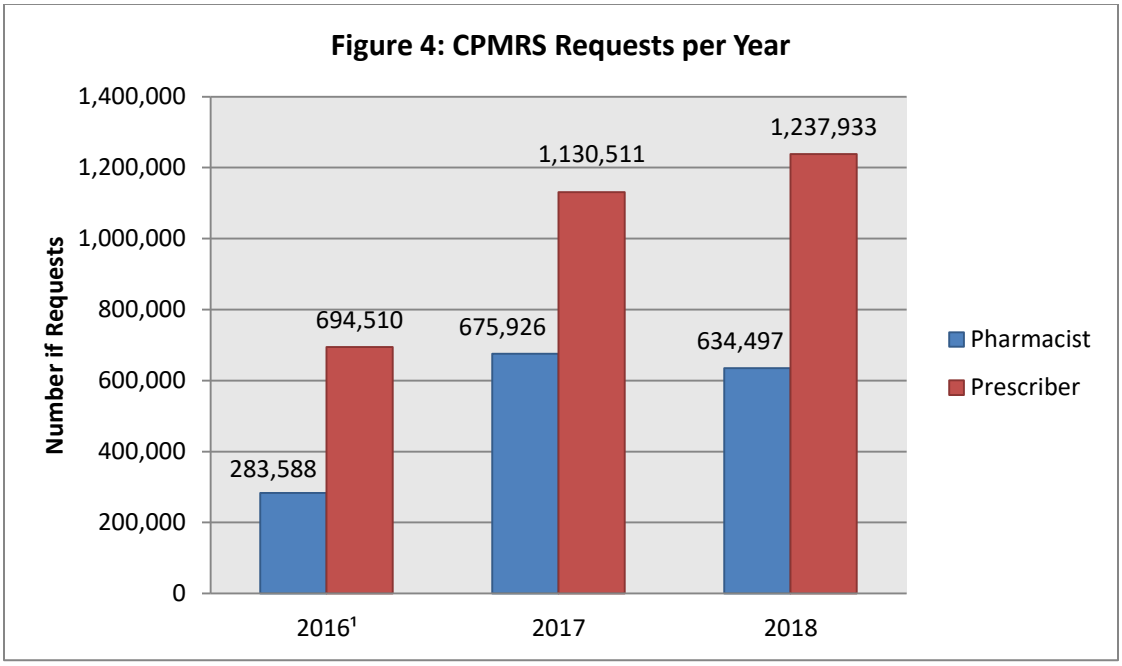
1) 2016 data does not reflect a full calendar year and delegate usage was not calculated.
2) 2018 data is as of November 5, 2018

While pharmacists dispensing controlled substances to Connecticut patients must report that data to the PMP every 24 hours, Connecticut pharmacists are not mandated to register and lookup patient prescription history in the CPMRS.

Many retail pharmacy chains have voluntarily implemented policies that require their pharmacists to review the CPMRS before dispensing a controlled substance to a patient. Unlike prescribers, pharmacists currently do not have the capability to have delegates assist them in conducting searches in the system. The lack of this capability may make it more difficult for pharmacists to incorporate the CPMRS as part of their daily workflow.

Figure 4 depicts the total number of requests per year that the CPMRS received from registered prescriber and dispenser users.

Figure 4: CPMRS Requests per Year



1 2016 data does not reflect a full calendar year and delegate usage was not calculated.

Uploading Compliance

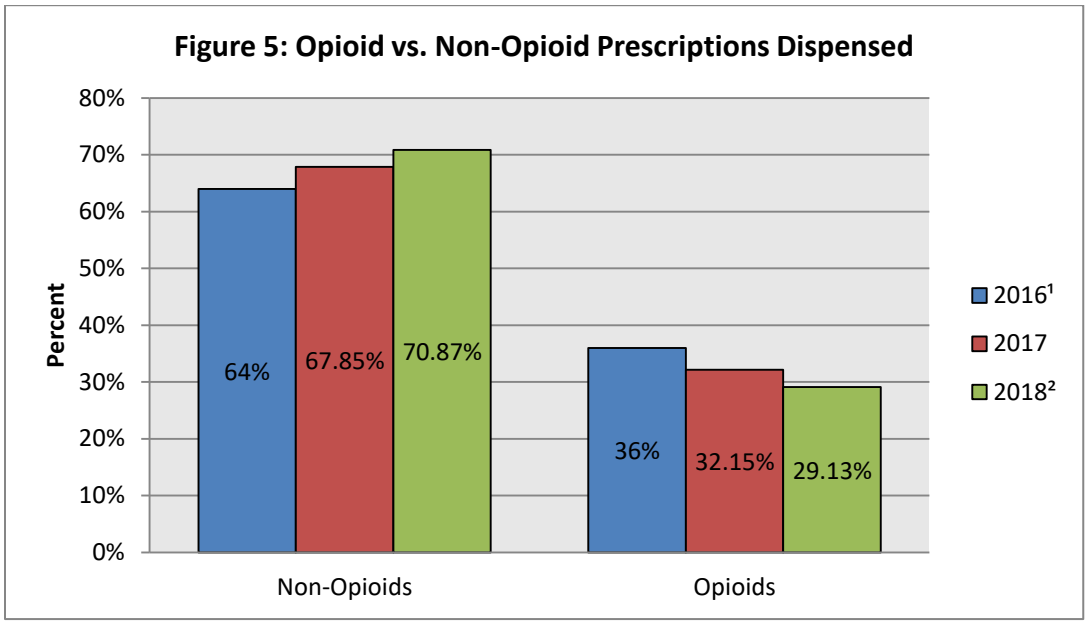
There are only 695 pharmacies licensed and 999 non-resident (out-of-state) pharmacies, and 7,161 practitioners that are permitted to dispense medications, including controlled substances, in the state. The vast majority of in-state pharmacies will dispense a controlled substance prescription every day. In general, the in-state pharmacies are compliant with uploading requirement for the CPMRS and respond to PMP compliance letters rapidly with uploads. In 2011, the PMP sent out a total of 70 compliance letters for delinquent uploading to

in-state pharmacies, and as a result thirteen pharmacies paid civil penalties. Currently, all 695 in-state pharmacies are complying with the uploading requirement.

Practitioners and non-resident pharmacies may not necessarily dispense a controlled substance prescription every day in Connecticut. Determining compliance with uploading for dispensing practitioners and non-resident pharmacies is much more challenging than in-state pharmacies. The challenge is that acquiring and validating this information requires direct communication with each individual practitioner or non-resident pharmacy. It is a PMP best practice that all mandated uploaders submit a "zero report" which identifies that they were in compliance with the daily upload mandate but had no controlled substance prescriptions to report. At this time, monitoring this compliance is very labor intensive for the PMP staff. The PMP is currently attempting to purchase a module from Appriss Health to improve the ability to monitor all pharmacy and dispensing practitioners for uploading compliance. The analytic module will allow the PMP the ability to improve the efficiency of enforcement activities.

Controlled Substances Prescriptions Rates

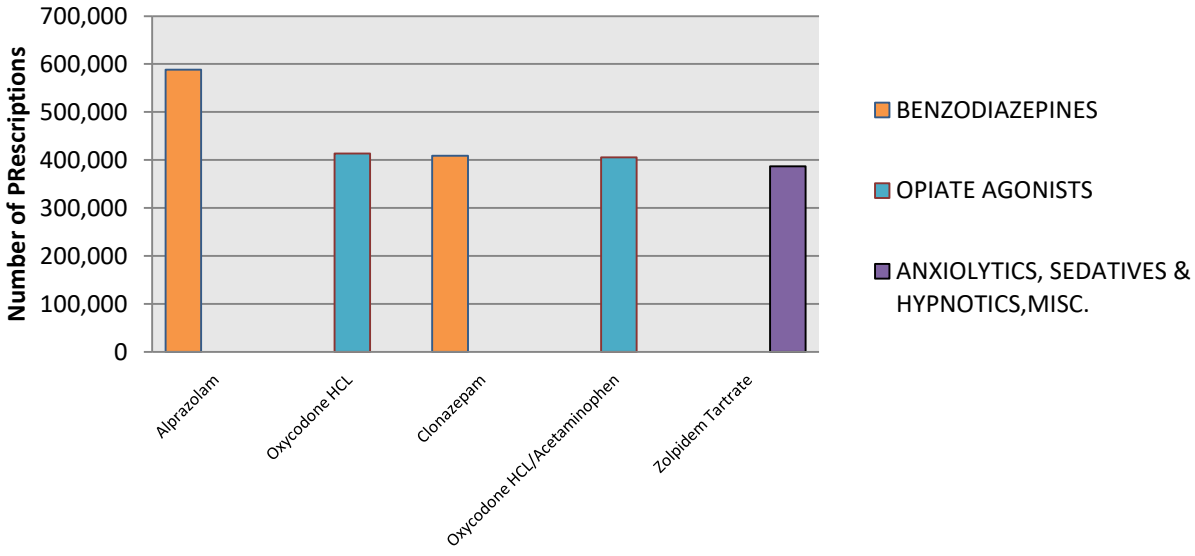
Historically, the majority of controlled substance prescriptions written in Connecticut are for non-opioid medication and the volume of this type of prescriptions appear to be increasing. It is evident that a declining trend over the last three years has occurred concerning the prescribing of opioid medications. Figure 5 illustrates the total number of opioid versus non-opioid controlled substances prescribed and dispensed in the state for the last three years.



1) 2016 data does not reflect a full calendar year; 2) 2018 data is as of November 5, 2018

The bar graph in Figure 6 illustrates the most prescribed controlled substances in the state for 2017. The top 5 most prescribed controlled substances are opiate agonists and benzodiazepines. Benzodiazepines, commonly referred to as "benzos," are widely prescribed for a variety of medical and mental health concerns. Benzos have sedative, anxiolytic, hypnotic, muscle-relaxant, or anticonvulsant properties.

Figure 6: Top 5 Most Prescribed Controlled Substances, 2017



Compliance Challenges, Opportunities and Recommendations

It has been three years since PA 15-198 mandated that practitioners review a patient's controlled substance prescription history prior to prescribing controlled substances, and that pharmacists report controlled substance dispensing on a daily basis. Through continual outreach and education efforts, PMP compliance levels have consistently increased.

Since 2015, DCP has sent multiple rounds of compliance letters and emails to prescribers who held a CSP registration but were not registered in the CPRMS. During the most recent round of notifications, which began in 2018, prescribers not registered with the CPMRS were informed that they must provide evidence of CPMRS registration, complete a new CPMRS registration, or voluntarily surrender their CSP within 30 days. Otherwise, they were summoned to a compliance meeting.

Compliance notifications have proven to be a very effective tool for increasing CPMRS registrations, but due to limited staffing resources the process is somewhat slow. Increased

funding would allow DCP to intensify this enforcement activity in order to ensure that all prescribers with an active CSP are complying with the CPMRS registration mandate.

Lack of access to enhanced analytics has also made DCP's enforcement of the prescriber lookup mandate more challenging. Prior to 2017, there was no consistent way to track whether or not CSP/CPMRS registrants who wrote a controlled substance prescription were reviewing a patient's record when prescribing more than a 3-day supply. In 2017, through a collaborative effort supported by a federal grant with DPH, DCP was able to hire a durational employee with technical expertise in data analytics. This new employee recently was able to utilize the data from the reports generated in CPMRS to run additional reports that aggregate the number of prescribers who have never reviewed any patient's controlled substance prescription records. Although the aggregate data flags practitioners who appear to be out of compliance, further investigatory work must be done before enforcement action can be taken.

While there is no way, at this point, to generate automated, comprehensive reports to flag prescribers who fail to follow the 3-day supply mandated lookup, Appriss Health has a new analytical tool that will enable the PMP to identify those who are not compliant with the lookup mandate. Acquisition of the analytical tool would allow the PMP to better identify prescribers who aren't in compliance with the law.

The enforcement of the mandated lookup requirements is handled by Drug Control Agents. So far, because of the lack of analytical tools, enforcement has been based on individual complaints to the Drug Control Division.

With the new, limited report that identifies prescribers who have never reviewed any patient's controlled substance prescription records the PMP will work with Drug Control Agents to investigate and take action when appropriate. This new report, along with new enhancements DCP is hoping to acquire in the CPMRS will help to increase PMP compliance. Increasing investigations and enforcement, however, would require additional investigatory staff, which current budgetary constraints make challenging to implement. Therefore, a significant increase in compliance rates through this method is unlikely.

The PMP partnerships with the Departments of Public Health (DPH), and Mental Health and Addiction Services (DMHAS) should continue because collaboration with the PMP informs the various agencies' statewide opioid and prescription drug abuse initiatives. CPMRS data informs planning and decision making, such as identification of geographical hot spots for prescribed opioids and other controlled substances, prescriber outreach, and relationships between reported prescription drug use and overdose deaths. The DPH and DMHAS partnerships also

allow for better allocation and alignment of drug abuse prevention programs, planning and siting of drug treatment programs and office-based opioid treatment, and other activities that address prescription drug abuse.

There are three strategic areas where the PMP's continued expansion will enhance usage by practitioners: 1) ease of access; 2) enhanced analytics; and 3) availability of interstate data.

Ease of Access

To address **ease of access** issues, the PMP has been working diligently to encourage and facilitate integration of the CPMRS into electronic health records (EHR). This integration puts the CPMRS data directly into the workflow of the healthcare professional, bypassing multiple password requirements and the need to exit their EHR to access the CPMRS from a separate web portal. Although this effort has been successful and the data has been integrated with 26 different healthcare institutions, the PMP understands that integration into the Health Information Exchange (HIE) may be the more sustainable option. Leveraging the HIE infrastructure would potentially allow for the most efficient pathway for practitioners and dispensers to access a complete patient profile that includes their controlled substance history. The PMP has been working with the Office of Healthcare Strategy (OHS) for the purpose of integrating the CPRMS into the Health Information Exchange once the infrastructure is built.

Enhanced Analytics

Enhanced analytics are being offered to prescribers in an ongoing manner as funding permits. In 2016, the CPMRS introduced automated clinical notifications for prescribers and dispensers to assist them with timely information about patients they are treating. In 2018, the CPMRS added the prescriber report which provides prescribers with individual controlled substance prescribing data to assist them in understanding how their prescribing compares against their peers. More can still be done to further the advancement of prescribing analytics. In the near future, the PMP hopes to add to the CPMRS the NarxCare™ platform via a federal grant.

NarxCare™ provides a comprehensive tool to assess narcotic overdose and diversion risk. NarxCare™ aggregates and analyzes controlled substance prescription information from providers and pharmacies, and presents interactive, visual representations of that information, as well as advanced analytic insights, complex risk scores and more features to aid physicians, pharmacists and care teams to increase patient safety and outcomes. The platform can also accommodate additional information sources to create more holistic risk models, assessments and alerts. The PMP is currently working with the vendor to implement this tool in the CPMRS.

One large healthcare system and one national pharmacy chain have already purchased this enhanced analytic on their own.

The continued identification of enhanced analytics tools and availability to users promotes the utility of the CPMRS system and helps drive the appropriate clinical use of controlled substance medication in the care and treatment of patients in Connecticut.

Interstate Sharing of CPMRS Data

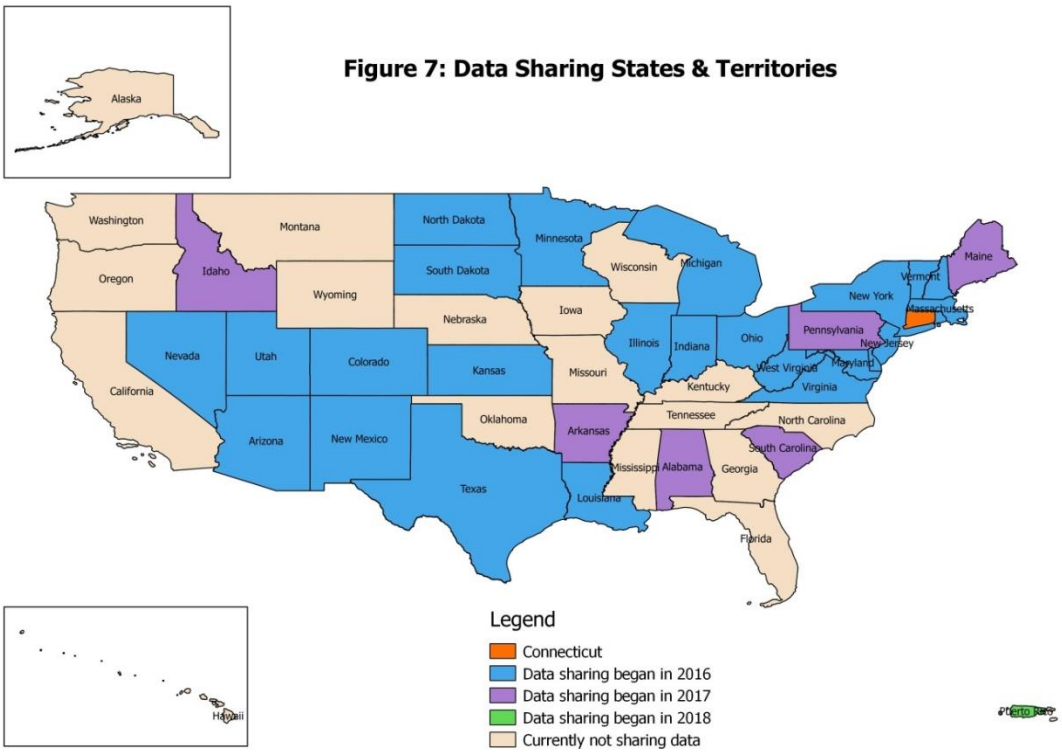
Interstate misuse and abuse of prescription drugs is a continuing problem faced by all states. Sharing of PMP data across state lines can occur by statute, regulation or interstate agreement and are specific to each state. PMP data from other states may be made available to prescribers, dispensers, PMP officials or other specified authorities. The benefits of state PMPs are enhanced by this type of interstate sharing, particularly for prescribers and dispensers in towns that border Connecticut.

PMP data-sharing provides a means for prescribers and dispensers to more easily identify patients with prescription drug abuse and misuse problems, and if those patients are crossing state lines to obtain drugs. Interstate data sharing provides for medication reconciliation and assessment for concurrent use of multiple controlled substances by a patient (polypharmacy).

Currently there are 45 active and pending participants in the data sharing platform known as the Prescription Monitoring Program InterConnect (PMPI). Figure 7 illustrates that Connecticut has activated interstate data sharing with 31 states and two territories, Washington D.C. and Puerto Rico, and includes all states bordering Connecticut and the Northeast Region. The CT PMP has not connected with all participants due to several factors, with the most common being:

- A state is focusing on connecting with their border states first;
- A state is currently transitioning to a new PMP system; and/or
- A state has prioritized other PMP projects over interstate connectivity.

Figure 7: Data Sharing States & Territories



**CT began sharing data with the District of Columbia in 2017*

Conclusion

Achievement of the PMP programmatic goals is expected to increase use of the CPMRS, thereby contributing to higher-quality clinical decision making and in turn leading to improved clinical outcomes such as reduced levels of inappropriate prescribing of controlled substances, and decreases in overdoses involving prescription drugs. The multifaceted goals of the PMP are to bridge education, primary prevention and law enforcement. A common goal is to uphold the laws of Connecticut which encompass both the promotion of access to appropriate pharmaceutical care by the states' citizens, the deterrence of pharmaceutical diversion and abuse, while informing clinical practice improvements.

The PMP data is useful in the identification of patients with at-risk controlled substance use behavior, especially opioids. For example, it allows the prescriber to identify such individuals and to get them the help they need. However, it should be noted that there are some unintended and negative consequences of evaluating CPMRS data due in part to user misunderstanding and lack of education. Certain patients may appear to be targeted by data and system generated alerts that are not fully understood by the prescriber or pharmacist. In these cases the CPMRS user may actually do more harm than good, such as taking away much needed medications from those targeted patients. Therefore the results could include poorly managed pain, inadequate palliative therapy, and a potential for driving patients to turn to

illicitly obtained prescriptions or street drugs like heroin and fentanyl. While the number of patients impacted by these unintended consequences is believed to be small, it is extremely important to make sure that there is continued discussion, training and education to users about best practices when reviewing PMP data.

The objectives of the PMP do not, and should never include any restrictions on the legitimate prescribing or dispensing of pharmaceuticals. The PMP strives to uphold statutory mandates with a methodology that is the most supportive of and the least disruptive to medical and pharmacy practice and, most importantly, maintains a high quality of patient care.

AN ACT CONCERNING PHARMACIST AND PRACTITIONER COMPLIANCE RATES AND THE ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective from passage*) (a) The Commissioners of Public Health and Consumer Protection shall review the compliance rate of pharmacists and practitioners utilizing the electronic prescription drug monitoring program established pursuant to section 21a-254 of the general statutes.

(b) Not later than January 1, 2019, the Commissioners of Public Health and Consumer Protection shall jointly report, in accordance with section 11-4a of the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to public health and consumer protection, regarding recommendations, if any, that they agree are necessary for pharmacists and practitioners to achieve one hundred per cent compliance with the electronic prescription drug monitoring program.

Approved June 7, 2018