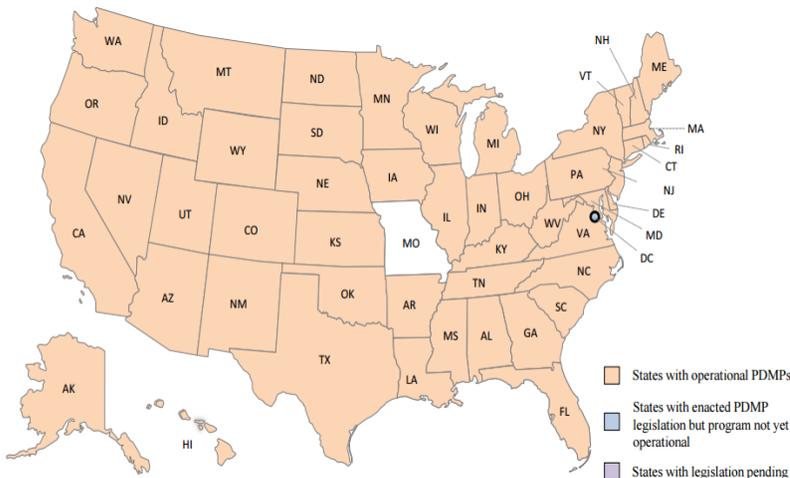




### Prescription Drug Monitoring Program Compliance

The purpose of a Prescription Drug Monitoring Program (PDMP) is to improve the ability to identify and reduce diversion of prescription drugs and to enhance patient care by ensuring the appropriate and legitimate use of controlled substances (CS). State PDMPs accomplish these tasks by means of an electronic database in which dispensers of controlled substances upload data to track CS use by patients. Patient demographics, prescriber and pharmacy name, as well as prescription information (drug name, quantity, and day supply) are among the usual information reported to a PDMP. As of October 2016, 48 states, the District of Columbia, and one U.S. Territory (Guam) have enacted legislation for operational PDMPs (Illustration 1).<sup>1</sup> In 2017, Nebraska and three counties in the St. Louis, MO region will join the list of PDMPs that require CS dispense reports to be uploaded to their PDMP website.<sup>2,3,4</sup>

#### Status of Prescription Monitoring Programs



**Illustration 1:** NAMSDL. "Compilation of Prescription Monitoring Program Maps". May 2016. Accessed at <http://www.namsdl.org>

The list of controlled substances and non-controlled substances requiring reporting vary state-to-state; as well as the frequency for data uploading. Additionally, this information changes frequently. For example,

starting January 1, 2017 Nebraska will require daily data uploading for all Schedule II through Schedule V controlled substances. Beginning January 1, 2018, they will require all dispensed prescriptions to be reported daily, controlled and non-controlled.<sup>4</sup> Nebraska is only one of the many examples of how PDMP rules and regulation changes affect pharmacies.

Foundation Care Pharmacy (FC) specializes in the treatment of patients with cystic fibrosis. Because of our specialized patient populations, we have chronically ill patients in need of controlled substances in all 50 states. Our model surrounding the dispensing of controlled substances is to improve patient care by providing one place for our patients to receive all of their medication needs. The frequently changing rules and regulations surrounding state PDMPs pose a challenge for any pharmacy to be compliant, especially one that ships to all 50 states. The National Council for Prescription Drug Programs (NCPDP) submitted a white paper in 2013 that detailed challenges with the current PDMP structures. Problems identified by NCPDP based on the pharmacy's perspective include:<sup>5</sup>

- **REPORTING/DATA SUBMISSION**
  - o Pharmacy has varying requirements by state for submitting PDMP data. The result is supporting multiple transaction layouts that increase administrative costs.
  - o If the data submitted is inaccurate or incomplete (i.e. missing patient zip code), the notification and update process is inconsistent amongst the different programs.
  - o Data and format requirements vary from state to state. Most states require data formatted in various versions of the American Society for Automation in Pharmacy Standards (ASAP).

o Data is delivered using many automated and manual methods such as:

- Secure FTP over SSH
- Encrypted File with OpenPGP via FTP
- SSL Website
- Physical Media (Tape, Diskette, CD, DVD)
- Universal Claim Form submission

o Frequency of data submission varies from state to state (Illustration 2)<sup>6</sup>:

### Data Interval

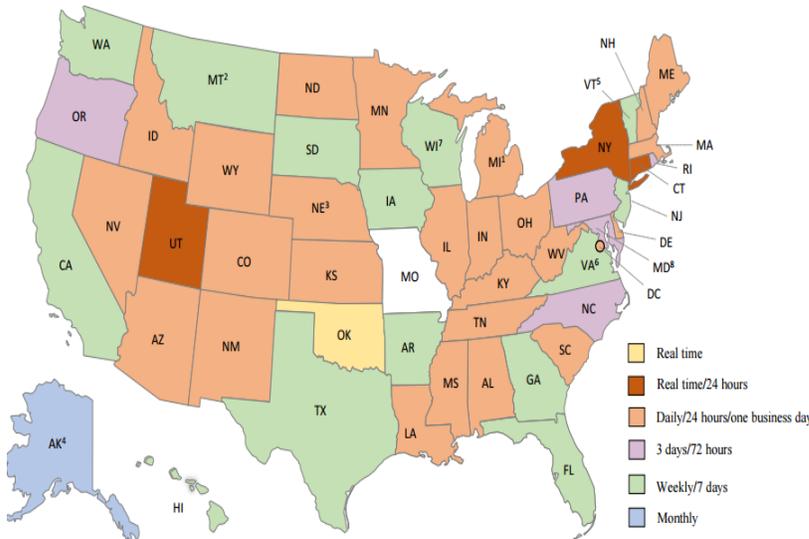


Illustration 2:  
NAMSDL. "Data Collection Interval". May 2016. Accessed at <http://www.namsdl.org>

#### • ACCESSIBILITY

- o Gaining access to state PDMPs varies widely from state to state.
- o Pharmacy does not have access to PDMP data within their workflow and must interrupt workflow to access an external database.
- o Lack of access to PDMP data across state lines impacts the pharmacy's ability to make accurate clinical decisions.

#### • DATA INTEGRITY

- o Missing, incomplete and/or invalid data due to lag in reporting and validation leads to incomplete records

***The purpose of this whitepaper is to share how FC has overcome these challenges to maintain compliance for all operational state Prescription Drug Monitoring Programs.***

Reporting/Data Submission

At FC, the team has developed PDMP data upload binders. These binders provide one centralized location to update and record all state information such as changes to: logins, data collection interval, data to be reported (including zero dispensing), and changes to the state PDMP programs or websites. Our team is held responsible for staying up-to-date on all changes to the state PDMPs as mentioned previously. We have tasked three employees with the responsibility of generating and uploading dispense reports based on state requirements. Two of these employees complete reporting on a daily basis by splitting the states in half alphabetically. The third person serves as a back-up reporter. The binders are organized first by the data collection interval and then alphabetically.

- Daily reporting = tab highlighted in orange
- Weekly reporting = tab highlighted in green
- Monthly reporting = tab highlighted in yellow

We only submit data in these intervals and go with the strictest of reporting intervals when there is a discrepancy. For example, Utah requires data to be uploaded every 72 hours, which is a difficult interval to maintain. Therefore, we submit data for Utah daily to ensure our frequency stays on track. Daily reporting takes place for the previous business day. Weekly reporting occurs for the previous Monday through Sunday schedule. Monthly reporting occurs within the first 5 days of the month (which currently only applies to Alaska).

FC utilizes the CPR+ software from Mediware for all prescriptions dispensed; and the data uploaders utilize this software daily to generate CS reports. To generate a controlled substance dispense report, the data uploaders run the report and create an ASAP disk file for all controlled substances dispensed. These reports are then electronically filed in the respective state's folders; these files are then uploaded to each state based on the reporting frequency described above. Once the data has been uploaded to each state's PDMP site, the number of CS prescriptions dispensed is recorded on the state log in the CS binder. This log serves as a quick reference to ensure all data intervals

have been accounted for. By following these precise steps, our employees have achieved a daily data upload time of less than ten minutes.

Our team continually works to stay abreast of any changes to the PDMPs by enrolling in the state PDMP newsletters and updates via email, or going to the state websites. Additionally, the team may utilize resources such as the National Alliance for Model State Drug Laws (NAMSDL at [www.namsdl.org](http://www.namsdl.org)) or the Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC at [pdmpassist.org](http://pdmpassist.org)). These websites offer great summary references for each state’s PDMP program, as well as links to the current rules and regulations.

**Accessibility**

To date, there are ten states that have language mandating the pharmacist to query the PDMP prior to dispensing a controlled substance for a patient residing in their state (Illustration 3). The nature, types of controlled substances requiring querying and the ability of a non-resident pharmacy to access this data varies state to state. For example, New Jersey mandates the pharmacist check the patient’s history via the PDMP prior to dispensing a CII if they suspect inappropriate use.<sup>8</sup> However, New Jersey (NJPMP) does not allow a non-resident pharmacy or pharmacist licensed in another state access to query the PDMP directly.

**Illustration 3:**

States Mandating Pharmacist Query				
Delaware	Louisiana	Massachusetts	Ohio	Utah
North Dakota	New Jersey	Oklahoma	New York	Vermont

Many states will allow a non-resident pharmacy to access PDMP by reciprocity with the resident state’s PDMP. Unfortunately for FC, Missouri is the only state that does not currently have legislation to enact a PDMP (3 counties in the St. Louis region are pending legislation). Therefore, we were not able to participate under these terms. However, our pharmacist in charge (PIC) is licensed in all 49 states and Washing DC. This

allowed our other pharmacist staff to register as delegates under the PIC’s account in most states.

Additionally, to overcome the accessibility barrier, we have exercised the interstate data sharing via PMP InterConnect to access the data for patients residing in the excluded states.<sup>10</sup> Although we are not able to directly access NJPMP, we are able to see patient data via Delaware’s PDMP. Furthermore, we have begun to compile a spreadsheet of states that participate in interstate data sharing and with which state for future use (Illustration 4-note *this is a small example*).

States	How to access
ALABAMA	AL
ALASKA	AK
ARIZONA	ND, OH, UT
ARKANSAS	LA, OH, UT
CALIFORNIA	CA
COLORADO	DE, ND, OH, UT
CONNECTICUT	DE, LA, NJ, ND, OH, UT
DELAWARE	DE, NJ, ND

**Illustration 4**

To incorporate querying into our pharmacy workflow, we have placed the responsibility on the pharmacist performing the last check prior to dispensing. This location ensures the medication has been billed appropriately and ready for dispensing to avoid lag time between fill request and dispensing. If a patient requests a CS to be filled, but does not actually want the medication for 1week, staff may miss a CS fill by another pharmacy during this week time period. Placing the PDMP check directly before the medication is dispensed allows our pharmacist to have the most up-to-date fill history as allowed by PDMPs to facilitate an accurate clinical decision.

**Data Integrity**

We have centralized all follow-up emails to one distribution list in order to quickly resolve any issues or discrepancies with uploaded reports. To ensure all controlled substances (CS) and non-controlled

substances (NCS) are reported as required, we have scheduled these substances by the strictest regulation. For example, pentazocine is federally scheduled as a C IV. However, we reclassified this medication in our inventory due to South Carolina's regulations that schedule this medication as a C II.<sup>9</sup> This ensures that all reports pulled for controlled substances are accurate, and at times overly compliant, for every state.

## Summary

State PDMP compliance poses a challenge for pharmacies and staff. By taking time to outline steps to perform PDMP requirements and utilizing appropriate resources, pharmacies can save staff time and ensure PDMP compliance.



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9. South Carolina Legislature. "Poisons, Drugs and Other Controlled Substances." Title 44;Chapter 53. Oct 2016. Accessed at <http://www.scstatehouse.gov/code/t44c053.php>
10. NABP. "PMP InterConnect." National Association of Boards of Pharmacy. 2016. Accessed at <https://nabp.pharmacy/initiatives/pmp-interconnect/>

For questions or comments, please contact

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314-291-1122

[help@foundcare.com](mailto:help@foundcare.com)

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1. National Alliance for Model State Drug Laws. "Compilation of Prescription Monitoring Program Maps". May 2016. Accessed at <http://www.namsdl.org/library/CAE654BF-BBEA-211E-694C755E16C2DD21/>