



February 16, 2018

The Honorable Orrin G. Hatch
U.S. Senate
104 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
U.S. Senate
221 Dirksen Senate Office Building
Washington, D.C. 20510

Submitted electronically via opioids@finance.senate.gov

Dear Chairman Hatch and Ranking Member Wyden,

On behalf of the members and staff of the National Council for Prescription Drug Programs (NCPDP), we appreciate the opportunity to comment on methods to address the opioid epidemic.

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,600 members who are interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

For 40 years NCPDP has developed and promoted industry standards and business solutions that improve patient safety and health outcomes, while also decreasing costs. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting, and other functions in the pharmacy services industry as named in HIPAA. The NCPDP SCRIPT Standard and the Formulary and Benefit Standard are the standards used in electronic prescribing as named in MMA. NCPDP standards are named in HITECH and Meaningful Use (MU) as well.

As the opioid epidemic continues to be a pervasive part of American communities we are pleased the Senate Finance Committee is taking swift action to address this crisis.

Our comments to specific questions posed in the letter are as follows:

- *How can Medicare or Medicaid better prevent, identify and educate health professionals who have high prescribing patterns of opioids?*

Current state Prescription Drug Monitoring Program (PDMP) regulations lack standards to share drug abuse information effectively to address the opioid epidemic. PDMPs are governed at the state level and each state can designate a different entity responsible for administering the PDMP. To aid in preventing and identifying health professionals who have high prescribing patterns of opioids, a standardized set of reporting requirements for PDMPs should be implemented. Using a standardized set of policies and

standards supports patient safety and could help curb the opioid public health crisis by providing more transparent data on prescribing patterns of physicians.

NCPDP has developed a Standards-based Facilitator Model for Patient Safety that leverages best practices to address many of the challenges facing the current system today. The attached white paper, entitled, [*NCPDP's Recommendations for an Integrated, Interoperable Solution to Ensure Patient Safe Use of Controlled Substances details this model*](#). The white paper was developed by the industry, using the same consensus-building process that we use for federally mandated standards and industry guidance documents.

NCPDP's model engages the use of a national facilitator that connects to both the dispensing pharmacy (via NCPDP's Telecommunication Standard) and the prescriber (via NCPDP's SCRIPT Standard).

The facilitator, under a user agreement, could proactively identify health professionals who have a high prescribing pattern of opioids. Information contained at the facilitator could provide the general prescribing volume and frequency of prescribing opioids, which could be used to compare with other prescribers of similar practice type. This information could then be shared with Medicare and Medicaid.

Additionally, the NCPDP Model could be utilized to provide a similar comparison to identify patients who are at high risk of abuse. NCPDP's SCRIPT Standard has the capability to identify Medicare and Medicaid recipients who qualify for further review within PDMP networks, based upon a select set of criteria. This proactive risk alert would then be sent to the appropriate provider.

- *What can be done to improve data sharing and coordination between Medicare, Medicaid and state initiatives, such as Prescription Drug Monitoring Programs?*

Historically, PDMPs have been used to retroactively track dispensing data for patients instead of being utilized to stop the prescription before it is dispensed, or, in some cases, before the prescription is even written. To better utilize PDMPs, the systems need to be less burdensome to providers, be updated in real-time and have interstate connectivity as well as be interoperable with other forms of health IT, such as EHRs.

In order to check a state PDMP, most prescribers and pharmacists have to log in to a completely separate system, run the query, analyze the results and then go back to their original workflow. Providers need a single, efficient, timely method to access PDMPs within their workflow to ensure data is utilized at point-of-care and so that data can be shared in real-time across the network.

Data collection intervals for PDMPs vary across states, ranging from near real-time to weekly reporting. The majority of states report data once daily, which limits provider's ability to make clinical decisions at the point-of-care. Providers need access to PDMPs in real-time to allow for a more efficient, collaborative, and patient-centered care by healthcare professionals.

In addition to implementing real-time data sharing, interstate connectivity needs to be improved among current state PDMP networks. Interstate connectivity gives providers the ability to easily check patient records from across the country and will limit prescriber and pharmacy shopping across state borders. Using a standardized set of policies and standards supports patient safety and will help curb the opioid

public health crisis by alerting providers when an individual is exhibiting signs of Substance Use Disorder or patterns indicative of opioid misuse before the medication is prescribed or dispensed. A standardized set of policies for state PDMPs will ensure state's efforts to improve their respective PDMP programs and will deliver benefits nationwide.

Standardizing information across all networks is crucial to progress in this area – as outlined in NCPDP's white paper. NCPDP's model utilizes existing infrastructure and connects prescribers and pharmacists to a national facilitator via two real-time, bi-directional, HIPAA-compliant standards as a means of providing those entrusted with the care of patients with complete, timely and accurate information on which to base their clinical decisions. Additionally, as mentioned earlier, both standards have the ability to send back risk alerts to providers identifying patients who visit multiple pharmacies and multiple prescribers. Implementing a single, efficient, timely method to access PDMPs, within a provider's workflow, should be a precedent for all providers who prescribe and dispense opioids to curb high prescribing patterns.

Today, NCPDP standards can be used by any covered entity to securely exchange PDMP data. For 40 years, NCPDP has developed new and improved upon existing standards to provide a more comprehensive exchange of information, as the need arises. While the standards-based facilitator does not exist today and would need to be created, models such as the successful Medicare TrOOP facilitator or the FDA REMS Elements To Ensure Safe Use (ETASU) program could be used as a basis.

We appreciate your consideration of our comments and thank you for your leadership on this important issue.

Sincerely,



Lee Ann Stember
President and CEO

Attachment

NCPDP's Recommendations for an Integrated, Interoperable Solution to Ensure Patient Safe Use of Controlled Substances

Version 2.1

November 2016



This white paper details a plan to nationally standardize PDMPs to better track and deter abuse of controlled substance prescriptions. The plan leverages NCPDP's Telecommunication and SCRIPT Standards in use industry-wide. It includes best practices to improve prescriber and pharmacy clinical decision making at point-of-care, and supports real-time access to PDMP data across state lines. It integrates the prescription monitoring process into workflows and provides timely clinical data to prescribers and pharmacists, which also helps ensure access for patients with a valid medical need for controlled substances.

NCPDP's Recommendations for an Integrated, Interoperable Solution to Ensure Patient Safe Use of Controlled Substances

Version 2.1

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The writers of this paper will review and possibly update their recommendations should any significant changes occur.

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Executive Summary

Even though heavy investment in Prescription Drug Monitoring Programs (PDMP) has been made in the recent year, the problem of prescription drug abuse has continued to be the fastest growing drug problem in the U.S. Someone in the United States dies from an unintentional prescription drug overdose every 19 minutes.¹ Current PDMPs lack methods to share prescription information effectively to address potential drug abuse and diversion or evaluate patient risk. The current prescription monitoring communication process is burdensome and does not provide information in a timely manner in order to make clinical decisions at point of care.

Prescription drug abuse has captured the attention of the federal government in the Comprehensive Addiction and Recovery Act (CARA)² for PDMP enhancements. President Obama signed this bipartisan bill into law in July 2016. The CARA highlights the need to enhance today's Prescription Drug Monitoring Programs which currently lack uniform best practices. CARA paves the way for leveraging existing technology and standards to address prescription drug abuse now through:

- Electronic prescribing of controlled substances (EPCS) technology which is key to helping providers more efficiently ensure prescription medicines are being prescribed properly.
- Medication adherence monitoring technologies that allows providers to gauge in real-time, at the point of care, a patient's level of drug compliance.
- Clinical decision support that assists providers in preventing adverse drug events.
- Full adoption of PDMPs will likely never be achieved until the PDMP information is accessible in the provider's technology workflow.

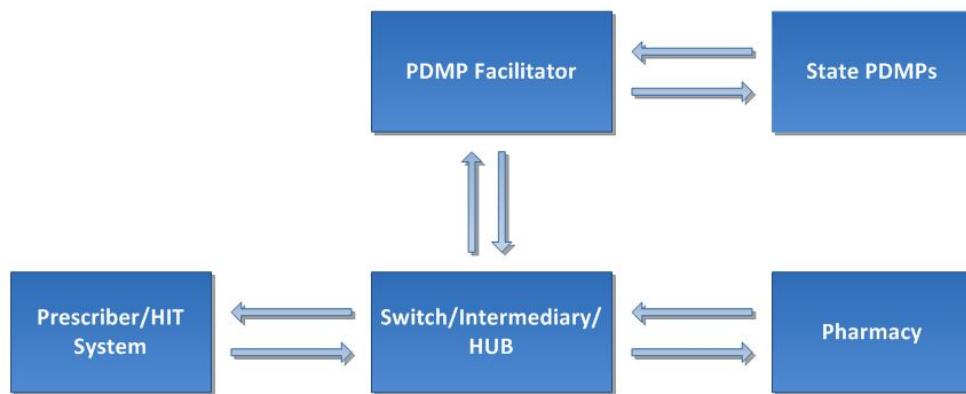
NCPDP's recommendations for an integrated, interoperable solution will ensure a patient's safe use of controlled substances by:

- Sharing real-time information at point of care through the use of existing bidirectional industry standards.
- Reducing the burden on providers by incorporating potential drug abuse information in both pharmacy and prescriber's workflow.
- Enabling a proactive notification to providers when a patient exhibits patterns indicative of opioid misuse.
- Ensuring access to appropriate therapy for patients with valid medical needs.

¹ American Public Health Association's [Prevention and Intervention Strategies to Decrease Misuse of Prescription Pain Medication](#) (10/11/2016)

² [Comprehensive Addiction and Recovery Act](#)

NCPDP's Recommendations for an Integrated, Interoperable Solution to Ensure Patient Safe Use of Controlled Substances



Utilization of NCPDP's existing standards within the data flow above will enable healthcare providers to deter prescription drug abuse and ensure access for patients with a valid medical need before controlled substances are prescribed or dispensed using real-time alerts and responses. This sustainable approach eliminates data silos and promotes interoperability, provides actionable and timely information to prescribers and pharmacists using existing workflows to ease adoption, and supports patient safety efforts to curb a public health crisis. NCPDP and its stakeholders are working to finalize details of the role of the prescription monitoring hub (PDMP Facilitator), as described in CARA, to enable the exchange of information as outlined in NCPDP's solution to ensure a patient's safe use of controlled substances.

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1. Purpose and Scope

A focus group on Prescription Drug Monitoring Programs (PDMPs) was held in Baltimore, MD on October 18, 2012, facilitated by the National Council for Prescription Drug Programs (NCPDP). Goals and Objectives of the focus group were to identify the current and future issues and needs regarding the exchange of information for PDMPs. Identifying the specific industry challenges and the goals of the PDMPs, providers, prescribers, and regulatory agencies, would allow NCPDP to propose efficient solutions leveraging existing standards and methodologies as well as develop applicable enhancements that would be standardized across the industry.

The focus group included attendees from pharmacies, Pharmacy Benefit Managers (PBMs), intermediaries, prescriber vendors, ePrescribing vendors, software vendors, drug compendia, consultants, state agencies, Federal Drug Administration (FDA), Drug Enforcement Administration (DEA), United States Department of Health and Human Services (HHS), the MITRE group, and NCPDP.

At the request of the PDMP focus group, during the November 2012 NCPDP Maintenance and Control Work Group meeting, the PDMP Task Group was formed with the initial task of developing this white paper to: (1) examine the problems; (2) identify future needs; and (3) recommend solutions for PDMP reporting as well as the role of NCPDP. The goals are (1) to complete the white paper and send it to the Office of the National Coordinator (ONC) by March 2013 to coincide with the MITRE contract timeline, and (2) make the white paper available to the industry.

To address the prescription abuse program ONC formed a Standards & Interoperability (S&I) Framework to bring together the PDMP and health IT system communities to standardize the data format, transport, and security protocols to exchange patient controlled substance history information between PDMPs and health IT systems. NCPDP participation has been a high priority for the NCPDP Task Group. As a result of pilot testing, several enhancements have been made to the NCPDP SCRIPT Medication History Request and Response transactions, which convey information to the prescriber about the previous prescriptions written.

At the request of the NCPDP Strategic Planning Committee in November 2014 the NCPDP PDMP White Paper Task Group re-convened to update the white paper based on any additional industry information including results of the ONC S&I Framework. This task was completed in April 2015.

After the introduction of the Comprehensive Addiction and Recovery Act calling for specific enhancements to PDMP programs and the NCPDP EDvocacy meetings, additional updates were made to the white paper in October 2016 including the addition of an Executive Summary.

2. Background

A PDMP is an electronic database that collects designated data on controlled substances dispensed or prescribed within a given state. The data collected usually includes the names and/or demographic information for the patient, prescriber, and dispenser; the name and dosage of the drug; the quantity supplied; the number of authorized refills; and the method of payment.

PDMPs are established and managed at the state level and can vary considerably from state-to-state. Some areas of variation include:

- **Organizational structure.** Each state determines which agency houses the PDMP and how it is operated.
- **Substances monitored.** PDMPs allow monitoring of controlled substance prescriptions and other drugs with potential for abuse. This varies by state.
- **Level of access.** Some PDMPs allow law enforcement to access the database directly; others require law enforcement to obtain a court order or subpoena to access data; and some allow indirect access via a report in response to a request from law enforcement as a part of an active investigation.
- **Solicited and Unsolicited Reporting.** In some states, the PDMP is “reactive” meaning that only solicited reports are generated in response to a query by authorized users such as prescribers, dispensers and other groups with the appropriate authority. PDMPs of other states, in addition to providing solicited reports, are “proactive,” generating unsolicited reports when there is reason to suspect that violations on the part of the patients or users have occurred but only for law enforcement, not providers.³
- **Purpose and Usage.** The purpose is dependent on user intent and varies by user. Users may be law enforcement, regulatory agencies, state payer programs, researchers or providers.
- **Reporting of Prescription Data.** Timeliness of reporting the prescription data to a PDMP varies by state.
- **Prescription Data reporting formats.** State PDMPs are currently using different versions of the American Society for Automation in Pharmacy (ASAP) data transmission formats. ASAP format employs a batch data submission and is not an ANSI-accredited standard. In addition, pharmacies are required to submit prescription data based on state specific requirements/rules, which include the submission of a different identifier and required data elements by state.

³Simeone R, Holland L. Simeone Associates, Inc. (2006, September 1). An evaluation of prescription drug monitoring programs. Retrieved September 7, 2009, from National Alliance for Model State Drug Laws Official Site website: <http://www.simeoneassociates.com/simeone3.pdf>

NCPDP's Recommendations for an Integrated, Interoperable Solution to Ensure Patient Safe Use of Controlled Substances

- **Interoperability.** State PDMPs vary widely as to whether information contained in the database is shared with other states. While some states do not have measures in place allowing interstate sharing of information, others have specific practices for sharing. An effort is ongoing to facilitate information sharing using prescription monitoring information exchange.

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3. The Problem

According to the Office of National Drug Control Policy, prescription drug abuse is the nation's fastest growing drug problem, and prescription drug overdose deaths have been classified as epidemic by the Centers for Disease Control and Prevention. An integrated workflow solution to provide a streamlined, standard communication process would enhance the ability of the health care provider to address the epidemic and mitigate patient care risks. The current prescription monitoring communication process is outside the workflow process and systemically burdensome. It does not effectively provide information in a timely manner or evaluations across all state lines and across all pharmacies.

From a pharmacist's and prescriber's perspective, workflow integration and the adoption of national standards is critical to allow the provider to identify potential drug abuse, diversion, and evaluate patient safety risk and to make appropriate clinical decisions before a prescription is written or dispensed.

There are other entities that impact prescription drug monitoring programs, such as emergency departments, pain clinics, dispensing physicians, and ambulatory surgery centers. These entities may provide information for PDMP reporting and may need access to reporting information.

3.1 Pharmacy Perspective

From a pharmacy perspective, today's processes for using PMDPs for preventing prescription abuse and evaluating patient safety risk are not adequate. Barriers include:

- Lack of real-time interoperable databases among all the states.
- Lack of a nationally adopted ANSI or other accredited standard for real-time reporting to state PDMP databases.
- Lack of a standard set of data elements and values to make interoperability possible.
- Lack of real-time response for validating accurate data.
- Lack of a real-time response in order to make clinical decisions before the prescription is dispensed. The current process is manual and outside of the pharmacy workflow.
- Lack of standardized patient matching criteria at the PDMP or intermediaries.
- Lack of consistency among state requirements when a pharmacy is required to check PDMP data prior to dispensing.

3.1.1 Evaluation of Prescription Data

- No standard measurement for evaluating clinical risk among patient and pharmacy history and doctor prescribing data submission and verification.
- Response to data submissions and queries is untimely. As a result, the process of storing the data is inefficient, whereby clinical decisions could be at risk.
- Lack of validation of accurate prescription data elements required for PDMP at the time the prescription is dispensed.
- PDMP alerts are not available within the pharmacy dispensing workflow.

3.1.2 Reporting/Data Submission

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- Pharmacy has varying requirements by state for submitting PDMP data. The result is supporting multiple transaction layouts that increase administrative costs.
- Frequency of data submission varies from state to state between near real-time to monthly.
- 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.
- Data and format requirements vary from state to state. Most states require data formatted in various versions of the (ASAP) Standards.
- Pharmacy compliance monitoring varies by state.
- Data is not normalized (i.e., address/city/state, "one" vs. "1")
- 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)

3.1.3 Data Accessibility

- Internal security firewalls can prevent access to databases.
- Gaining access to state PDMPs varies widely from state to state.
 - Those individuals that are allowed access to PDMP data vary by State.
 - Process of registering for access varies by State.
 - Validation of access varies by State.
- Access is not available to all those participating in the dispensing and clinical processes.
- Pharmacy does not have access to PDMP data within their workflow as a result must interrupt operational processes to access an external database.
- Consistent access to PDMP data across state lines impacts the pharmacy's ability to make accurate clinical decisions.
- Pharmacists providing patient care (clinical services such as Drug Utilization Review and Medication Therapy Management) should have access to PDMP data prior to comprehensive medication reviews.

3.1.4 Data Integrity

- Gaps in data:
 - Not all entities are required to submit data (e.g., Indian Health Services, Veterans Administration, state specific programs, and other providers and locations that are administering and dispensing medications are included).
 - Drugs required to be reported vary by State.
 - NDC matching may vary by compendia companies.
- Missing, incomplete and/or invalid data due to lag in reporting and validation leads to incomplete records.

3.2 Prescriber Perspective

From a prescriber perspective, the current process for preventing prescription drug abuse is not adequate for addressing the need for improving patient safety. The ePrescribing process is a method to help data verification reporting accessibility but prescription drug monitoring information needs to fit into the prescriber's ePrescribing workflow. Barriers include:

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- Lack of real-time interoperable databases among all the states.
- Lack of a standard set of data elements and values to make interoperability possible.
- Lack of real-time response for validating accurate data.
- Lack of a real-time response in order to make clinical decisions before the prescription is written. The current process is manual and outside of the prescribers workflow.
- Lack of standardized patient matching criteria at the PDMP or intermediaries.
- Lack of consistency among state requirements when a prescriber is required to check PDMP data prior to prescribing.

3.2.1 Data Verification

- Access to the PDMP data is a manual process and does not fit into the prescriber's workflow.
- Data varies by state and is inconsistently organized and/or presented.
- Clinical decisions are not integrated into the prescribing process.
- Individual state record look-up often times-out after several seconds.

3.2.2 Data Accessibility

- Internal security firewalls can prevent access to databases.
- Gaining access to state PDMPs varies widely from state to state.
 - Individuals who are allowed access to PDMP data varies by State.
 - Process of registering for access varies by State.
 - Validation of access varies by State.
- Access is not available to all those participating in the prescribing and clinical processes.
- Prescriber does not have access to PDMP data within their workflow and as a result, must interrupt operational processes to access an external database.
- Consistent access to PDMP data across state lines impacts the prescriber's ability to make accurate clinical decisions.
- Prescribers are notified of doctor shopping issues outside of their workflow, i.e., email.

3.2.3 Data Integrity

- Gaps in data:
 - Not all entities are required to submit data (e.g., Indian Health Services, Veterans Administration, state specific programs, and other providers and locations that are administering and dispensing medications are included).
 - Drugs required to be reported vary by States.
 - NDC matching may vary by compendia companies.
- Missing, incomplete and/or invalid data due to lag in reporting and validation leads to incomplete records.

4. Improvement Recommendations

By leveraging existing industry standards and processes, several recognized problems could be resolved.

4.1 Standardization

- Require a standard set of data elements to be reported by dispensers' systems to the PDMP to be adopted by all states.
- Require one standard transaction format/version for reporting PDMP to the states.
- Require one standard transaction for the request and response of PDMP data.
- Create and adopt a nationally recognized clinical risk score to assist prescribers and dispensers with clinical decisions.

4.2 Real-Time Reporting

4.2.1 Dispenser Reporting of Data

- Reduce reporting delays by allowing PDMP type rejections to be corrected at point of sale.
- Enable the exchange of information across states to create a comprehensive picture of prescribing and dispensing patterns.
- Report Date Filled or Date of Service rather than Date Sold (date delivered or shipped).
- Real-time reporting would eliminate the need for zero reports (no schedules filled).

4.2.2 Retrieval of PDMP Data

- Improve patient quality of care with clinical decision alerts presented at the time of prescription writing or dispensing.
- Provide access to the most current data within workflow as appropriate to all impacted parties for making clinical decisions at point of care.

4.3 Central Data Repository

- Provide PDMPs with more comprehensive multi-state access to data.
- Provide PDMPs with more accurate, timely and consistent data.
- Provide prescribers and pharmacies centralized access to accurate and up-to-date data for clinical and other decision making reasons.
- Provide clinical data to pharmacies and prescribers that are integrated within their workflow.
- Provide data analytics that are more consistent and inclusive.

5. Proposed Solutions

The task group recommends the following solutions to allow authorized healthcare providers, including prescribers and pharmacists, to make more informed clinical decisions prior to writing and dispensing medications, in an effort to reduce patient prescription drug overdosing and abuse.

1. Create a national repository for all PDMP data.
2. Adopt a minimum data set and standard transaction format for submission of dispensing data to the national repository.
3. Leverage the NCPDP Telecommunication Standard to support real-time reporting within the pharmacy's workflow to a PDMP national repository.
4. Leverage the NCPDP Telecommunication Standard to support clinical alerts to the pharmacy prior to dispensing.
5. Leverage the NCPDP SCRIPT Standard, including the Medication History transaction, to query PDMP data in real-time within the prescriber's work flow to enable appropriate clinical decisions before the medication is prescribed.
6. Create and adopt a nationally recognized clinical risk score to be reported in the NCPDP SCRIPT Medication History transaction to assist prescribers and dispensers with clinical decisions.

6. Flow Charts

NCPDP's model provides an onramp for existing PDMPs to optimize value of the programs at both the state and national levels.

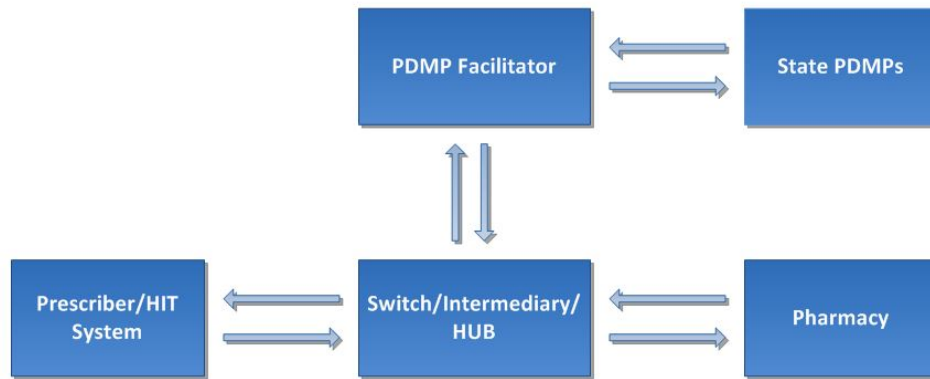


Figure1. Suggested Flow for PDMP Data

NCPDP's integrated workflow solution uses existing NCPDP industry standards for proactive intervention at **both** the points of prescribing and dispensing, allowing for electronic access to prescription drug abuse data.

1. Pharmacy reports controlled substance in real-time to PDMP Facilitator. [NCPDP Telecommunication Standard]
2. Prescriber/HIT System queries PDMP data from PDMP Facilitator at point of care to make appropriate clinical decisions before the medication is prescribed. [NCPDP SCRIPT Standard/Medication History transaction]
3. Pharmacy receives clinical alerts from PDMP Facilitator that PDMP data needs to be checked prior to dispensing. [NCPDP Telecommunication Standard]
4. Pharmacy queries PDMP data from PDMP Facilitator at point of service to enable appropriate clinical decisions before the medication dispensed. [NCPDP SCRIPT Standard/Medication History transaction]
5. PDMP Facilitator provides State PDMPs with information regarding medications dispensed to meet individual state requirements. [NCPDP Telecommunication Standard Controlled Substance Reporting (C1) transaction]

Utilization of NCPDP's existing standards will enable healthcare providers to deter prescription drug abuse and ensure access for patients with a valid medical need before substances are prescribed using real-time alerts and responses. This **sustainable, national** approach eliminates data silos and promotes **interoperability**, provides **actionable and timely** information to prescribers and pharmacists using **existing workflows** to ease adoption, and **supports patient safety** efforts to curb a public health crisis.

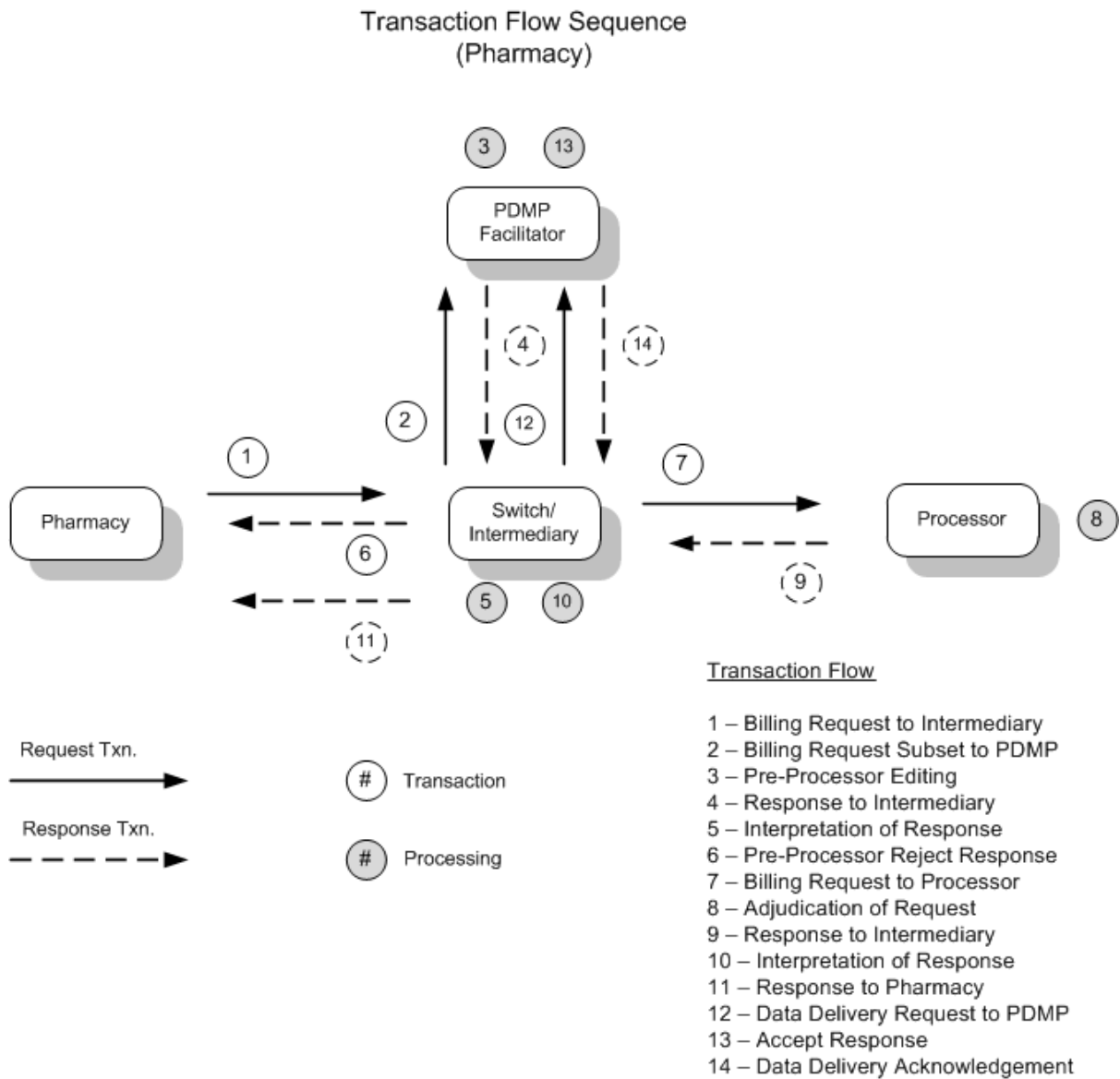


Figure 2. Pharmacy Flow based on NCPDP Telecommunication Standard

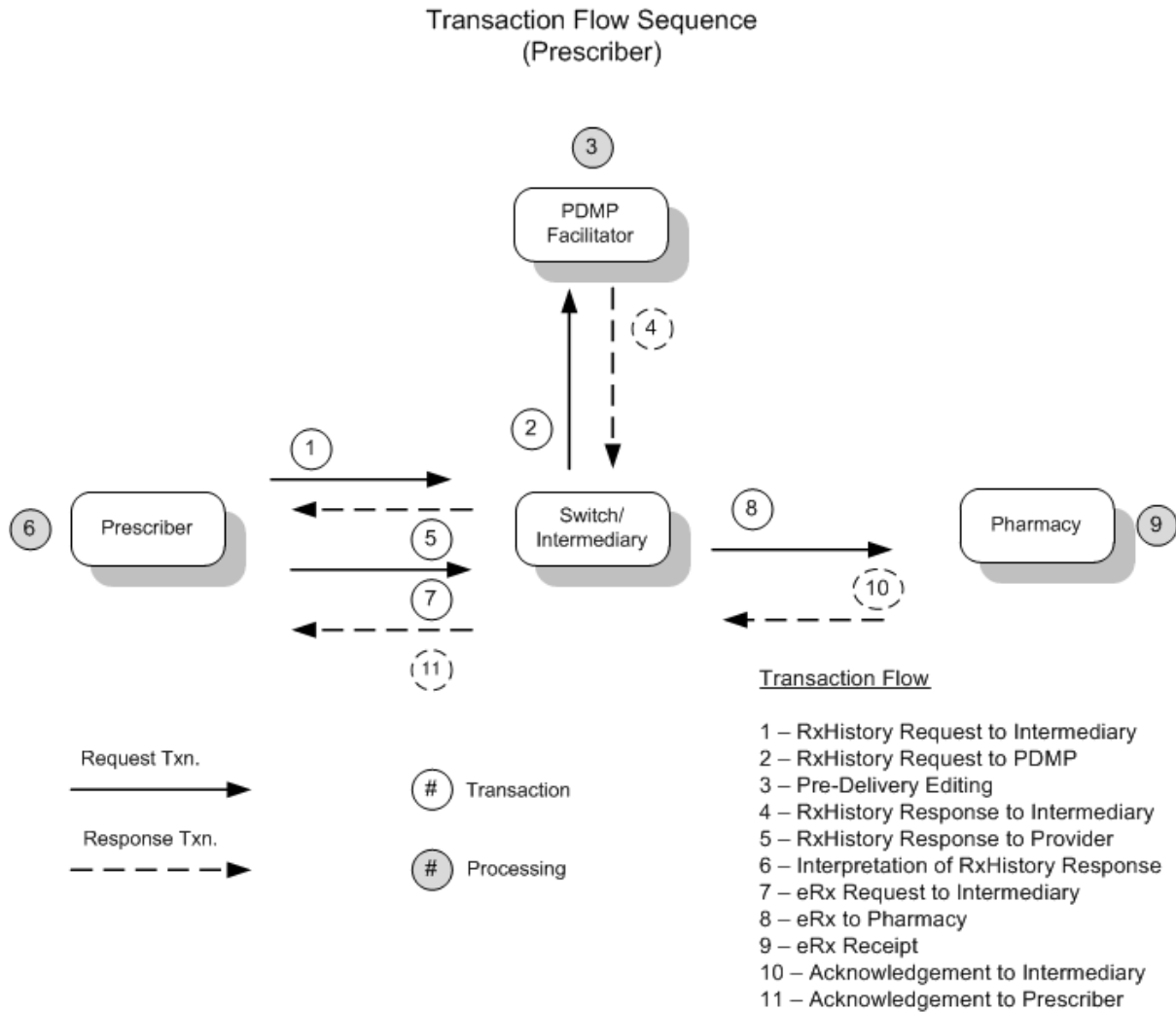


Figure 3. Prescriber Flow based on NCPDP SCRIPT Standard

7. Appendix A. History of Changes

7.1 Version 2.0

Section: Purpose and Scope was modified to add the following:

To address the prescription abuse program, the ONC formed an S&I Framework to bring together the PDMP and health IT system communities to standardize the data format, transport, and security protocols to exchange patient controlled substance history information between PDMPs and health IT systems. NCPDP participation has been a high priority for the NCPDP Task Group. As a result of pilot testing, several enhancements have been made to the NCPDP Medication History Request and Response.

At the request of the NCPDP Strategic Planning Committee in November 2014, the NCPDP PDMP White Paper Task Group re-convened to update the white paper based on any additional industry information including results of the ONC S&I Framework. This task was completed in April 2015.

Section: Background was updated as follows:

- Updated statistics and picture to reflect October 2014 data
- *"Timeliness of Data"* was modified to *"Reporting of Prescription Data"* and text updated to the following:

Timeliness of reporting the prescription data to a PDMP varies by state and can be anywhere from monthly to daily.

- Add new bullet *"Prescription Data Reporting Formats"* with the following text:
State PDMPs are currently using different versions of the American Society for Automation in Pharmacy (ASAP) data transmission formats. ASAP is a batch data submission using a non-ANSI accredited standard. In addition, pharmacies are required to submit prescription data based on state specific requirements/rules, which include the submission of different identifiers and required data elements by state.
- Deleted bullet *"Reporting Format"* and combined with the new bullet for *"Prescription Data Reporting Formats"*.
- The bullet *"Multiple Work Groups"* was deleted from the paper.

Section 3: Glossary was moved to Appendix B. Definitions were added for the following:

Health Information Exchange (HIE)

Electronic health information exchange (HIE) allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically—improving the speed, quality, safety and cost of patient care.

Hub

A highly secure communications exchange platform that facilitates transmission of PDMP data to authorized requestors, allowing for in-state and, where allowed, out-of-state queries on a person of interest.

PDMP Gateway

PDMP Gateway is an interface that simplifies integration of controlled substance prescription

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history into health IT systems. PMP Gateway provides health IT systems, a single access point to many state prescription drug monitoring programs' data via PMP Interconnect, thus saving healthcare providers, the effort of doing individual integrations with each state PDMP

Prescription Monitoring Information eXchange (PMIX)

The Prescription Monitoring Information Exchange (PMIX) National Architecture enables Interoperability between systems PDMPs use for interstate exchange of PDMP data.

S&I Framework

The S&I Framework is a collaborative community of participants from the public and private sectors who are focused on providing the tools, services and guidance to facilitate the functional exchange of health information. The S&I Framework uses a set of integrated functions, processes, and tools that enable execution of specific value-creating initiatives. Each S&I Initiative tackles a critical interoperability challenge through a rigorous process that typically includes:

- Development of clinically-oriented user stories and robust use cases
- Harmonization of interoperability specifications and implementation guidance
- Provision of real-world experience and implementer support through new initiatives, workgroups and pilot projects
- Mechanisms for feedback and testing of implementations, often in conjunction with ONC partners such as NIST

Added bullet to Section: [Pharmacy Perspective](#) under Section: [The Problem](#)

- Lack of standardized patient matching criteria at the PDMP or intermediaries.

Updated Section: [Reporting/Data Submissions](#) under Section: [Pharmacy Perspective](#) as follows:

- Pharmacy has varying requirements by state for submitting PDMP data. The result is supporting multiple transaction layouts that increase administrative costs,
- Frequency of data submission varies from state to state between near real-time to monthly.
- 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.
- 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).
- Pharmacy compliance monitoring varies by state.
- Data is not normalized (i.e. address/city/state, one vs. 1)
- 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)

Updated Section: Accessibility under Section: [Pharmacy Perspective](#) to Section: [Data Accessibility](#) and updated as follows:

- Internal security firewalls can prevent access to databases.

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- Gaining access to state PDMPs varies widely from state to state.
 - Those individuals that are allowed access to PDMP data vary by State.
 - Process of registering for access varies by State.
 - Validation of access varies by State.
- Access is not available to all those participating in the dispensing and clinical processes.
- Pharmacy does not have access to PDMP data within their workflow as a result must interrupt operational processes to access an external database.
- Consistent access to PDMP data across state lines impacts the pharmacy's ability to make accurate clinical decisions.
- Pharmacists providing patient care (clinical services such as Drug Utilization Review and Medication Therapy Management) should have access to PDMP data prior to comprehensive medication reviews.

Updated Section: [Data Integrity](#) under Section: [Pharmacy Perspective](#) as follows:

- Gaps in data:
 - Not all entities required to submit data (e.g. Indian Health Services, Veterans Administration, state specific programs, and other providers and locations that are administering and dispensing medications are included.)
 - Drugs required to be reported vary by States.
 - NDC matching may vary by compendia companies.
- Missing, incomplete and/or invalid data due to lag in reporting and validation leads to incomplete records.

Updated Section: [Prescriber Perspective](#) with the following bullets:

- Lack of real-time interoperable databases among all the states.
- Lack of a standard set of data elements and values to make interoperability possible.
- Lack of real-time response for validating accurate data.
- Lack of a real-time response in order to make clinical decisions before the prescription is written. The current process is manual and outside of the prescribers workflow.
- Lack of standardized patient matching criteria at the PDMP or intermediaries.

Combined Sections: *Reporting* and *Accessibility* under Section: [Prescriber Perspective](#) into Section: [Data Accessibility](#) and modified as follows:

- Internal security firewalls can prevent access to databases.
- Gaining access to state PDMPs varies widely from state to state.
 - Those individuals that are allowed access to PDMP data vary by State.
 - Process of registering for access varies by State.
 - Validation of access varies by State.
- Access is not available to all those participating in the prescribing and clinical processes.
- Prescriber does not have access to PDMP data within their workflow as a result must interrupt operational processes to access an external database.
- Consistent access to PDMP data across state lines impacts the prescriber's ability to make accurate clinical decisions.

Updated Section: [Data Integrity](#) under Section: [Prescriber Perspective](#) as follows:

- Gaps in data:

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- Not all entities required to submit data (e.g., Indian Health Services, Veterans Administration, state specific programs, and other providers and locations that are administering and dispensing medications are included.)
- Drugs required to be reported vary by States.
- NDC matching may vary by compendia companies.
- Missing, incomplete and/or invalid data due to lag in reporting and validation leads to incomplete records.

Updated Section: [Improvement Recommendations](#) as follows:

By leveraging existing industry standards and processes, several recognized problems could be resolved.

Updated Section: [Standardization](#) under Section: [Improvement Recommendations](#) as follows:

- Require a standard set of data elements to be reported by dispenser's systems to the PDMP to be adopted by all states.
- Require one standard transaction format/version for reporting PDMP to the states,
- Require one standard transaction for the request and response of PDMP data.
- Create and adopt a nationally recognized clinical risk score to assist prescribers and dispensers with clinical decisions.

Created Section: [Real-Time Reporting](#)

Created Section: [Dispenser Report of Data](#) under Section [Real-Time Reporting](#)

- Reduce reporting delays by allowing PDMP type rejections to be corrected at point of adjudication.
- Enable the exchange of information across states to create a comprehensive picture of prescribing and dispensing patterns.
- Report Date Filled or Date of Service rather than Date Sold (Date delivered or shipped.)
- Real-time reporting would eliminate the need for zero reports (no schedules filled).

Created Section: [Retrieval of PDMP Data](#)

- Improve patient quality of care with clinical decision alerts presented at the time of prescription writing or dispensing.
- Provide access to the most current data within workflow as appropriate to all impacted parties for making clinical decisions at point of care.

Updated Section: [Proposed Solution](#) as follows:

1. Create a national repository for all PDMP data.
2. Adopt a minimum data set and standard transaction format for submission of dispensing data to the national repository
3. Leverage the NCPDP Telecommunication Standard to support real-time reporting within the pharmacy's workflow to PDMP a national repository.
4. Leverage the NCPDP Telecommunication Standard to support clinical alerts to the pharmacy prior to dispensing.

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5. Leverage the NCPDP SCRIPT Standard, including the Medication History transaction, to query PDMP data in real-time within the prescriber's work flow to enable appropriate clinical decisions before the medication is prescribed.
6. Leverage the NCPDP SCRIPT Standard, including the Medication History transaction, to query PDMP data in real-time within the pharmacy's work flow to enable appropriate clinical decisions before the medication is dispensed.
7. Create and adopt a nationally recognized clinical risk score to be reported in the NCPDP SCRIPT Medication History transaction to assist prescribers and dispensers with clinical decisions.

Added a high level flow to Section: [Flow Charts](#)

Updated Transaction Flow for both Pharmacy and Prescriber in Section: [Flow Charts](#)

Updated List of Participants in [Appendix C](#)

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Title of the white paper was changed to *NCPDP's Recommendations for an Integrated, Interoperable Solution to Ensure Patient Safe Use of Controlled Substances*.

[Executive Summary](#) was added.

[Purpose and Scope](#) – paragraph inserted:

- After the introduction of the Comprehensive Addiction and Recovery Act (CARA Bill) for PDMP Enhancements that calls for specific enhancements to PDMP programs and the NCPDP EDvacy meetings, additional updates were made to the white paper in October 2016 including an Executive Summary.

[Background](#)

- The illustration displaying the status of PDMPs across the United States was removed from the white paper and the information will be available in NCPDP's State PMP Tracking Document which is updated quarterly. <http://www.ncdp.org/Resources/Hot-Topics>
- The paragraph, **Interoperability**, was modified to remove the PMIX architecture information.

Updated [3.1 Pharmacy Perspective](#) with the following bullet:

- Lack of consistency among state requirements when a pharmacy is required to check PDMP data prior to dispensing.

Updated [3.2 Prescriber Perspective](#) with the following bullet:

- Lack of consistency among state requirements when a prescriber is required to check PDMP data prior to prescribing.

[6. Flow Charts](#)

Modified the following bullets to remove the reference to "National" PDMP Facilitator and reference NCPDP standards within the bullets instead of using footnotes.

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1. Pharmacy reports controlled substance in real-time to PDMP Facilitator. [NCPDP Telecommunication Standard]
2. Prescriber/HIT System queries PDMP data from PDMP Facilitator at point of care to make appropriate clinical decisions before the medication is prescribed. [NCPDP SCRIPT Standard/Medication History transaction]
3. Pharmacy receives clinical alerts from PDMP Facilitator that PDMP data needs to be checked prior to dispensing. [NCPDP Telecommunication Standard]
4. Pharmacy queries PDMP data from PDMP Facilitator at point of service to enable appropriate clinical decisions before the medication dispensed. [NCPDP SCRIPT Standard/Medication History transaction]
5. PDMP Facilitator provides State PDMPs with information regarding medications dispensed to meet individual state requirements. [NCPDP Telecom C1 transaction]

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8. Appendix B. Glossary

ASAP

American Society for Automation in Pharmacy (ASAP) has various versions of different layouts for PDMP reporting.

Authorized Healthcare Professionals

Healthcare professionals involved in patient treatment who may or may not have prescribing or dispensing authority, need access to PDMP data, and have the ability to appoint delegates. These licensed healthcare professionals could include practitioners who work in fields such as medication therapy management, disease management, behavioral health that involves utilization management review and case management, and practitioners such as substance abuse clinicians and psychologists.

Clinical Data

Concepts or terms applying to the clinical delivery of care.

Clinical Decisions

Judgmental process clinicians use to make logical, rational decisions to decide whether an action is right or wrong. *Clinical Decision Support (CDS) is defined as "providing clinicians or patients with clinical knowledge and patient-related information, intelligently filtered or presented at appropriate times, to enhance patient care."*⁴

DEA Number

A number assigned to a health care provider by the U.S. Drug Enforcement Administration (DEA) allowing them to write prescriptions for controlled substances. Legally, the DEA number is solely to be used for tracking controlled substances. It is used by the industry, however, as a general "prescriber number" that is a unique identifier for anyone who can prescribe medication.

Dispenser

Pharmacy or physician authorized to dispense controlled substances

FTP

File Transfer Protocol; commonly used protocol for exchanging files over any network.

Health Information Exchange (HIE)

Electronic health information exchange (HIE) allows doctors, nurses, pharmacists, other health care providers and patients to appropriately access and securely share a patient's vital medical information electronically—improving the speed, quality, safety and cost of patient care.

⁴ *Informatics and Clinical Decision Support*, Kathryn A. Walker, PharmD, BCPS Faculty and Disclosures CE Released: 03/07/2008; Valid for credit through 03/07/2009 accessed February 14, 2013 <http://www.medscape.org/viewarticle/571099>

Hub

A highly secure communications exchange platform that facilitates transmission of PDMP data to authorized requestors, allowing for in state and, where allowed, out of state queries on a person of interest.

Manual Claim Form

Various forms used by the provider of service to submit a claim to the patient's payer or insurer or the state.

NABP

National Association of Boards of Pharmacy

NCPDP

National Council for Prescription Drug Programs

NDC

National Drug Code describes specific drugs by drug manufacturer and package size.

NPI

National Provider Identifier is a unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services.

ONC

Office of the National Coordinator for Health Information Technology

PDMP

A PDMP is a **statewide** electronic database which collects designated data on substances dispensed in the state. The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency. The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession.⁵

PDMP Gateway

PMP Gateway is an interface that simplifies integration of controlled substance prescription history into health IT systems. PMP Gateway provides health IT systems, a single access point to many state prescription drug monitoring programs' data via PMP Interconnect, thus saving healthcare providers, the effort of doing individual integrations with each state PDMP.

PMP InterConnect

PMP InterConnect is a highly secure communications exchange platform that is owned by the National Association of Boards of Pharmacy. PMP InterConnect facilitates the transfer of prescription monitoring program (PMP) data across state lines to authorized users. It allows

⁵ Source, U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control accessed February 27, 2013 website: http://www.deadiversion.usdoj.gov/fag/rx_monitor.htm. Accredited to the **National Alliance for Model State Drug Laws (NAMSDL)** website: <http://www.namsdl.org/home.htm>

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participating state PMPs across the United States to be linked, providing a more effective means of combating drug diversion and drug abuse nationwide.

Prescription Monitoring Information eXchange (PMIX)

The Prescription Monitoring Information Exchange (PMIX) National Architecture enables Interoperability between systems PDMPs use for interstate exchange of PDMP data.

Prescriber

A practitioner authorized by state and federal agencies to prescribe controlled substances.

SCRIPT Standard

The NCPDP SCRIPT Standard is used for transmitting prescription information electronically between prescribers, providers, and other entities. The standard addresses the electronic transmission of new prescriptions, changes of prescriptions, prescription refill requests, prescription fill status notifications, cancellation notifications, relaying of medication history, transactions for long-term care, and other transaction functions. The SCRIPT Standard is named in the Medicare Modernization Act.

SFTP

Secure File Transfer Protocol (also referred to as SSH File Transfer Protocol); provides file transfer and manipulation functionality over any reliable data stream.

S&I Framework

The S&I Framework is a collaborative community of participants from the public and private sectors who are focused on providing the tools, services and guidance to facilitate the functional exchange of health information. The S&I Framework uses a set of integrated functions, processes, and tools that enable execution of specific value-creating initiatives. Each S&I Initiative tackles a critical interoperability challenge through a rigorous process that typically includes:

- Development of clinically-oriented user stories and robust use cases
- Harmonization of interoperability specifications and implementation guidance
- Provision of real-world experience and implementer support through new initiatives, workgroups and pilot projects
- Mechanisms for feedback and testing of implementations, often in conjunction with ONC partners such as NIST

SSL

Secure Sockets Layer; cryptographic protocol that provides secure communications for data transfers.

Telecommunication Standard

The NCPDP Telecommunication Standard is used for the electronic submission of eligibility verification, claim and service billing, predetermination of benefits, prior authorization, information reporting, and controlled substance (general and regulated) transaction exchanges. The Telecommunication Standard is named in HIPAA and the Medicare Modernization Act.

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