

NCPDP Standards-based Facilitator Model for PDMP

An Interoperable Framework for Patient Safety

Version 10

January 2019



This white paper outlines the latest changes in federal activity and industry impact to address the prescription drug abuse crisis. It explains how NCPDP standards can provide more timely and efficient information to providers in order to make more informed clinical decisions at the point of care.

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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 United States. Data from the National Vital Statistics System, Mortality In 2017, there were 70,237 drug overdose deaths in the United States. The drug overdose deaths in 2017 (21.7 per 100,000) was 9.6% higher than the rate in 2016 (19.8). The rate of drug overdose deaths involving synthetic opioids other than methadone (drugs such as fentanyl, fentanyl analogs, and tramadol) increased by 45% between 2016 and 2017, from 6.2 to 9.0 per 100,000. 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 outside the provider's workflow and does not provide information in a timely manner in order to make clinical decisions at point of care.

Combatting prescription drug abuse, specifically the opioid crisis, is an issue that transcends political party lines. In 2017, President Trump signed an executive order establishing the President's Commission on Combating Drug Addiction and the Opioid Crisis. In its final report, the Commission included recommendations to enhance today's PDMPs, such as funding the establishment of a data-sharing hub to facilitate interoperability among states, integrating PDMP data within electronic health records and increasing utilization of electronic prescribing for controlled substances. These recommendations would expand upon the 2016 bipartisan Comprehensive Addiction and Recovery Act (CARA)¹ which highlights the need to strengthen today's PDMP systems, that currently lack uniform best practices.

The Analyzing and Leveraging Existing Rx Transaction (ALERT) Act introduced in 2018 would implement a prescription safety alert system to prevent opioid misuse and abuse, under the existing Food & Drug Administration (FDA) Risk Evaluation and Mitigation Strategies (REMS) Program. The ALERT Act requires the Department of Health and Human Services (HHS) to use transactions to better inform pharmacists as they treat patients and dispense medications. Specifically, the bill references NCPDP in Section 1171(8) of the Social Security Act as the standard setting organization responsible for designing the transaction standards used in the Alert System.

These recent actions at the Federal level should pave the way for leveraging existing technology and standards to address prescription drug abuse now through:

- Electronic prescribing of controlled substances (EPCS) transactions which is key to helping providers more efficiently ensure prescription medicines are being prescribed properly.
- Medication adherence monitoring technologies that allow providers to evaluate a patient's medication history in real-time², at the point of care.
- Clinical decision support that assists providers in preventing adverse drug events.

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

- Reporting information real-time at point of care through the use of existing bidirectional

¹ [Comprehensive Addiction and Recovery Act](#)

² Real-Time NCPDP transactions are measured in seconds (typically 3-10).

industry standards.

- Reducing the burden on providers by incorporating potential drug misuse, abuse or diversion 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 drug therapy for patients with valid medical needs.

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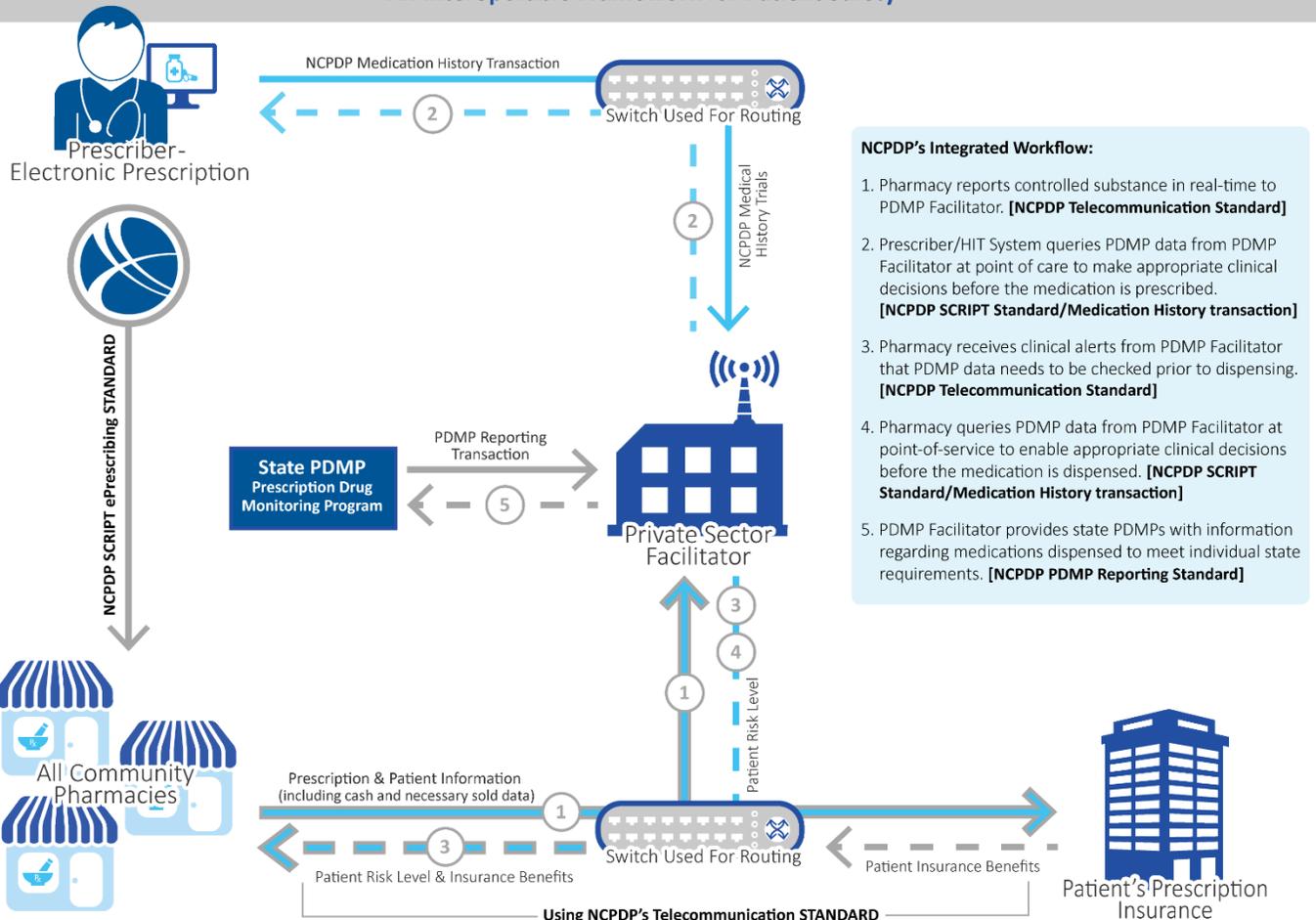


Figure 1. Suggested Flow for PDMP Data

Utilization of NCPDP’s existing standards within the data flow above will enable healthcare providers to prevent 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 facilitate adoption, and supports patient safety efforts to curb a public health crisis. NCPDP’s facilitator model for PDMP enables the exchange of information to promote a patient’s safe use of controlled substances.

1. Purpose and Scope

To address the prescription abuse crisis, the Office of the National Coordinator for Health Information Technology (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, where 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 patient's controlled substance use history. Additionally, NCPDP's PDMP Task Group set out to identify industry challenges and opportunities to improve upon state PDMPs and recommend standards solution for PDMP reporting and accessing prescription claim drug data to improve patient safety.

The purpose of this NCPDP Standards-based Facilitator Model for PDMP White Paper is to explain how NCPDP standards can provide more timely and efficient information to providers in order to make more informed clinical decisions at the point of care.

2. Background

A PDMP is an electronic database that collects designated data on controlled substances and other reportable dispensed medication within a given geographic area (typically, a state). The data collected 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 generally 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 reviewing of controlled substance prescriptions and other drugs with potential for abuse and some may require such a review before prescribing or dispensing activities. These requirements vary 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. Access is typically granted for clinicians involved in the treatment of a patient or when considering the prescribing or dispensing of these drugs.
- **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 violations have occurred on the part of the patients or users, but access is supported only for law enforcement, not providers.³
- **Purpose and Usage.** The purpose is dependent on user roles and therefore 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. The ASAP format employs a batch data submission and is not an ANSI-approved standard. In addition, pharmacies are required to submit prescription data based on state-specific requirements and rules, which include the submission of a different identifier and required data elements by state.

³ Simeone 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>

- **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 the sharing of data with other state PDMPs, the vast majority have specific practices for data sharing. Efforts are ongoing to facilitate information sharing processes using prescription monitoring information exchanges.

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. Integrated workflow solutions that provide a streamlined, standard communication process enhance the ability of the health care provider to address the opioid epidemic and mitigate patient drug therapy risks. The current prescription monitoring communication process is inefficient and compromises security protocols in that they are outside the clinical workflow and leverage antiquated user ID log-ons. As a result, comprehensive critical patient safety information is not made available in a timely manner or may not be accessible across state boundaries.

From the pharmacist and prescriber perspectives, workflow integration and the adoption of national standards is critical to allow the provider to identify potential drug misuse, drug abuse or diversion, and to evaluate patient safety risks 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 out of workflow processes for accessing PDMPs for evaluating patient safety risks are not adequate. Challenges include the lack of:

- Real-time interoperable databases among the state PDMPs.
- A nationally adopted ANSI-approved standard for real-time reporting to state PDMP databases.
- A standard set of data elements and values.
- Real-time response to make clinical decisions before the prescription is dispensed. Many current processes are manual and outside of the pharmacy workflow.
- Standardized patient matching criteria at the PDMP or intermediaries.
- Consistent state PDMP requirements that mandate a PDMP data review prior to dispensing.

3.1.1 Evaluation of Prescription Data

- No standard measurement for evaluating the clinical risk of additional drug therapy, based on the patient's PDMP data history.
- Response to data submissions and queries is often untimely, potentially jeopardizing sound clinical decisions.
- 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

- Pharmacy has varying requirements by state for submitting PDMP data. As a result, multiple transaction layouts and reporting frequencies increase administrative costs and compromise the clinical evaluation process.
- If the data submitted is inaccurate or incomplete (i.e., missing patient zip code), the notification and update process is inconsistent among the different programs.

- ASAP formats are not ANSI-approved.
- 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 or delay access to databases.
- State PDMPs use non-secure user ID access.
- 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 applicable individuals participating in the dispensing and clinical processes.
- Without a standards-based solution, pharmacies are required to make system modifications to have access to PDMP data within their workflow.
- Inefficient and inconsistent access to PDMP data across PDMPs impacts the pharmacy’s ability to make appropriate clinical decisions.
- Pharmacists providing patient care (clinical services such as Drug Utilization Review and Medication Therapy Management) need access to PDMP data that is readily available in order to perform 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 administering and dispensing medications).
 - Drugs required to be reported vary by state.
- 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, most current processes for mitigating prescription drug abuse are not adequate for addressing the need to improve patient safety. The ePrescribing process, specifically the NCPDP SCRIPT Medication History Request and Response transaction, should be used to access prescription drug monitoring program data within the prescriber’s ePrescribing workflow. Medication History is an ONC certification requirement. Challenges to accessing this data include the lack of:

- Real-time interoperable databases among state PDMPs.
- A standard set of data elements and values.
- Real-time response to make clinical decisions before the prescription is written. Some current processes are manual and outside of the prescriber’s workflow.
- Standardized patient matching criteria at the PDMP or intermediaries.
- Consistency among program requirements that mandate when a prescriber is required to check PDMP data prior to prescribing.

3.2.1 Data Verification

- Access to the PDMP data is often a manual process that does not fit into the prescriber's workflow.
- Data varies by state and is inconsistently organized and/or presented.
- Clinical decisions may not be integrated into the prescribing process.
- Individual state systems can require reauthorization after several minutes unless the access is provided in workflow.

3.2.2 Data Accessibility

- Internal security firewalls can delay access to databases.
- State PDMPs use non-secure user ID access.
- The process to gain 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 clinicians participating in the prescribing and clinical processes.
- Prescriber does not have access to PDMP data within their workflow and as a result would need to interrupt operational processes to access an external database.
- Inefficient and inconsistent access to PDMP data across state lines impacts the prescriber's ability to make appropriate clinical decisions.
- Prescribers may be notified of doctor shopping issues outside of their workflow, (e.g., email).

3.2.3 Data Integrity

- Gaps in data:
 - Not all entities are required to submit data (e.g., Indian Health Services, state specific programs, and other providers and locations administering and dispensing medications).
 - Drugs required to be reported vary by states.
- Missing, incomplete and/or invalid data due to lag in reporting and validation can lead to incomplete records.

4. Improvement Recommendations

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

4.1 Standardization

- Support a standard set of data elements to be reported by dispensers' systems to the PDMP to be adopted by all states using the NCPDP Telecommunication Standard.
- Support one standard transaction format/version for reporting data to the states. [NCPDP PDMP Reporting Standard]
- Support one standard transaction for the request and response of PDMP data [NCPDP SCRIPT Medication History Request and Response transaction]
- Create and adopt a nationally recognized clinical risk score to assist prescribers and dispensers with clinical decisions.
- Promote the use of ANSI-approved transactions developed and maintained by an ANSI-accredited organization.

4.2 Reporting

4.2.1 Real-Time Dispenser Reporting of Data

- Reduce reporting delays by ensuring required data elements are present prior to reporting using the NCPDP Telecommunication Standard response to correct missing or incomplete data.
- Enable the exchange of information across states to create a comprehensive picture of prescribing and dispensing patterns.
- Report on 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 Supplemental Dispenser Reporting of Data

- Purchaser data can be reported using the NCPDP PDMP Reporting Standard.
- The NCPDP PDMP Reporting Standard can also be used to report data from the Facilitator to the state PDMP.

4.2.3 Retrieval of PDMP Data

- Improve patient quality of care with additional 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 state PDMPs standardized data files at the patient level that offer secure access to patient level data that may be across state lines.
- Provide PDMPs with more accurate, timely and consistent data.
- Provide prescribers and pharmacies centralized access to more accurate and up-to-date data for clinical and other decision-making activities.
- Provide clinical data to pharmacies and prescribers that are integrated within their

workflow.

- Provide data analytics that are consistent and inclusive.

5. Proposed Solutions

In an effort to reduce patient prescription drug overdoses and drug abuse, NCPDP recommends the following solutions to assist authorized healthcare providers, including prescribers and pharmacists, in making more informed clinical decisions prior to writing and dispensing medications:

1. Create a comprehensive repository for all PDMP data.
2. Leverage the NCPDP Telecommunication Standard to support real-time reporting within the pharmacy's workflow to a PDMP comprehensive repository.
3. Leverage the NCPDP Telecommunication Standard to support clinical alerts to the pharmacy prior to dispensing.
4. Leverage the NCPDP SCRIPT Standard, including the Medication History transaction, to query PDMP data in real-time within the prescriber's workflow to facilitate appropriate clinical decisions before the medication is prescribed.
5. 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. Adopt a minimum data set and standard transaction format for submission of post dispensing data to the comprehensive repository, to complete the history of the prescription event.
7. Leverage the comprehensive repository to send one standard file to state PDMPs for non-clinical use based on their schedule rather than receiving thousands of separate files.

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.

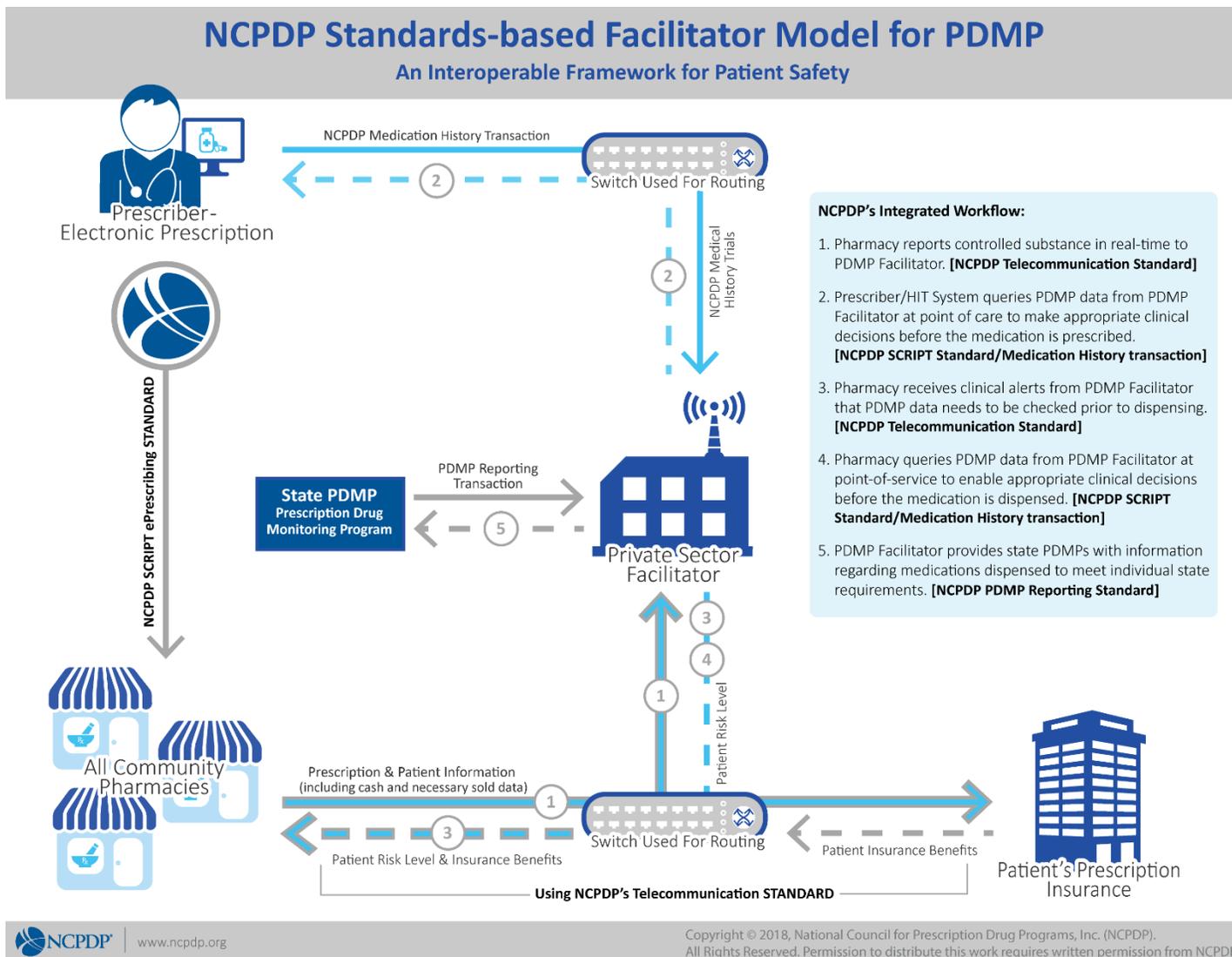


Figure 2. Suggested Flow for PDMP Data

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 utilization 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 is dispensed. [NCPDP SCRIPT Standard/Medication History transaction]
 5. PDMP Facilitator provides state PDMPs with information regarding medications dispensed to meet individual state requirements. [NCPDP PDMP Reporting Standard]

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, comprehensive** approach eliminates data silos and promotes **interoperability**, provides **actionable and timely** information to prescribers and pharmacists using **existing workflows** to facilitate adoption, and **support patient safety** efforts to curb the public health crisis.

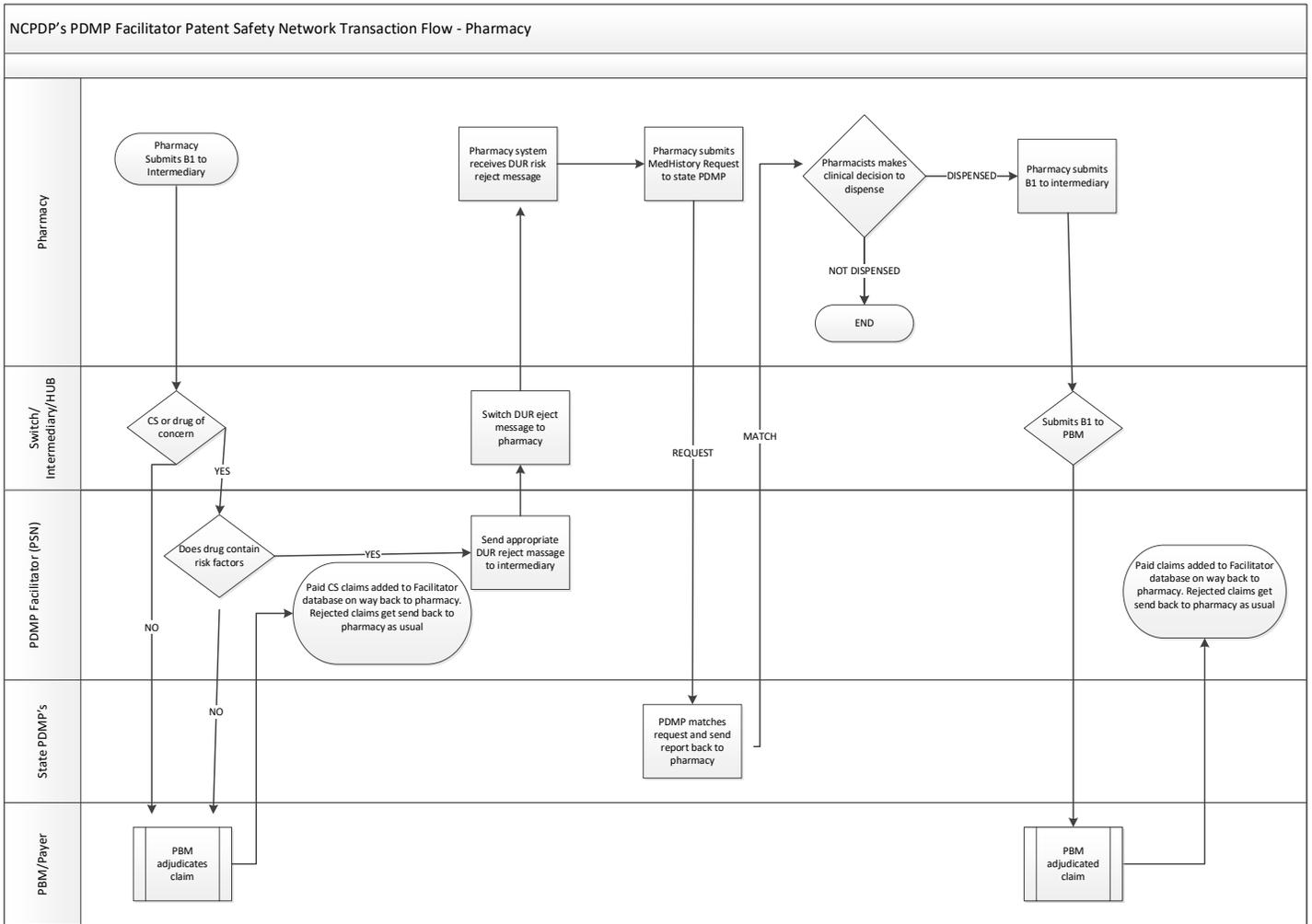


Figure 3. Pharmacy Flow based on NCPDP Telecommunication Standard

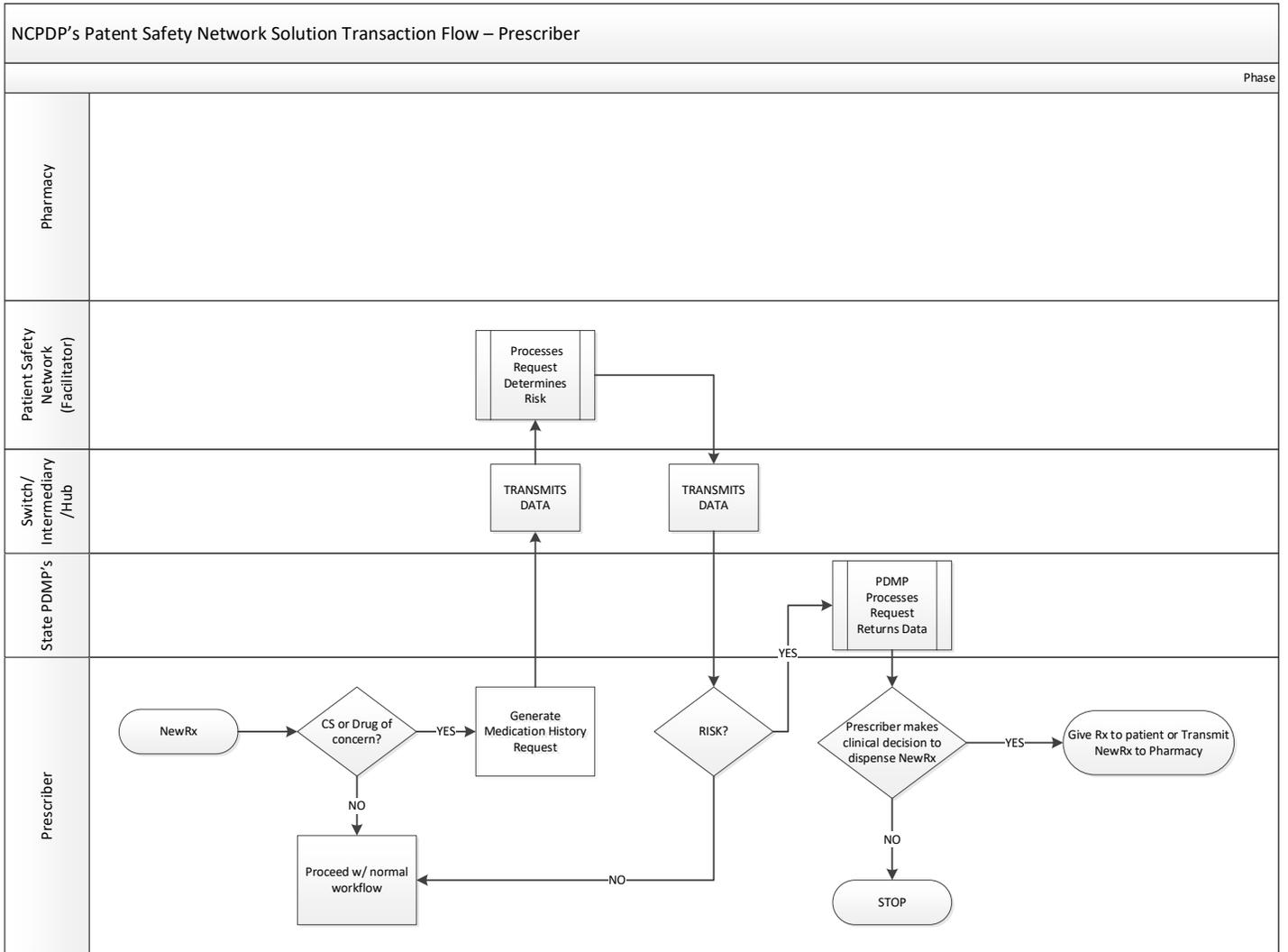


Figure 4. Prescriber Flow based on NCPDP SCRIPT Standard

7. 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.

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.

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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