January 28, 2019

The Honorable Donald W. Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

Dear Dr. Rucker:

Thank you for the opportunity to comment on the draft *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*. Health IT Now (HITN) is a diverse coalition of health care providers, patient advocates, consumers, employers, technology companies and payers who support the adoption and use of health IT to improve health outcomes and to lower costs.

General Comments

HITN supports the sentiment and general direction expressed in the draft report. Generally speaking, we believe private sector entities –such as specialty societies, professional boards, and standards development organizations –are better equipped to make informed decisions about what is best for patients and least burdensome for practitioners than the federal government.

In February of 2018, HITN, the Bipartisan Policy Center, and nearly 50 individuals representing clinicians, patients, hospitals, and technology companies, released a report entitled *The Future Role of Government in Health Information Technology and Digital Health*. The report called for a modern health framework for technology-enabled healthcare that assures consumer protections, reduces burden among users and developers, and accelerates innovation. Many of our comments are reflected in this consensus report.

While many of the general findings of the report are aligned with the draft strategy, we would like to highlight one issue that is not reflected, which is the direct correlation between regulatory requirements on developers and the operational burdens on providers. The early stages of the Meaningful Use (MU) program were highly prescriptive and created implementation challenges for developers, providers, and hospitals alike. We understand the goal of the staged approach to MU was to create a glide path towards a fully implemented and fully realized technology-enabled system, we now know that it has not and, instead, interoperability and usability challenges are leading to unexpected costs and provider burnout.

Anecdotally, we have learned from developers that they were sometimes forced to forgo usability improvements for practitioners to accommodate extensive changes in certification requirements. While we attribute these incidents in part to the rigidity of the certification program, we understand that the patchwork nature of the nascent EHR marketplace posed significant challenges. The downstream effect of

this, however, has been that the healthcare marketplace has moved towards automation, but these technologies have not led to meaningful transformation. To this end, we believe that missing incentives or and requirements for interoperability are at the root of provider frustration, burden, and burnout. We encourage ONC to use this opportunity to study the relationship between certification requirements and provider burden so that we may better understand and assuage the challenges facing them both.

HITN appreciates the recent work ONC has done to move aspects of the certification to private-sector test beds; however, we recognize the burden faced by developers by certification requirements – whether tested through ONC or a private sector body. As called for in our report, we urge ONC to narrow the scope of the certification program to core consumer protections, that way allowing developers flexibility to address provider concerns.

Specific Comments

Clinical Documentation

Evaluation & Management Coding

HITN supports ONC's continued work with CMS to ease clinical documentation burdens. In response to the proposed evaluation and management (E/M) coding and documentation changes in the CY19 Medicare Physician Fee Schedule proposed rule, HITN supported the proposed E/M documentation changes. We provided the following suggestions related to reporting by medical decision-making (MDM) and reporting by time:

Reporting by MDM

- The recordkeeping and electronic transmission abilities of the EHR allow for significant reductions in the amount of data duplication currently done by practitioners. If information is already present in the medical record, practitioners should not be required to duplicate that information for the purposes of billing. The focus on reporting leverages clinical summary collection in reporting, which is already done by the majority of EHR systems in the marketplace and is an accepted part of the workflow for practitioners. The emphasis on the notable items that have –or have not changed– between patient interactions, and the removal of requirements to re-document defined elements, drives practitioners to more fundamentally incorporate their EHR systems into the overall management of their practices, which was the original intention of the HITECH Act.
- We believe that CMS rulemaking should incentivize the use of prior data available to practitioners through interoperable EHRs wherever possible. This is alignment with the interoperability policies laid out in the IPPS rule and is a direct demonstration of the importance of interoperability as well as the business case of data exchange and Health Information Exchanges.
- Unnecessary administrative duplication creates opportunities for cut-and-paste-errors that could omit changes to the patient record that have occurred between visits. This may cause inconsistencies in a patient's medical history, which could pose significant risks an electronically-enabled care coordination settings that rely on the ready availability of accurate information such as Accountable Care Organizations (ACOs).

Reporting by Time

- We believe there is a larger analytical value to allowing practitioners use time as a primary factor in E/M reporting when it is done as a function of the EHR. Time studies have been core to practice management improvement as well as usability in EHR system design. While we encourage flexibility in reporting we believe there should be additional consideration into how the time data

is collected, including through biometric enabled actual time data at the point of care. Further, we believe CMS should allow for the billing practitioner to use time information that has come from prior data accessed through an interoperable EHR.

We were pleased to see the finalization of some of these changes in the final rule, including the elimination of the need to document the medical necessity of a home visit in lieu of an office visit, the expansion/clarification of current policy for history and exam, such that certain data already present in the medical record need not to be re-documented but rather can be reviewed, updated, and signed off on by the billing practitioner, and removal of potentially duplicative requirements for notations in the medical records.

Electronic Prior Authorization

HITN is also a strong supporter of electronic prior authorization (ePA). As noted in the draft strategy, prior authorization requirements are extremely burdensome for providers, but also often directly impact patient care. In fact, approximately two-thirds of prescriptions that are rejected at the pharmacy counter require PA and 36 percent of those will be abandoned.[1] Those abandoned prescriptions contribute to an increase in the chance for worsening conditions, decreased medication adherence, and increased hospital admissions among others, contributing to negative outcomes and increased costs. Providers also report additional burden, spending more time on prior authorizations when using the traditional paper forms, phone or fax submission methods versus when using a true ePA solution.[2]

HITN and members of our Opioid Safety Alliance – an initiative comprising both HITN and non-HITN members including prescribers, dispensers, manufacturers, professional societies and patients that support the increased use of technology to fight opioid misuse, abuse and addiction – encourage the adoption of policies such as section 6002 of the *SUPPORT for Patients and Communities Act* (P.L. 115-271) that provides for the increased use of ePA for covered drugs in the Medicare Part D and MA-PD programs.

We are similarly encouraged by industry's progress in simplifying and digitizing the medical prior authorization process. While this process is certainly burdensome for providers, more alarmingly, the current prior authorization process directly impacts patient care. A 2017 survey of 1,000 physicians found that 92 percent of providers report care delays related to the prior authorization process and the same percentage report that it can have a negative impact on patient care.[3] We encourage ONC to continue to prioritize work with standards development organizations in developing processes and standards related to electronic prior authorization for medical services.

Health IT Usability and the User Experience

As mentioned in our general comments, HITN urges ONC and CMS to consider how burdens placed on health IT vendors directly impact usability issues. Specifically, we recommend that all ONC certification requirements be mapped to provider requirements under the Quality Payment Program (QPP). Subsequently, all government requirements not related to baseline consumer safety issues should be shifted to private sector entities.

While HITN supports the recommendations pertaining to health IT usability and the user experience, many of the recommendations are broad suggestions for health care institutions or health IT developers. We note that many of these suggestions are actions that developers and institutions know that they

[1] https://www.covermymeds.com/main/insights/scorecard/impact/
[2] Ibid.
[3] https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf

"could" or "should" do. In order for this strategy to be successful, the agency should focus on reducing burdens under existing program requirements.

Connectivity creates value in healthcare by empowering patients, practitioners, payers, and innovators with access to information. Interoperability challenges, including instances of information blocking, remain among the most frustrating challenges facing practitioners and patients alike. We strongly ONC should consider unexpected deficits in interoperability to be both a usability and patient safety problem worth of measurement, investigation, and enforcement.

Clinical Workflow

We are pleased that federal agencies have begun to fundamentally build the use of EHRs into quality improvement and reporting programs. However, just because an operation can be done on a computer does not mean that it can be seamlessly integrated into provider workflows. We encourage ONC incorporate provider workflow considerations into future rulemaking to address provider burden as well as adoption reluctance. This is particularly evident when it comes to PDMP checks and the need for healthcare practitioners to check multiple disparate systems outside of the EHR workflow. We discuss this in detail in the Public Health Reporting section below.

User Interface Optimization

The array of EHR products available for practitioners has grown significantly since the passage of the HITECH Act and has evolved to more closely resemble the consumer marketplace of cloud-based software products than the large mainframe-style file systems of the previous decade. This is due, in large part to the consumer demand that products resemble the interfaces that users have become comfortable with. With increased competition in the marketplace there will be more demand for responsive UI design: we encourage ONC to use a very "light" regulatory hand in intervening on design consideration and instead should allow market forces to correct UI issues.

EHR Reporting

HITN appreciates both CMS' and ONC's dedication to fulfilling the vision of the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) by simplifying reporting requirements for providers. Our coalition members have experienced the challenges of eCQM reporting, particularly as Value-Based Payment Arrangements (VBAs) become more common. We believe some of the eCQM reporting challenges can be alleviated through a focus on standardization.

The draft report highlights vendor trade association comments that indicate standardization and data mapping to be looming issues. Lack of standardization leads to interoperability issues including both intentional and inadvertent information blocking. It is important to consider how eCQMs information will be presented to practitioners and extracted by developers. We believe that eCQM burden and weight should be measured in federal programs with a special consideration given to whether or not a consensus-developed standard exists for the measure.

At the start of the MU process, many of the measures were designed to ensure that providers and hospitals were being good stewards of taxpayer dollars and meaningfully using the technology that they had purchased. EHR adoption is now nearly ubiquitous and it is a significant minority of practitioners that are only passively using the EHR systems that they have purchased or licensed. We believe this indicates a need to shift focus more holistically towards outcome-oriented reporting measures and that ONC should start the process of evaluating and sunsetting eCQMs that are administrative or process-oriented.

Public Health Reporting

Prescription Drug Monitoring Programs (PDMPs)

One of the core priorities of HITN's Opioid Safety Alliance (OSA) is to see the enactment of a Prescription Safety Alert System (RxSAS), based on the Standards-based Facilitator Model for PDMPs. This concept is further explained in a detailed white paper authored by the National Council for Prescription Drug Programs (NCPDP), titled *NCPDP Standards-based Facilitator Model for PDMP*. The white paper is attached for further explanation.

As noted in the draft strategy the "insufficient interoperability between state prescription drug monitoring programs (PDMPs) and EHRs" creates barriers and increased burden for providers in the Public Health Reporting space. This concept, also mentioned in the Draft Trusted Exchange Framework, highlights that important data, such as that which is included in a state PDMP, does reside outside of both EHR and pharmacy dispensing systems (PDS) across the country, and a lack of integrated access through PDS, EHR, and HIE creates usability issues for providers and pharmacists, ultimately delaying progress in getting clinicians complete and accurate information in order to make the best clinical decision. As of November 2018, there is no integrated access to PDMP data through these tools in eight states and territories with state-wide PDMPs, with eighteen states offering access via HIE, EHR and PDS.[4] This is one of several challenges seen in the current system of PDMPs that a RxSAS would address including: interoperability among states; presenting data within workflow; and incorporating real-time data. The information needed to address these challenges is readily available and already flowing between the pharmacies and switches/payers every day.

The RxSAS would work by utilizing existing industry-proven electronic healthcare communication standards – Telecommunication and SCRIPT. By utilizing these transactions that are already available, secure and widely-used by prescribers and dispensers across the country, the RxSAS would be able to provide clinicians with needed information at the points of prescribing and dispensing while simultaneously alerting them of risk involved with the prescription and maintaining the autonomy of state PDMPs that are set up in accordance with each state's laws and regulations. The RxSAS would have the ability to enhance the information housed within the state PDMPs, it would not replace them.

As HITN and OSA noted in comments to CMS prior to implementing measures that would increase the use of PDMPs without addressing the current challenges, we encourage HHS to implement a RxSAS to improve the information presented to clinicians at the points of prescribing and dispensing as one method to combat the ongoing opioid misuse epidemic.

HITN and OSA believe that electronic prescribing of controlled substances (EPCS) is a critical tool, reducing burden on prescribers and pharmacists, decreasing fraudulent prescriptions and promoting technology to seamlessly allow a clinician to see a patient's medication history and other pertinent information prior to prescribing. We applauded the inclusion of Section 2003 of the SUPPORT Act requiring EPCS in Medicare Part D and would like to see continued increased adoption of the technology nationwide.

While EPCS is an effective tool, we remain concerned with the Public Health Reporting Strategy 1 as stated as it would require increased functionality from the PDMPs to be thoroughly effective. In the interest of reducing burden, PDMPs need to severely improve functionality through interoperability, integration and improved timeliness of the data. Improvement in just one of these areas, in this case,

[4] http://www.pdmpassist.org/pdf/PDMP_Integration_Status_20181128.pdf

integration, is a step in the right direction but the other two areas need to be addressed as well to provide clinicians with real-time, actionable information on a patient's controlled substance medication and prescription history. EPCS and a RxSAS would fit seamlessly together in this context to provide the needed data to clinicians when it would be the most powerful and useful.

Harmonizing Requirements Across Programs

The draft report highlights the challenges created by a lack of automated, standards-based public health and health care reporting requirements across federal programs. We implore the ONC to not only study the provider burdens this has created in federal programs but also the downstream effects that the existence or absence of standards may have on state reporting requirements.

Recently, several HITN member organizations participated in the Congenital Heart Disease Stakeholder Symposium hosted by the American College of Cardiology. The issue of public health reporting was raised as a frequent burden for practitioners and public health officials. A primary complaint was that EHR systems had been designed to comply with public health reporting in the Medicare program, which did little for younger patients, particularly pertaining to maternal and child health. Many hospitals have developed homegrown solutions fulfill electronic reporting requirements, which while they work for a single institution, have all but eliminated the opportunity for regional or national information exchange.

Standards development organizations have invested significant time and resources into developing standards for public health reporting through a consensus process that included developers, payers, state departments of health, practitioners, and academics. We strongly urge ONC to consider the continuum of those impacted by public health reporting when identifying sources of provider burden and making recommendations moving forward.

42 CFR Part 2

We commend ONC for mentioning the outdated 42 CFR Part 2 (Part 2) regulation as impacting provider burden; however, again, HITN is extremely concerned that the regulations are a significant threat to patient safety.

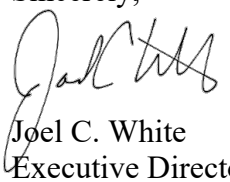
While well-intended, the real-world impact of Part 2 is that it isolates substance use disorder treatment records from the rest of a patient's medical history. Not only does this continue to stigmatize and separate substance use disorders from being considered a clinical issue, it creates very real patient safety concerns when treating providers do not have knowledge that a patient has a substance use disorder and prescribes an opioid pain medication. Part 2 prevents patients from receiving safe, effective, high-quality and coordinated care.

HITN supports aligning Part 2 consent requirements with HIPAA to allow for the transmission of patient records without additional consent for the purposes of treatment, payment, and health care operations. While additional guidance from HHS, as called for in the draft strategy, would be helpful – we believe the issue will only be fully addressed through an amendment to rather than clarification of existing regulation.

Conclusion

HITN appreciates the opportunity to comment on the draft strategy and we look forward to continuing to work with the agency to reduce provider burden and improve patient care by fully leveraging technology in health care.

Sincerely,



Joel C. White
Executive Director

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.

NCPDP Standards-based Facilitator Model for PDMP
An Interoperable Framework for Patient Safety

Version10

Published by:
National Council for Prescription Drug Programs, Inc.

Publication History:
Version 10 2019

Table of Contents

Disclaimer

While all information in this document is believed to be correct at the time of writing, this document is for educational purposes only and does not purport to provide legal advice. If you require legal advice, you should consult with an attorney. The information provided here is for reference use only and does not constitute the rendering of legal, financial, or other professional advice or recommendations by NCPDP.

The existence of a link or organizational reference in any of the following materials should not be assumed as an endorsement by NCPDP.

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

This document is for Education and Awareness Use Only.

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-time[2], 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.

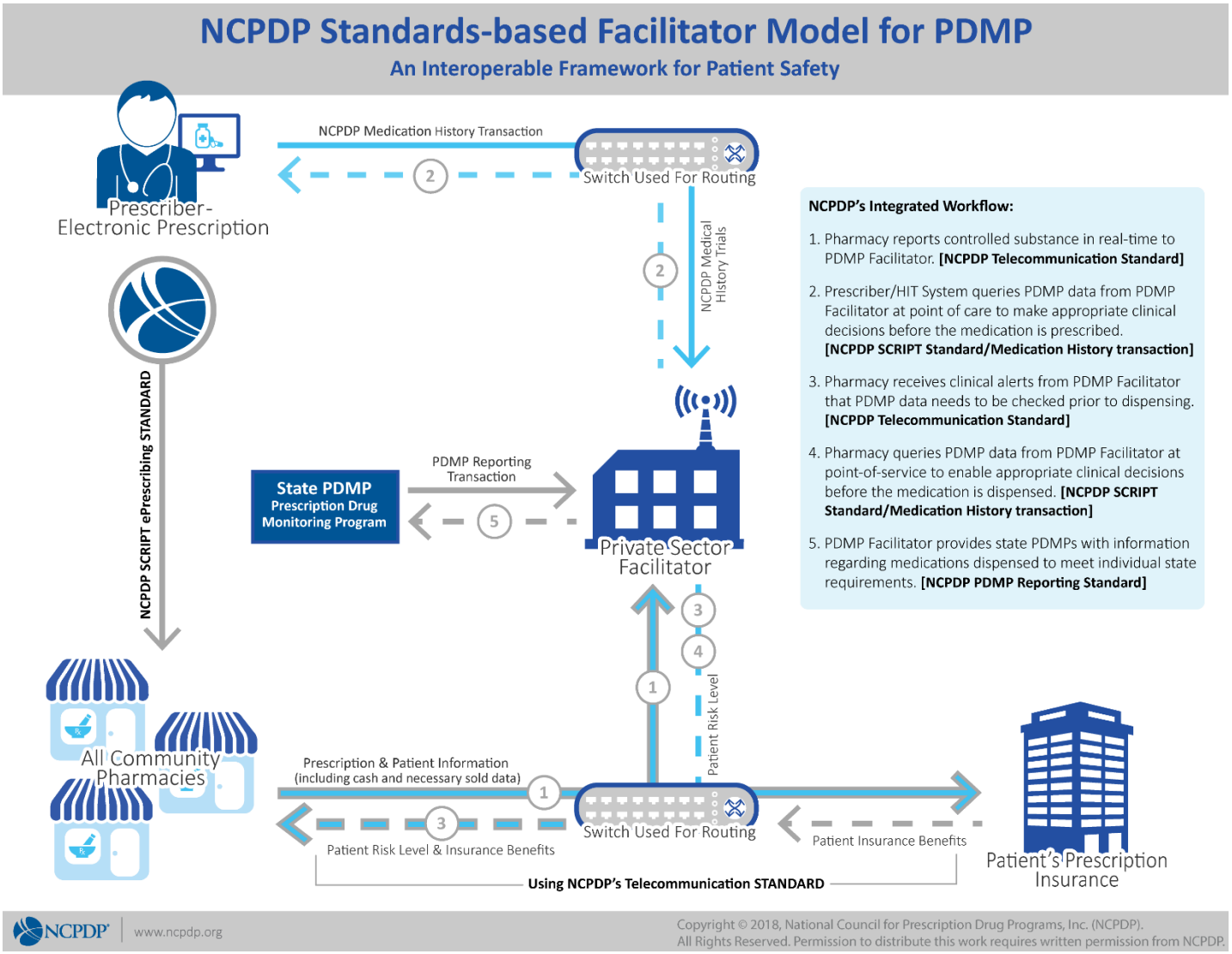


Figure 1. Suggested Flow for PDMP Data

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.

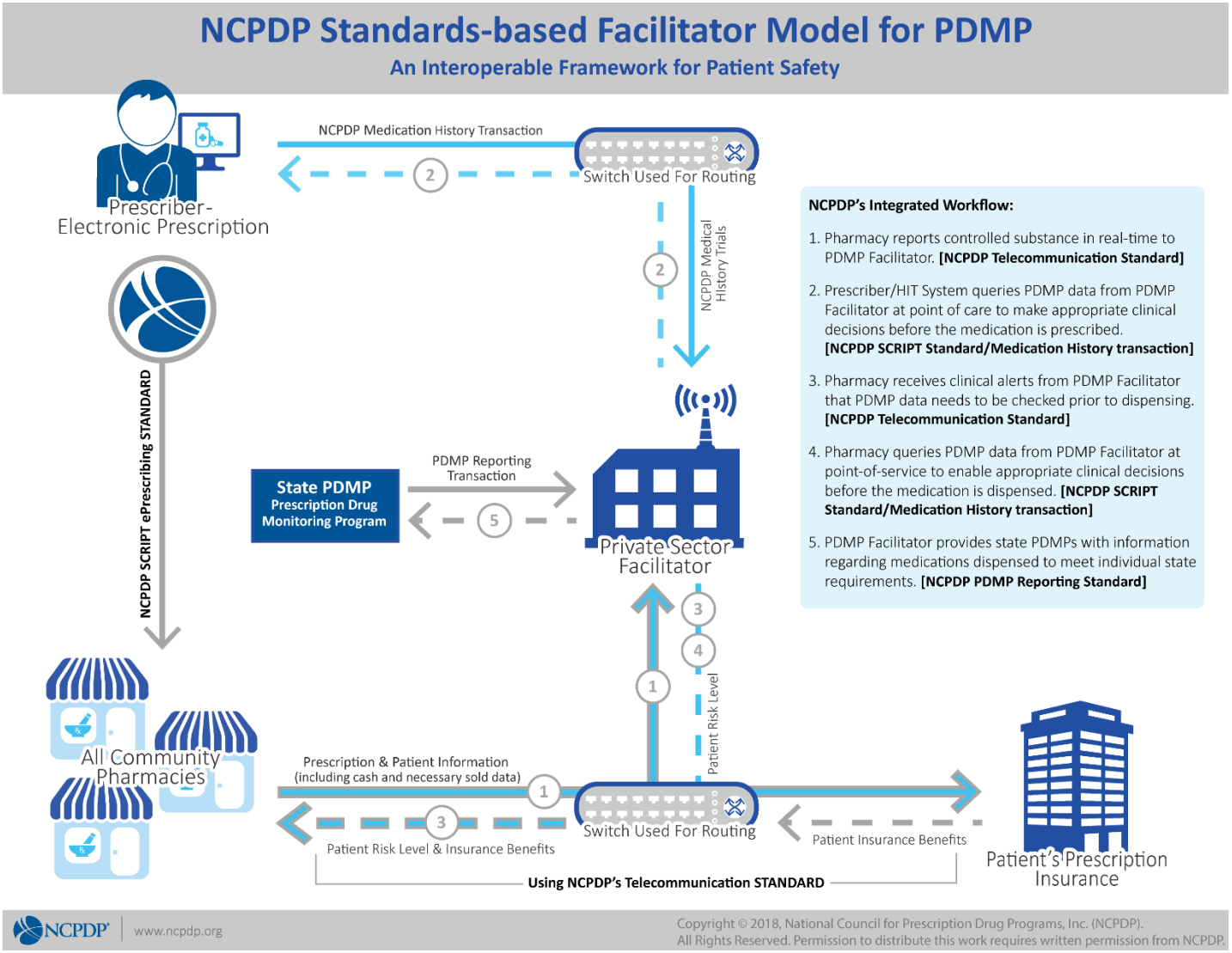


Figure 2. Suggested Flow for PDMP Data

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.

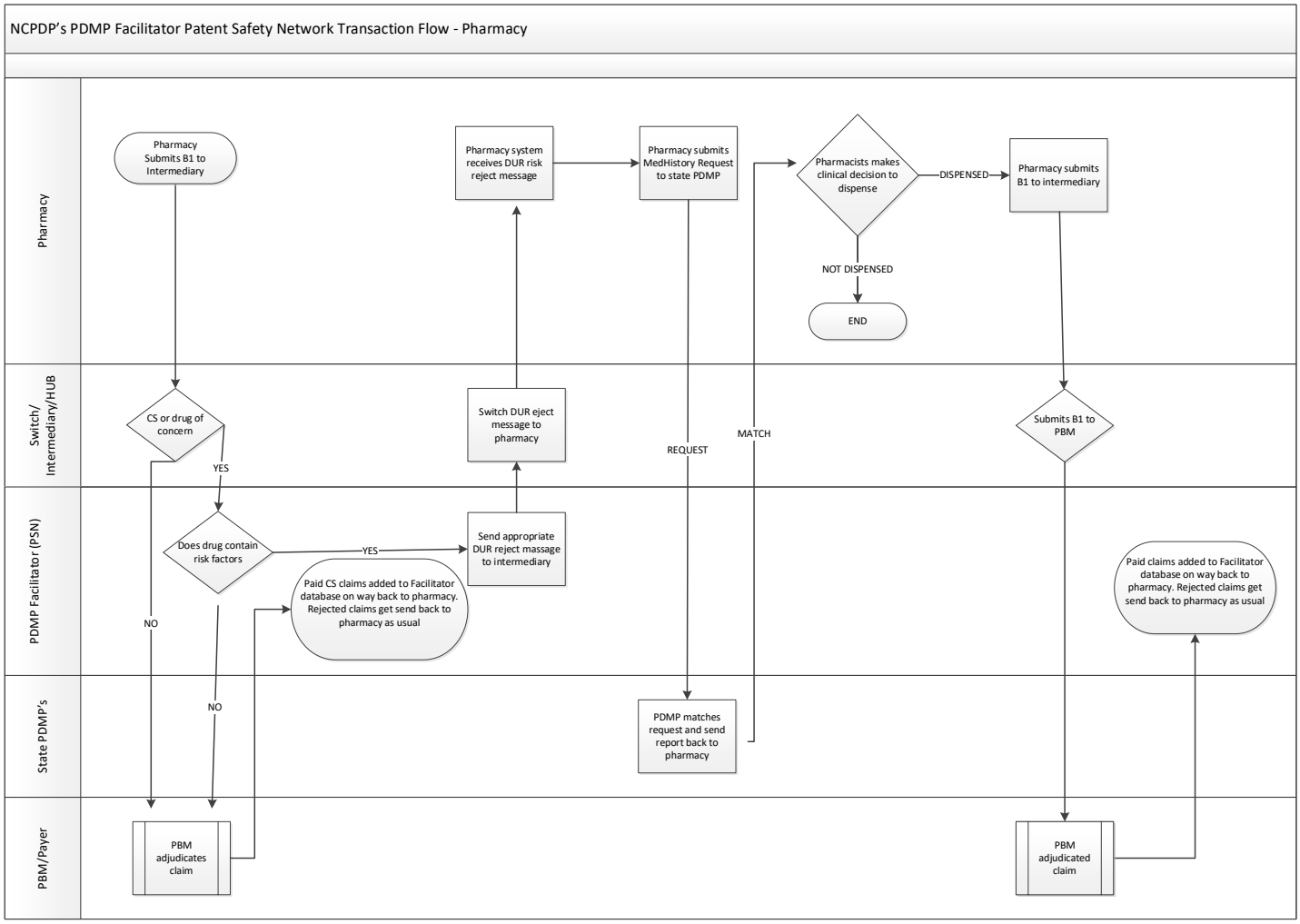


Figure 3. Pharmacy Flow based on NCPDP Telecommunication Standard

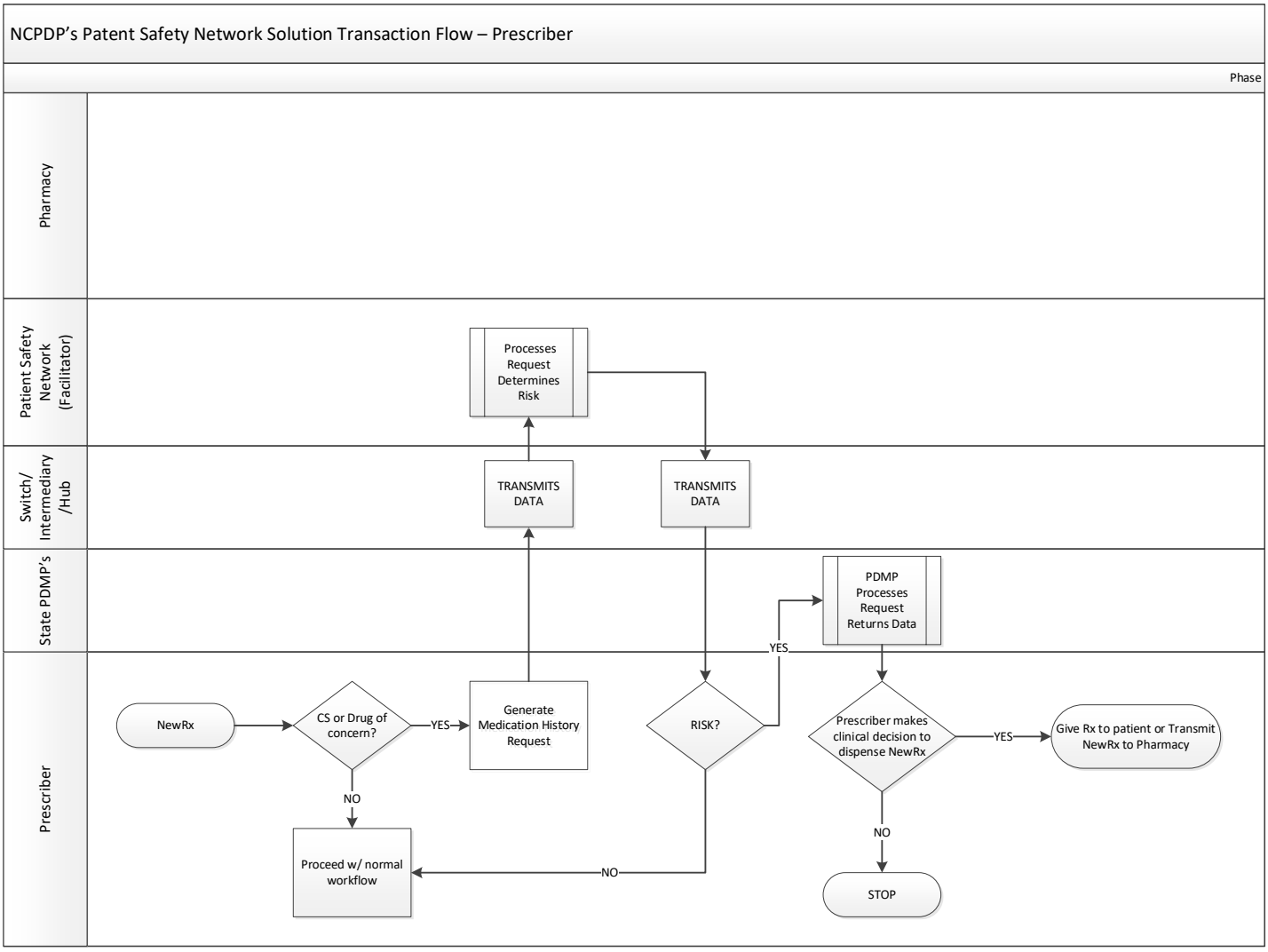


Figure 4. Prescriber Flow based on NCPDP SCRIPT Standard

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.

National Council for Prescription Drug Programs

9240 East Raintree Drive, Scottsdale, AZ 85260
phone: 480.477.1000 | fax: 480.767.1042
ncpdp@ncpdp.org | www.ncpdp.org

NCPDP®