NCPDP Recommendations for Improving Prescription Drug Monitoring Programs (PDMP)

Version 1.0

March 2013

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.

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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.

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. 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, will 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.

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.

As of February 2013, 49 states, the District of Columbia, and one U.S. Territory have enacted legislation that establishes a PDMP. Of those, 43 states have operational PDMPs while 6 other states, the District of Columbia, and Guam have PDMPs that are not yet operational. Illustration 1 below displays the status of the PDMPs across the United States. [1]

Illustration 1
Status of Prescription Drug Monitoring Programs
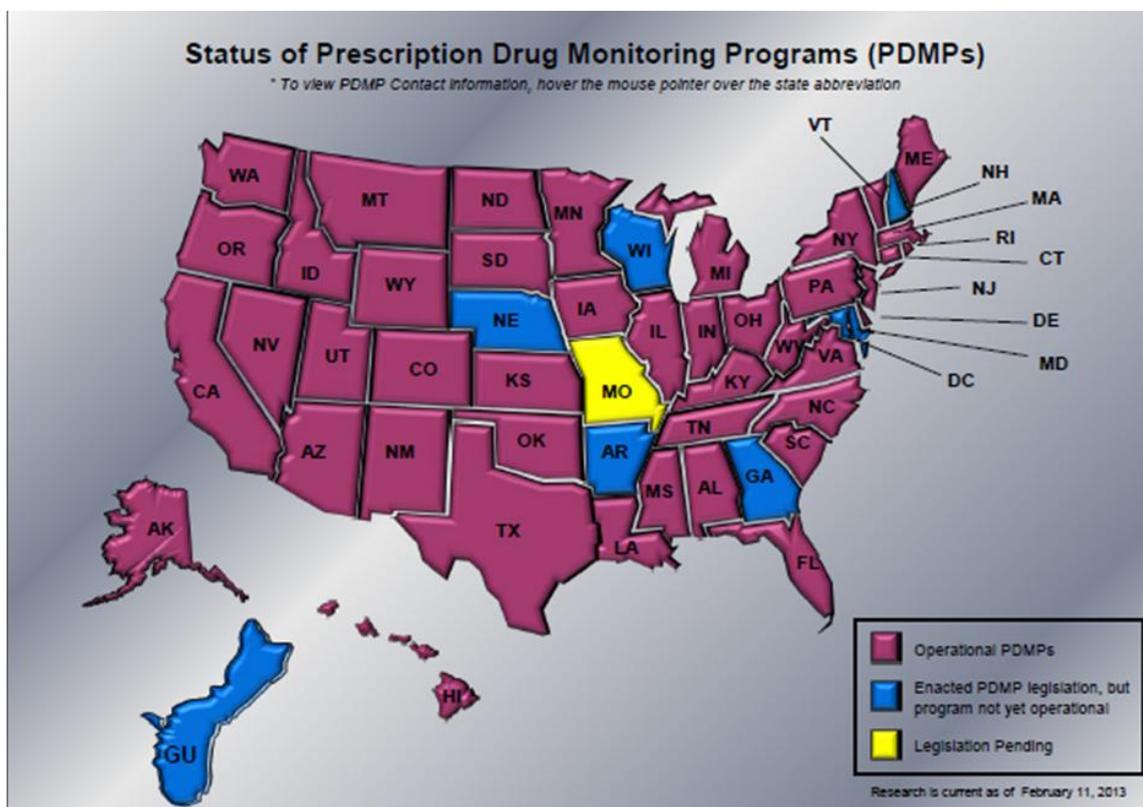
PDMPs are established and managed at the state level and can vary considerably from state-to-state. Some areas of variation include:

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[1] PDMP Training & Technical Assistance Center, Brandeis University. Available at
http://www.pdmpassist.org/pdf/pmpprogramstatus2013.pdf

- **Organizational structure.** Each state determines which agency houses the PDMP and how it is operated.

- **Substances monitored**. PDMPs monitor 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.[2]

- **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 and providers.

- **Timeliness of data.** Timeliness of PDMP reporting varies by state—anywhere from monthly to real-time.

- **Interoperability.** State PDMPs vary widely 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 (PMIX) architecture. The infrastructure of the PMIX program is based on the National Information Exchange Model (NIEM), which is a data sharing partnership among all levels of government as well as the private sector.[3] The PMIX Architecture utilizes "end-to-end encryption" so that no protected health information can be stored at the hub. The encrypted data leaves the sending state PDMP system and cannot be decrypted until it reaches the receiving state PDMP system.

- **Reporting Formats.** State PDMPs are currently using different versions of the American Society for Automation in Pharmacy (ASAP) data transmission formats.

- **Multiple Work Groups.** The Office of the National Coordinator for Health Information Technology (ONC) has various work groups determining best practices for standardizing the use of PDMP programs.[4]

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[2] 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
[3] Alliance of States with Prescription Monitoring Programs, *Prescription Monitoring Information Exchange (PMIX), is* available at http://pmpalliance.org/
[4] United States Department of Health and Human Services (HHS), *More doctors adopting EHRs to improve patient care and safety,* available at http://www.hhs.gov/news/press/2012pres/12/20121212b.html

3. 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."*[5]

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.

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.

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[5] *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 1 4, 2013 *http://www.medscape.org/viewarticle/571099*

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.[6]

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.

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

4. 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.

In addition to a pharmacist's and prescriber's perspective, 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.

4.1 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.

4.1.1 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.

4.1.2 REPORTING/DATA SUBMISSION

- Pharmacy has varying requirements by state for submitting PDMP data. The result is supporting multiple transaction layouts that increase administrative costs,
- 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.
- Frequency of data submission varies from state to state:
  - o Near real-time-1 state
  - o Daily-2 states
  - o Weekly-22 states
  - o Bi-weekly-11 states
  - o Monthly-6 states

- o Every 6 weeks-1 state
- 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):
  - o Secure FTP over SSH
  - o Encrypted File with OpenPGP via FTP
  - o SSL Website
  - o Physical Media (Tape, Diskette, CD, DVD)
  - o Universal Claim Form submission

4.1.3 ACCESSIBILITY
- Internal security firewalls can prevent access to databases.
- Gaining access to state PDMPs varies widely from state to state.
- Access is unavailable to those participating in the dispensing and clinical processes.
- Pharmacy does not have access to PDMP data within their workflow and must interrupt workflow to access an external database.
- Lack of 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.

4.1.4 DATA INTEGRITY
- Gaps in data (e.g. not all Indian Health Services, state specific programs, and other providers and locations that are administering and dispensing medications are included.)
- Missing, incomplete and/or invalid data due to lag in reporting and validation leads to incomplete records.

4.2 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:

4.2.1 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.

4.2.2 REPORTING
- Lack of completeness and filtering of data
- Data duplication
- Lack of timeliness in reporting the data makes it difficult for prescribers to make clinical decisions.

- Data and Format requirements vary by state making it difficult for prescriber vendors consuming the data.

4.2.3 ACCESSIBILITY

- Medication history is not shared real-time on a national level.
- Prescribers are notified of doctor shopping issues outside of their workflow, i.e. email.
- State specific regulations, i.e. California not allowing prescriber access to medication history.

4.2.4 DATA INTEGRITY

- Gaps in data (e.g. not all Indian Health Services, state specific programs, and other providers and locations that are administering and dispensing medications are included.)
- Missing, incomplete and/or invalid data due to lag in reporting and validation leads to incomplete records.

5. IMPROVEMENT RECOMMENDATIONS

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

5.1 STANDARDIZATION

- Require a minimum set of data elements to be submitted by dispensers systems to the PDMP to be adopted by all states.
- Require one standard transaction format for reporting PDMP, one standard transaction for inquiry and one standard transaction for response.
- Enable accurate reporting of prescriber NPI and DEA numbers.
- Require accurate reporting of all reportable ingredients including compound ingredients.
- Create and adopt a nationally recognized clinical risk score to assist prescribers and dispensers with clinical decisions.

5.2 REAL-TIME REPORTING

- Provide timely access to data as appropriate to all impacted parties for real-time decision making.
- Reduce reporting delays by allowing PDMP type rejections to be corrected at point of adjudication.
- Improve patient quality of care with clinical decision alerts presented at the time of prescription writing or dispensing.
- 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.)
- Eliminate the need for zero reports (no schedules filled).

5.3 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.

6. 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. Adopt a minimum data set and standard transaction format across all states for submission of prescription data to PDMPs.
2. Adopt a minimum data set and standard transaction format across all states for submission of dispensing data to PDMPs.
3. 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.
4. 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 prescribed.
5. Leverage the NCPDP Telecommunication Standard to support real-time reporting within the pharmacy's workflow to PDMP state repositories.
6. Leverage the NCPDP Telecommunication Standard to support clinical alerts to the pharmacy prior to dispensing.
7. Leverage the NCPDP SCRIPT Standard RxFill transaction to report to the prescriber and/or PDMP the date the medication was delivered or shipped to the patient.
8. Enable a nationally recognized process to exchange data between PDMP databases.

7. FLOW CHARTS

Transaction Flow Sequence
(Pharmacy)
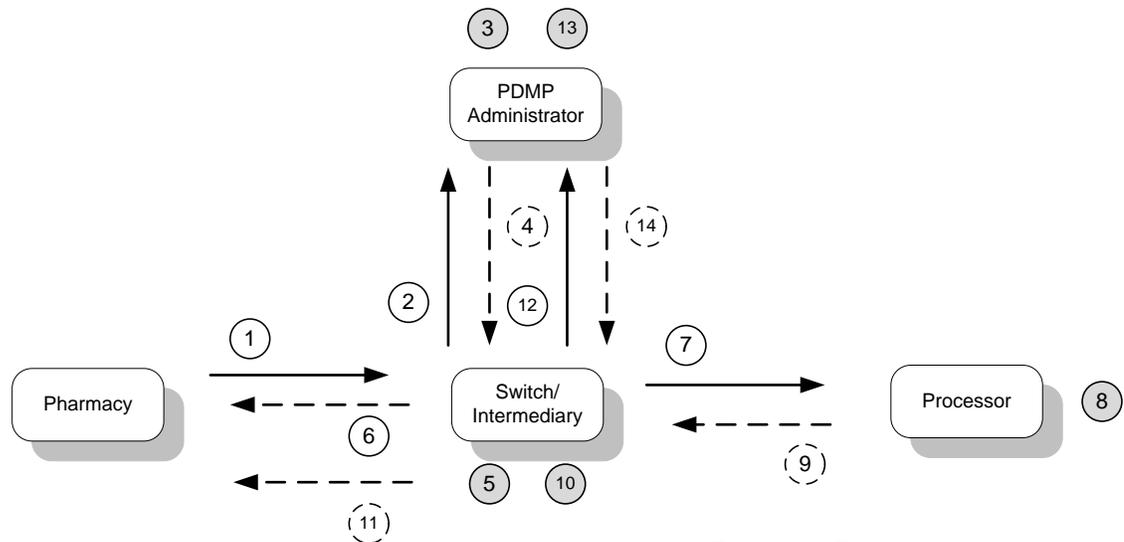
Transaction Flow
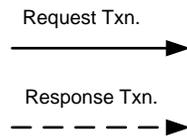
1 – Billing Request to Intermediary
2 – Billing Request Subset to PDMP
3 – Pre-Processor Editing
4 – Response to Intermediary
5 – Interpretation of Response
6 – Pre-Processor Reject Response
7 – Billing Request to Processor
8 – Adjudication of Request
9 – Response to Intermediary
10 – Interpretation of Response
11 – Response to Pharmacy
12 – Data Delivery Request to PDMP
13 – Accept Response
14 – Data Delivery Acknowledgement

Transaction Flow Sequence
(Prescriber)
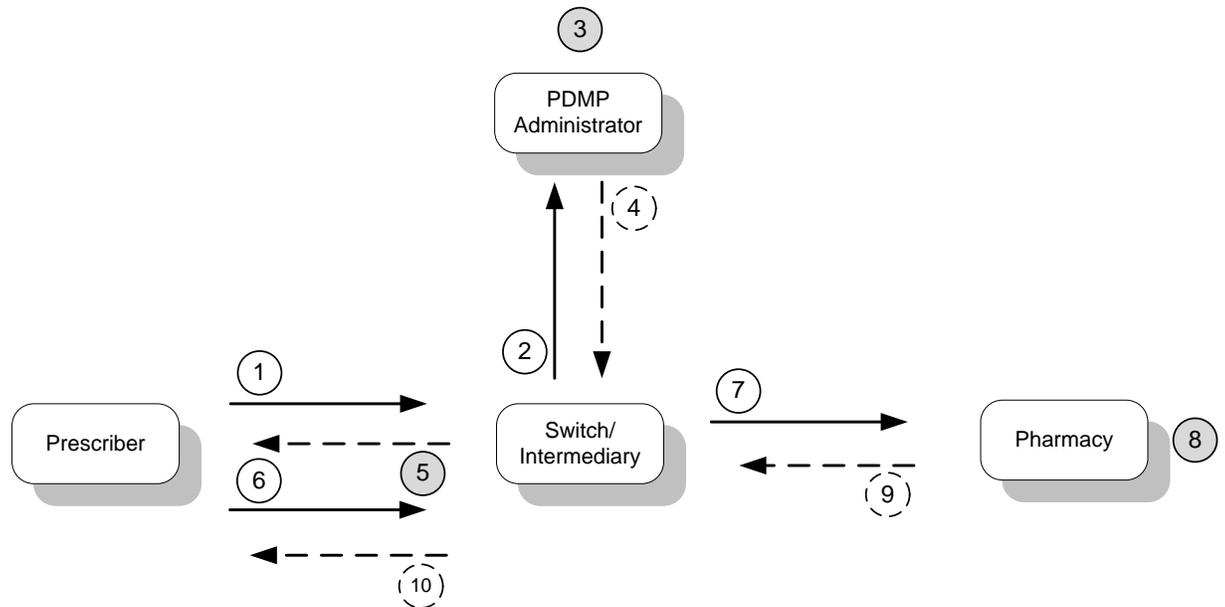
Transaction Flow
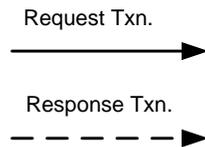
1 – Medication History to Intermediary
2 – Medication History to PDMP
3 – Medication History Processing
4 – Response to Intermediary
5 – Response to prescriber
6 – eRx to Switch/Intermediary
7 – eRx to Pharmacy
8 – eRx Receipt
9 – Acknowledgement to Intermediary
10 – Acknowledgement to Prescriber

8. APPENDIX A. HISTORY OF CHANGES

9. APPENDIX B. LIST OF PARTICIPANTS

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Anne Kling	MITRE
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Charlie Oltman	Target Corporation-Task Group Leader
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