

Prescription Drug Monitoring Program & HIT Integration Initiative

Use Case

3/25/2014

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

Table of Contents

1.0 Preface and Introduction	5
2.0 Initiative Overview	5
2.1 Initiative Challenge Statement.....	6
3.0 Use Case Scope	6
3.1 In Scope.....	7
3.2 Out of Scope.....	7
3.3 Communities of Interest (Stakeholders).....	7
4.0 Value Statement	9
5.0 Use Case Assumptions	9
6.0 Pre-Conditions.....	10
7.0 Post Conditions	10
8.0 Actors and Roles	10
9.0 Use Case Diagram	11
10A.0 Scenario #1: HIT to PDMP directly.....	12
10A.1 User Stories.....	12
10A.2 Activity Diagram.....	13
10A.2.1 Base Flow	13
10A.3 Functional Requirements.....	14
10A.3.1 Information Interchange Requirements.....	14
10A.3.2 System Requirements.....	14
10A.4 Sequence Diagram.....	15
10B.0 Scenario #2: HIT to Hub	15
10B.1 User Stories.....	15
10B.2 Activity Diagram.....	17
10B.2.1 Base Flow	17
10B.3 Functional Requirements.....	18
10B.3.1 Information Interchange Requirements.....	18
10B.3.2 System Requirements.....	18
10B.4 Sequence Diagram	19
10C.0 Scenario #3: HIT to HIE/Pharmacy Intermediary.....	20

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

10C.1. User Stories	20
10C.2 Activity Diagram.....	21
10C.2.1 Base Flow	21
10C.3 Functional Requirements.....	22
10C.3.1 Information Interchange Requirements	22
10C.3.2 System Requirements	22
10C.4 Sequence Diagram	23
11.0 Dataset Requirements	24
12.0 Risks, Issues and Obstacles	30
Appendices.....	31
Appendix A: Privacy Considerations	31
Appendix B: Previous Work Efforts.....	33
Appendix C: References	33

List of Figures:

Figure 1: Use Case Diagram	11
Figure 2: Scenario #1, User Story #1	12
Figure 3: Scenario #1, User Story #2	12
Figure 4: Scenario #1, Activity Diagram	13
Figure 5: Scenario #1, Sequence Diagram	15
Figure 6: Scenario #2, User Story #1	16
Figure 7: Scenario #2, User Story #2	16
Figure 8: Scenario #2, Activity Diagram	17
Figure 9: Scenario #2, Sequence Diagram	19
Figure 10: Scenario #3, User Story #1	20
Figure 11: Scenario #3, User Story #2	20
Figure 12: Activity Diagram Scenario #3	21
Figure 13: Scenario #3, Sequence Diagram	24

List of Tables:

Table 1: Communities of Interest	9
Table 2: Actors and Roles.....	11
Table 3: Scenario #1, Base Flow	14
Table 4: Scenario #1, Information Interchange Requirements.....	14
Table 5: Scenario #1, System Requirements.....	14

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

Table 6: Scenario #2, Base Flow	18
Table 7: Scenario #2, Information Interchange Requirements.....	18
Table 8: Scenario #2, System Requirements.....	19
Table 9: Scenario #3, Base Flow.....	22
Table 10: Scenario #3, Information Interchange Requirements.....	22
Table 11: Scenario #3, System Requirements.....	23
Table 12: General Request Data Requirements.....	24
Table 13: Authorized User Request Data Requirements	25
Table 14: Patient Request Data Requirements.....	25
Table 15: General Response Data Requirements	26
Table 16: Patient Response Data Requirements	27
Table 17: Prescription Response Data Requirements.....	28
Table 18: Prescriber Response Data Requirements.....	28
Table 19: Dispenser Response Data Requirements	29

Use Case Development and Functional Requirements for Interoperability PDMP & Health IT Integration Use Case

1.0 Preface and Introduction

To fully realize the benefits of health IT, the Office of the National Coordinator for Health Information Technology (ONC), as part of the Standards and Interoperability (S&I) Framework is developing Use Cases that define the interoperability requirements for high priority health care data exchange; maximize efficiency, encourage rapid learning, and protect patients' privacy in an interoperable environment. These Use Cases address the requirements of a broad range of Communities of Interests including: patients, their significant others and family members, providers, payers, vendors, standards organizations, public health organizations, and Federal agencies.

These Use Cases describe:

- The operational context for the data exchange
- The stakeholders with an interest in the Use Case
- The information flows that must be supported by the data exchange
- The types of data and their specifications required in the data exchange

The Use Case is the foundation for identifying and specifying the standards required to support the data exchange and developing reference implementations and tools to ensure consistent and reliable adoption of the data exchange standards.

2.0 Initiative Overview

Prescription drug misuse and overdose is one of the fastest growing health epidemics in the United States. One of the most promising clinical tools to address prescription drug abuse are prescription drug monitoring programs (PDMPs). PDMPs are state-run electronic databases – functioning in 48 U.S. states and territories – that track the prescribing and dispensing of controlled prescription drugs to patients.

Information within PDMPs is intended to enhance health care professionals' (e.g. physicians, pharmacists, dispensers, delegated authorities with legal authorization) understanding of their patients' controlled substance history. While health care professionals see PDMPs as a valuable tool, they often do not use PDMPs because they are “stand alone” systems which are cumbersome and time consuming to access. When available at the point of care and point of dispensing, PDMP information can help health care professionals discern between patients who may need a controlled substance for legitimate medical treatment and those who may be seeking to misuse prescription drugs. It also provides an opportunity to intervene if there are signs of misuse and abuse. In some states health care professionals are required to check the PDMP prior to dispensing controlled substances. This underscores the need for PDMPs to share information with health IT systems in ambulatory and acute care settings.

Currently, many health care professionals must either interrupt their workflow and log on to a separate system to access the PDMP, or write and dispense prescriptions without consulting the PDMP- potentially leaving health care professionals without the information needed to make important clinical decisions. One way to improve and encourage PDMP access is to reduce the number of steps it takes to

Use Case Development and Functional Requirements for Interoperability PDMP & Health IT Integration Use Case

access the PDMP. Health IT systems can accomplish this by querying PDMPs for prescription information and presenting this information to health care professionals when they access a patient's health record.

2.1 Initiative Challenge Statement

While there are data exchange standards in place to share information between individual state PDMPs (also called PMPs) and standards to exchange information between Health IT Systems (eg. EHR, Pharmacy), there are no widely adopted standards for the flow of data from a PDMP to a Health IT System. As PDMP systems have evolved outside the health IT ecosystem, significant barriers to interoperability have resulted. One of the current technical barriers to interoperability is the lack of standard methods to exchange and integrate the prescription drug data available in PDMPs into health IT systems. There are a lack of common technical standards and vocabularies to enable PDMPs to share computable information with the health IT system that providers can use to support clinical decision-making.

To achieve interoperability, consistent and standardized electronic methods need to be established to enable seamless and secure data transmission between PDMPs and health IT systems.

3.0 Use Case Scope

It is understood that there are various workflows that could take place when a Healthcare Professional queries a PDMP and the specific processes may vary depending on the type of user.

A Healthcare Professional may need to obtain patient history of controlled substances dispensed from a PDMP for a Person of Interest. To do so, the Healthcare Professional may need to authenticate to his/her specific Health IT system. It is also understood that an adjudication process may take place between the Healthcare Professional's Health IT system and the PDMP to filter which prescriptions belong to the intended patient. At the end of the adjudication process, the Healthcare Professional's receiving system is hosting a set of prescription records and renders the records. After receiving the query response, the Healthcare Professional could make an informed decision of whether or not to prescribe/dispense the medication or modify the treatment based on the information received.

A Health IT system (EHR or Pharmacy IT system) can be used to seek out information stored in a PDMP regarding medications dispensed to patients. This Use Case considers 3 possible workflows:

1. HIT to In-State PDMP directly
2. HIT to Hub to PDMP
3. HIT to HIE/Pharmacy Intermediary to PDMP

For the purposes of this use case, we will be focusing on the transactions originating from the HIT to the next end point, which would be the PDMP, Hub, or HIE/Pharmacy Intermediary

Use Case Development and Functional Requirements for Interoperability PDMP & Health IT Integration Use Case

3.1 In Scope

1. Connecting PDMPs to Health IT systems using existing standards; (technical mechanism for actual exchange of data)*
2. If standards do not exist, identifying the gap in the current standards and working with the Standards Organizations (including Standards Development Organizations) to address the gaps* (Refers to harmonization activity)
3. Improving effective and efficient access to PDMP data by Healthcare Professionals*
4. Health IT system has ability to generate a query and receive a response from the PDMP system
 - a. Healthcare Professional querying additional state PDMP systems through their state's existing interstate data exchange infrastructure (i.e. hub)
5. Define standard set of data elements used to submit queries each time
6. Define system requirements for Healthcare Professionals to be able to access patient information already stored in a PDMP
 - a. Accessing a PDMP through a Health IT system (i.e. EHR system) instead of another portal
 - b. Note: The selection of a security mechanism will be defined during harmonization
7. Define system requirements that allow applications to access data in a consistent manner across the local Health IT system
8. Method of extraction

*These items have been leveraged from the Charter

3.2 Out of Scope

1. Defining the trigger event for how the PDMP is queried or initiated by the user (e.g., hyperlink while ordering, pressing a button, automatic trigger/ risk trigger etc.)*
2. Addressing delegation of rights to individuals not legally authorized to prescribe medications (this is an implementation specific decision and may vary by implementation and pilot sites)*
3. Third party access - (this is an implementation specific decision and may vary by implementation, pilot sites and state statues and law)*
4. Reporting patient prescription information from dispensers to state PDMP
5. Policy-based decisions on how PDMPs are managed, accessed, and updated that vary from state to state
6. Timeliness of PDMP: Currency of Data
7. Storing query response from PDMP within the Health IT system
8. Health IT system's structure of display for the query response
9. Unsolicited reporting (PDMP pushing information out to a variety of users)

* These items have been leveraged from the Charter

3.3 Communities of Interest (Stakeholders)

Member of Communities of Interests	Working Definition
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**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

Member of Communities of Interests	Working Definition
Healthcare Professionals	A medical practitioner or provider of care (or someone legally authorized to act on their behalf by relevant state laws, rules or regulations) who has legal authorization to access prescription drug data for patients at the point of care to make informed clinical decisions and appropriate treatment recommendations. This may include: Prescribers, dispensers, pharmacists, nurses, etc.
Patients and patient advocates	Healthcare consumers who are recipients of health care services and products.
EHR/EMR vendors	Vendors which provide specific EHR/EMR solutions to providers such as software applications and software services. These suppliers may include developers, providers, resellers, integrators, operators, and others who may provide these or similar capabilities.
State HIEs	Health Information Exchange (HIE) is defined as the mobilization of healthcare information electronically across organizations within a region, community or hospital system.
Local, State, Federal Government	Organizations within the federal and/or state governments that deliver, regulate, or provide funding for health, healthcare and clinical or biomedical research. This also includes organizations within the federal and/or state governments that disseminate clinical guidance.
Standards Organizations	Organizations whose purpose is to define, harmonize and integrate standards that will meet clinical and business needs for sharing information among organizations and for system interoperability.
Healthcare Payers	A third-party entity that establishes indications and limitations of coverage for payments or underwrites coverage for healthcare expense.
Trade Associations	An association of people or companies in a particular business or trade, organized to promote their common interests.
Professional Associations	A body of persons engaged in the same profession, formed usually to control entry into the profession, maintain standards, and represent the profession in discussions with other bodies
Prescription Drug Monitoring Programs	Statewide electronic database that collects designated data on substances dispensed in the state
PDMP Application Vendors	Vendors which provide specific PDMP application solutions to state PDMPs such as software applications and software services. These suppliers may include developers, providers, resellers, integrators, operators, and others who may provide these or similar capabilities.

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

Member of Communities of Interests	Working Definition
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
Third Party Organizations	Other healthcare vendors

Table 1: Communities of Interest

4.0 Value Statement

Successful outcomes and metrics of the Use Case include:

- The feedback received from health IT community between PDMP and Health IT systems will influence data format, application programmatic interface, and transport protocol for interfaces for querying data from PDMP instances;
- The outcome will be a specification describing the data interface for querying prescription information from a PDMP instance for use by health IT systems which enables
 - The ability for Health Care Professionals with legal authorization to access prescription drug data for patients at the point of care to make informed clinical decisions and appropriate treatment recommendations to reduce prescription drug misuse and overdose

5.0 Use Case Assumptions

1. Health IT system is capable of sending a request to a PDMP and receiving a response from the PDMP system
2. Healthcare Professionals have appropriate legal authority based on state regulations to request and receive information from state PDMP
3. Healthcare Professionals accessing the PDMP follow state guidelines as appropriate, including any privacy and security requirements as required by each individual state PDMP authority
4. While it is understood that a request is sent by the HC Professional through the Health IT system to the PDMP, the PDMP may return a number of positive patient matches back to the Health IT System; our Use Case assumes, the Healthcare professional or Health IT system positively identifies the subject of the request (person of interest)
5. The Healthcare Professional accesses information that already exists within the PDMP at the time of requesting
6. Each organization has the responsibility for determining how to present and integrate the response

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

6.0 Pre-Conditions

1. The necessary access controls and authorization protocols based on State and/or Federal regulations (which could include patient consent or privacy permissions) for any of the systems or users described, are in place
 - o The Health IT system application can provide necessary/required authorization, authentication or privacy information to the PDMP
 - o The Health IT system can apply PDMP authorization requirements to restrict access to PDMP data to authorized users
2. If an intermediary, such as a Hub, is used it provides necessary technology infrastructure to allow PDMP data exchange from the PDMP to the Health IT system
3. Parameters required to create the request in a standardized format by the Health IT system/Hub are recognized and accepted by the PDMP system
4. Health IT System or Hub is able to determine which state PDMP(s) should receive the request
5. The PDMP system can provide a response in a standardized format which is recognized and accepted by the Hub/Health IT system
6. Health IT System and PDMP have a common understanding of the shared vocabulary that are required to initiate the request and provide the response
7. In the event a request is parsed out to other states and the other states respond back, the Health IT system, Hub (if applicable) and PDMP systems will have knowledge about the order of succession to provide the response

7.0 Post Conditions

1. Health IT System has sent a request
2. PDMP system has received the request
3. PDMP system has sent a response to the Health IT system (which may include error conditions)
4. Health IT system has successfully received the response from the PDMP system
5. Health IT system can display/present response

8.0 Actors and Roles

Note: These do not reflect system functionality and requirements but section 10.3 will define specific system functionality in more detail

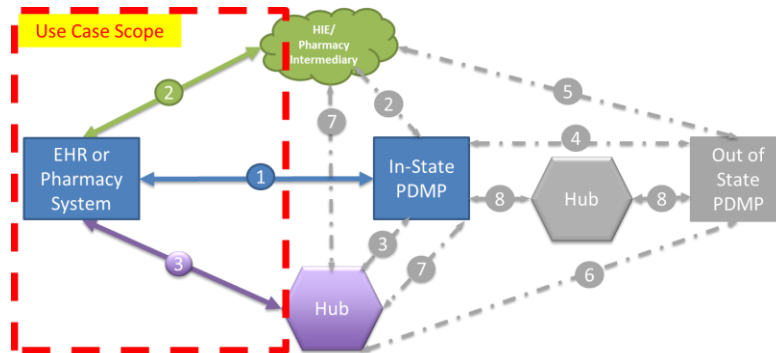
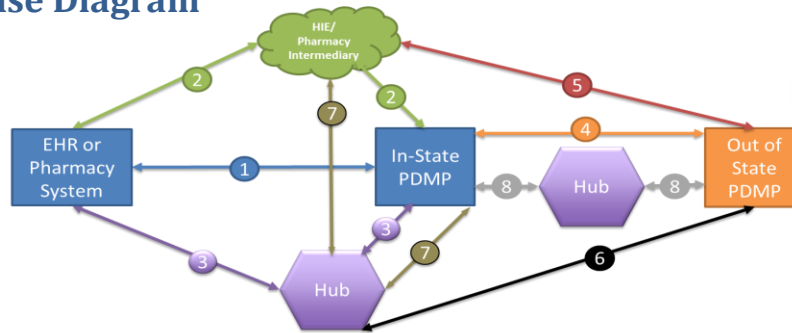
Business Actor	Technical Actor (Business Actor's System)	• Role
Healthcare Professional	Health IT System	<ul style="list-style-type: none"> • Send request • Receives response
PDMP	PDMP System	<ul style="list-style-type: none"> • Receive request • Return response
Hub	Hub System	<ul style="list-style-type: none"> • Receive request • Route request • Receive response(s) • Package response(s) • Return response(s)

Use Case Development and Functional Requirements for Interoperability PDMP & Health IT Integration Use Case

Business Actor	Technical Actor (Business Actor's System)	Role
Pharmacy Intermediary	Pharmacy Intermediary System	<ul style="list-style-type: none"> Receive request Route request Receive response(s) Package response(s) Return response(s)
HIE	HIE System	<ul style="list-style-type: none"> Receive request Route request Receive response(s) Package response(s) Return response(s)

Table 2: Actors and Roles

9.0 Use Case Diagram



Transactions	Scope	From	Via	To	
1	↔	✓	EHR/Pharmacy	-	In-State PDMP
2	↔	✓	EHR/Pharmacy	HIE	In-State PDMP
3	↔	✓	EHR/Pharmacy	Hub	In-State PDMP
4	→	×	In-State PDMP	-	Out of State PDMP
5	→	?	HIE/Ph. Intermediary	-	Out-of-State PDMP
6	↔	×	Hub	-	Out-of-State PDMP
7	→	?	HIE/Ph. Intermediary	Hub	In-State PDMP
8	→	×	In-State PDMP	Hub	Out-of-State PDMP

PDMP/HITI User Stories with Alternate Workflows

HIT to In-State PDMP:

- HIT to In-state PDMP
- HIT to In-state PDMP via HIE
- HIT to in-state PDMP via Hub

HIT to Out-of-State PDMP:

- 1+4: HIT to out-of-state PDMP via In-state PDMP
- 2+4: HIT to out-of-state PDMP via HIE & In-state PDMP
- 2+5: HIT to out-of-state PDMP via HIE
- 3+4: HIT to out-of-state PDMP via Hub & In-State PDMP
- 1+8: HIT to out-of-state PDMP via In-State PDMP & Hub
- 3+6: HIT to out-of-state PDMP via Hub
- 7: HIE to In-State PDMP via Hub

Figure 1: Use Case Diagram

10A.0 Scenario #1: Healthcare Professional requests patient history of controlled substances from in-state PDMP directly

10A.1 User Stories

User Story #1: Legally authorized provider queries PDMP before writing a prescription for a PDMP reported controlled substance for a patient

A patient arrives at the physician's office or hospital for treatment that may require a controlled substance prescription. If necessary, the physician authenticates to the Health IT system. At the appropriate point in the workflow, the request is sent to the State PDMP to obtain patient history of controlled substances dispensed. After receiving the response from the PDMP, the physician makes an informed decision of whether or not to prescribe the medication or modify the treatment based on the information received.

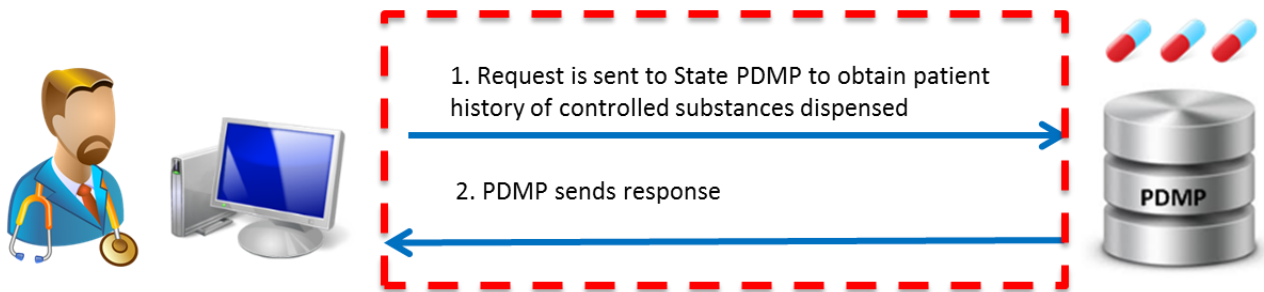


Figure 2: Scenario #1, User Story #1

User Story #2: Pharmacist queries PDMP prior to dispensing a PDMP reported controlled substance to a patient

A trigger event occurs, such as a patient arrives at the pharmacy to have a prescription filled or a prescription is sent to the pharmacy for dispensing. The pharmacist authenticates to the Pharmacy Dispensing system. After, the pharmacist sends a request to the State PDMP through the Pharmacy Dispensing system to obtain patient history of controlled substances dispensed. After receiving the response from the PDMP, the pharmacist makes an informed decision of whether or not to dispense the medication based on the information received.

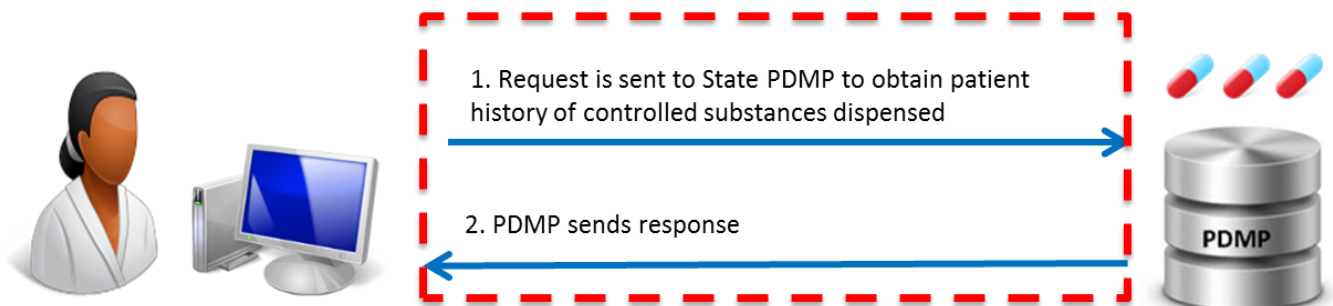


Figure 3: Scenario #1, User Story #2

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

10A.2 Activity Diagram

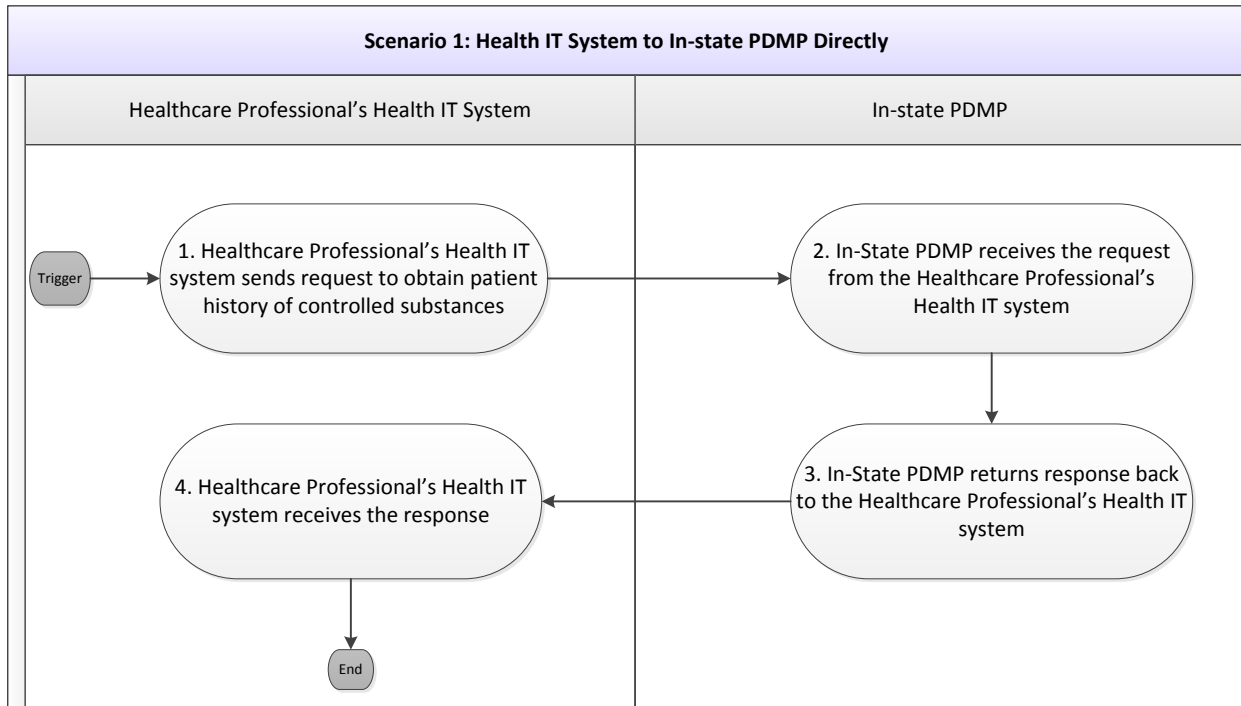


Figure 4: Scenario #1, Activity Diagram

10A.2.1 Base Flow

Step #	Actor	Role	Event/Description	Inputs	Outputs
1	Healthcare Professional	Request Sender	Healthcare Professional's HIT System sends request to obtain patient history of controlled substances	Healthcare Professional identifies patient of interest from his/her HIT System.	Patient history of controlled substances request initiated and sent in standard format and content specification
2	PDMP	Request Receiver	PDMP receives the request for patient history of controlled substances through Healthcare Professional's HIT System and processes the request	Patient history of controlled substances request	Patient history of controlled substances in standard format
3	PDMP	Response Sender	PDMP returns response through HIT system to the Healthcare Professional	Patient history of controlled substances	Patient history of controlled substances in standard format
4	Healthcare Professional	Response Receiver	Healthcare Professional receives the response through his/her HIT System	Patient history of controlled substances	END

Note: The patient history of controlled substances request and response is an agreed upon standard format

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

Table 3: Scenario #1, Base Flow

10A.3 Functional Requirements

10A.3.1 Information Interchange Requirements

Information Interchange Requirement	Initiating System	(describes action)	Information Interchange Requirement Name	Receiving System	(describes action)
IIR 01a.	HIT System	Sends	Request for patient history of controlled substances	PDMP System	Receives
IIR 02a.	PDMP System	Sends	Response to patient history of controlled substances	HIT System	Receives

Table 4: Scenario #1, Information Interchange Requirements

10A.3.2 System Requirements

System	System Requirement
HIT System	<ol style="list-style-type: none"> 1. Generate a query for patient history of controlled substances 2. Assemble authentication, authorization and consent information for PDMP system validation 3. Package the request in a specified standardized format
PDMP System	<ol style="list-style-type: none"> 1. Authenticate requesting application credentials and validate authorization for data access, and make determination to release patient data 2. Identify patient data that matches the query 3. Package the response in a specified standardized format

Table 5: Scenario #1, System Requirements

Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case

10A.4 Sequence Diagram

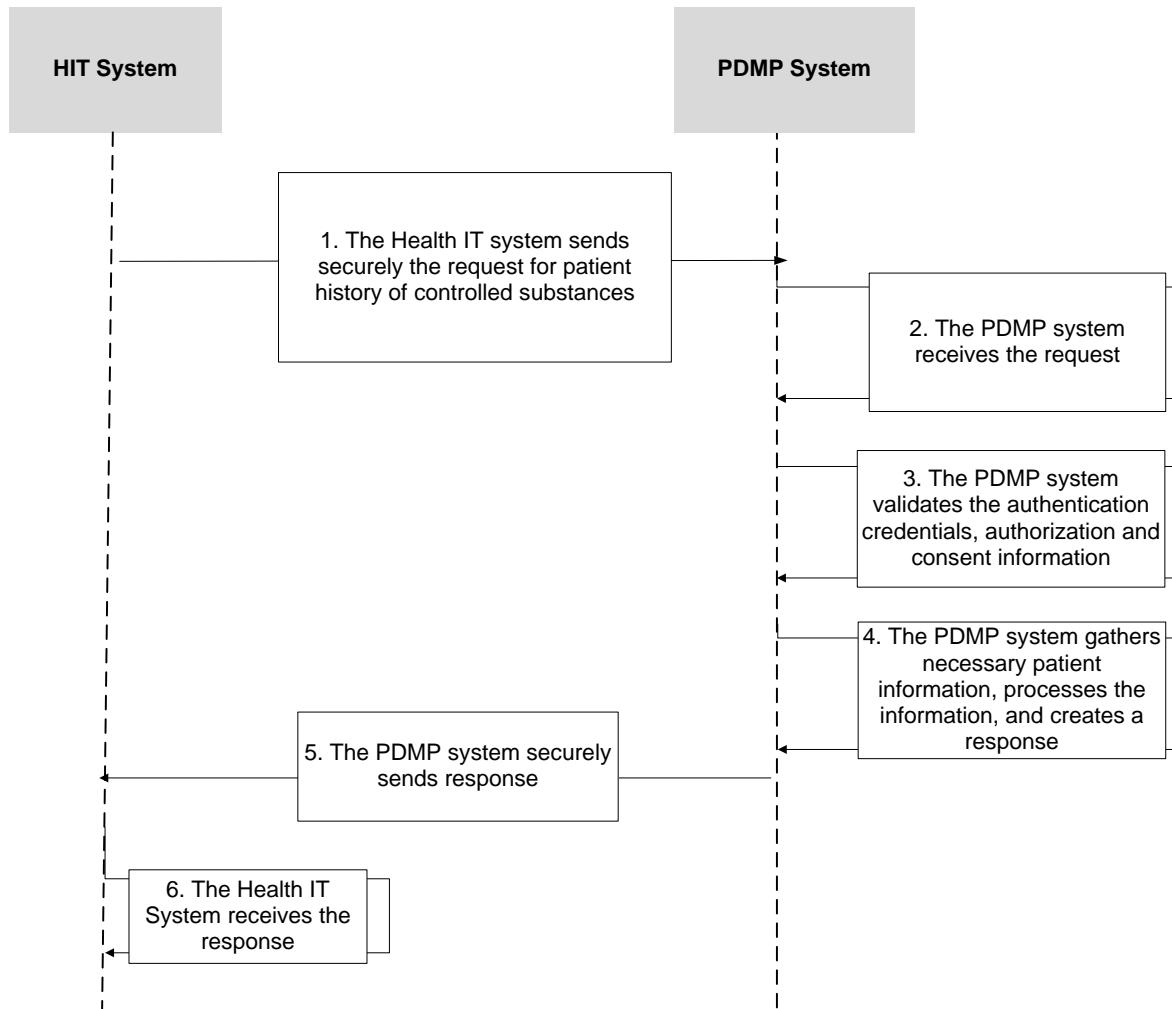


Figure 5: Scenario #1, Sequence Diagram

10B.0 Scenario #2: Healthcare Professional requests patient history of controlled substances from PDMP via a Hub

10B.1 User Stories

User Story #1: Legally authorized provider queries PDMP through a hub before writing a prescription for a PDMP reported controlled substance for a patient

A patient arrives at the physician’s office or hospital for treatment that may require a controlled substance prescription. If necessary, the physician authenticates to the Health IT system. At the appropriate point in the workflow, the request is sent to a Hub through the Health IT system to obtain patient history of controlled substances dispensed. The Hub receives the request. The Hub sends the

Use Case Development and Functional Requirements for Interoperability PDMP & Health IT Integration Use Case

response back to the Health IT system where the request originated. After receiving the response(s), the physician makes an informed decision of whether or not to prescribe the medication or modify the treatment based on the information received.

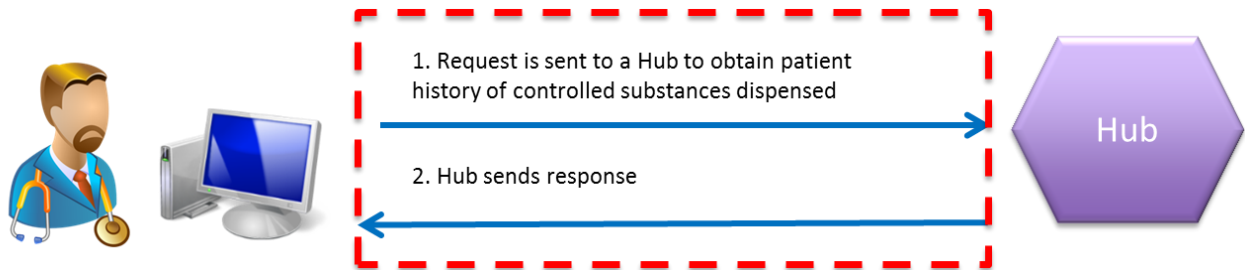


Figure 6: Scenario #2, User Story #1

User Story#2: Pharmacist queries PDMP through a Hub prior to dispensing a PDMP reported controlled substance to a patient

A trigger event occurs, such as a patient arrives at the pharmacy to have a prescription filled or a prescription is sent to the pharmacy for dispensing. After, the pharmacist sends a request to the Hub through the Pharmacy Dispensing system to obtain patient history of controlled substances dispensed. The hub receives the request. The hub sends the response back to the Health IT system where the request originated. After receiving the response, the pharmacist makes an informed decision of whether or not to dispense the medication based on the information received.

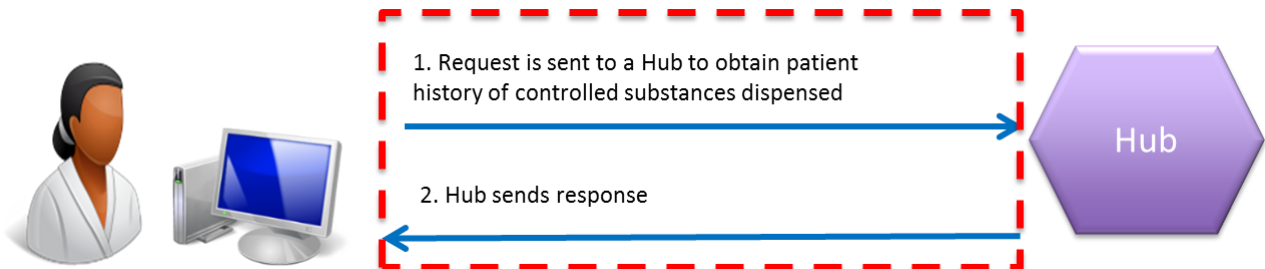
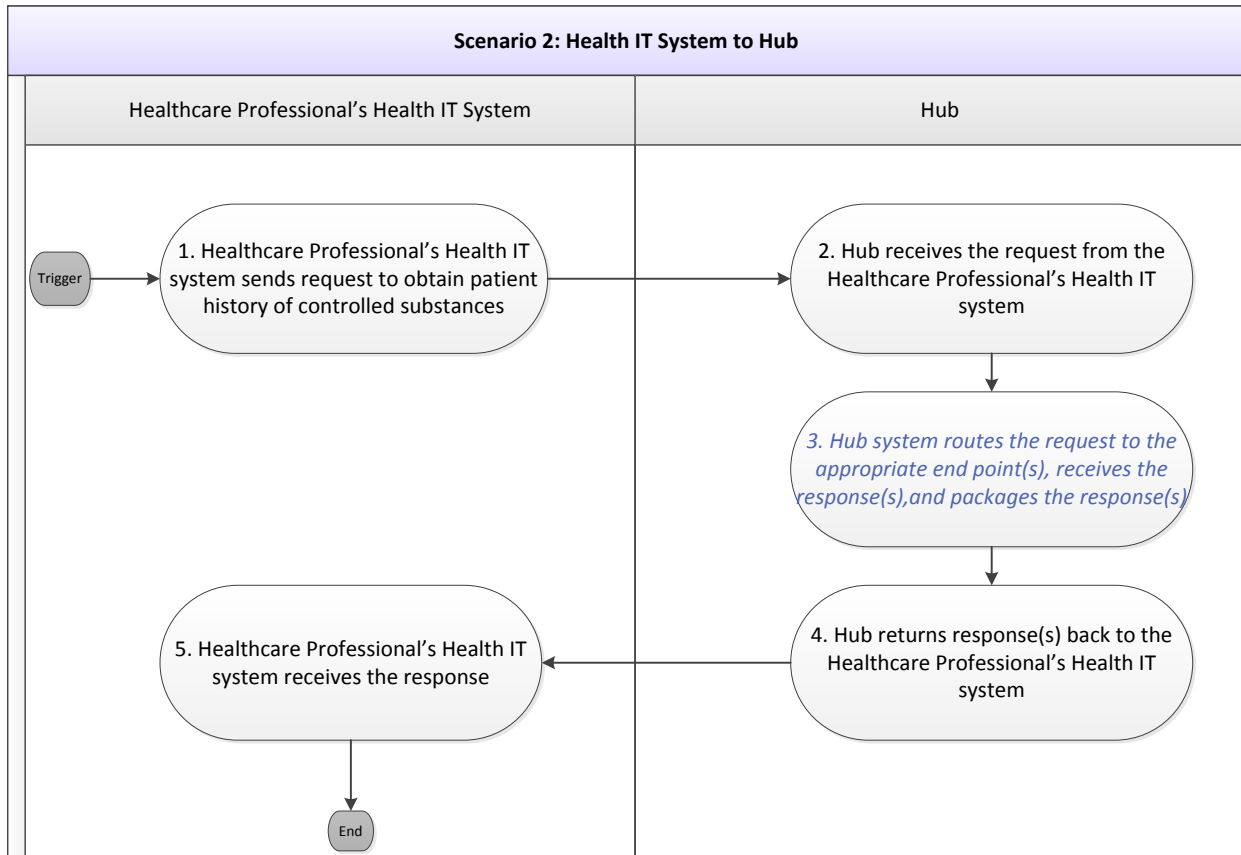


Figure 7: Scenario #2, User Story #2

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

10B.2 Activity Diagram



Note: In step 3, the Hub interacts with a PDMP system to receive the information for the patient's history of controlled substances; however, those transactions are not included in this scenario.

Figure 8: Scenario #2, Activity Diagram

10B.2.1 Base Flow

Step #	Actor	Role	Event/Description	Inputs	Outputs
1	Healthcare Professional	Request Sender	Healthcare Professional's HIT System sends request to obtain patient history of controlled substances	Healthcare Professional identifies patient of interest from his/her HIT System.	Patient history of controlled substances request initiated and sent in standard format and content specification
2	Hub	Request Receiver	Hub receives the request for patient history of controlled substances through Healthcare Professional's HIT System	Patient history of controlled substances request	Patient history of controlled substances request

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

Step #	Actor	Role	Event/Description	Inputs	Outputs
3	Hub	Request receiver	Hub routes the request to the appropriate end point(s), receives the response(s), and packages the response(s)	Patient history of controlled substances request	Patient history of controlled substances in standard format
4	Hub	Response Sender	Hub returns response(s) to Healthcare Professional through his/her HIT system	Patient history of controlled substances	Patient history of controlled substances in standard format
5	Healthcare Professional	Response Receiver	Healthcare Professional receives response through his/her HIT System	Patient history of controlled substances	END

Table 6: Scenario #2, Base Flow

10B.3 Functional Requirements

10B.3.1 Information Interchange Requirements

Information Interchange Requirement	Initiating System	(describes action)	Information Interchange Requirement Name	Receiving System	(describes action)
IIR 01a.	Health IT System	Sends	Request for patient history of controlled substances	Hub System	Receives
IIR 02a.	Hub System	Sends	Response to patient history of controlled substances	Health IT System	Receives

Table 7: Scenario #2, Information Interchange Requirements

10B.3.2 System Requirements

System	System Requirement
HIT System	<ol style="list-style-type: none"> 1. Generate a request for patient history of controlled substances 2. Assemble authentication, authorization and consent information for PDMP system validation 3. Package the request in a specified standardized format

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

System	System Requirement
Hub System	<ol style="list-style-type: none"> 1. Authenticate requesting application credentials 2. Route query to appropriate PDMPs 3. Package the PDMP response(s) in a specified standardized format 4. Transform request/response information from one format to another format recognized by PDMP and Health IT System

Table 8: Scenario #2, System Requirements

10B.4 Sequence Diagram

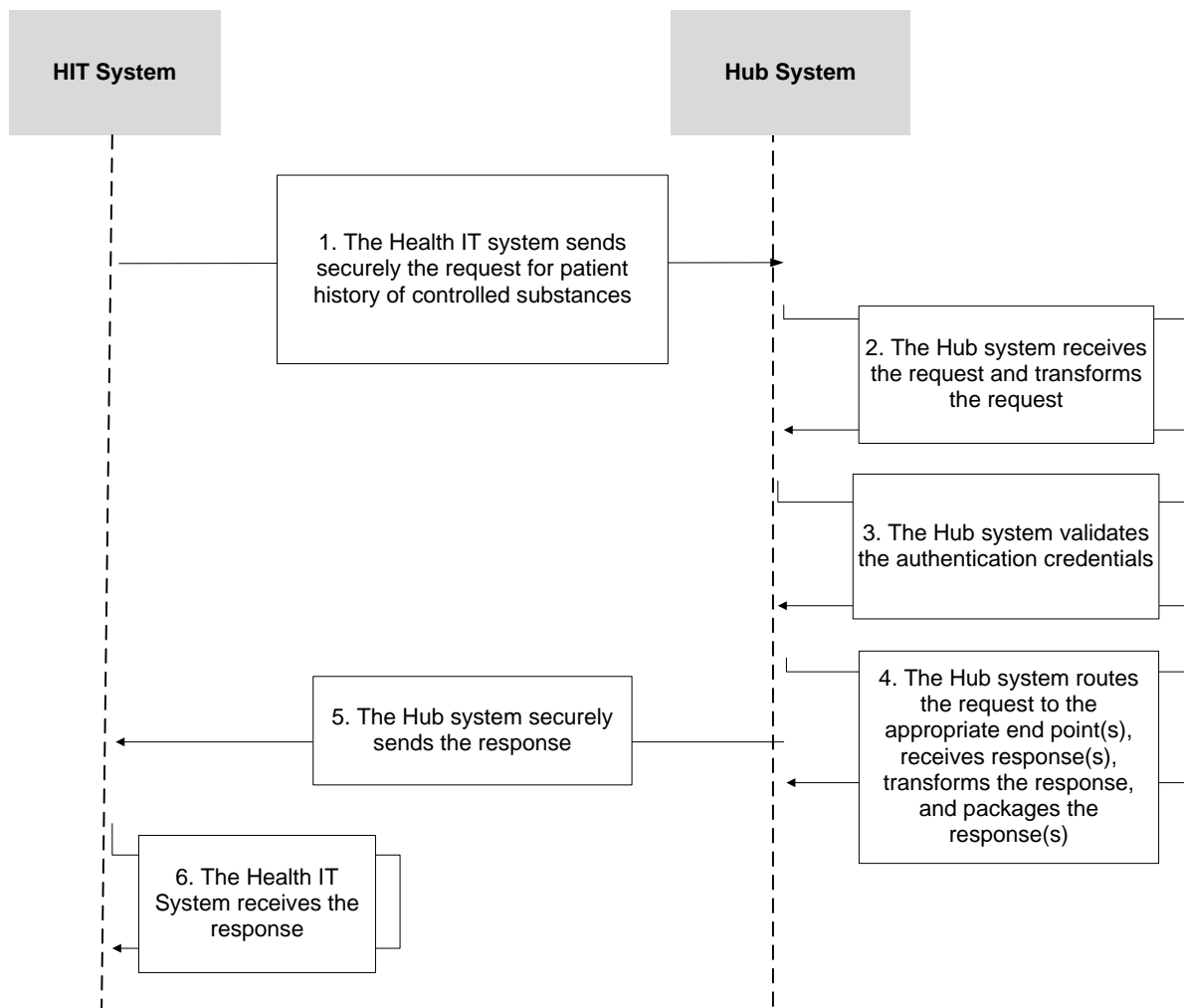


Figure 9: Scenario #2, Sequence Diagram

10C.0 Scenario #3: Healthcare Professional requests patient history of controlled substances from a PDMP via an HIE/Pharmacy Intermediary

10C.1. User Stories

User Story #1: Legally authorized provider queries PDMP through an HIE before writing a prescription for a PDMP reported controlled substance for a patient

A patient arrives at the physician's office or hospital for treatment that may require a controlled substance prescription. If necessary, the physician authenticates to the Health IT system. At the appropriate point in the workflow, the query is sent to an HIE through the Health IT system to obtain patient history of controlled substances dispensed. The HIE receives the query. The HIE sends the query response back to the Health IT system where the query originated. After receiving the query response(s), the physician makes an informed decision of whether or not to prescribe the medication or modify the treatment based on the information received.

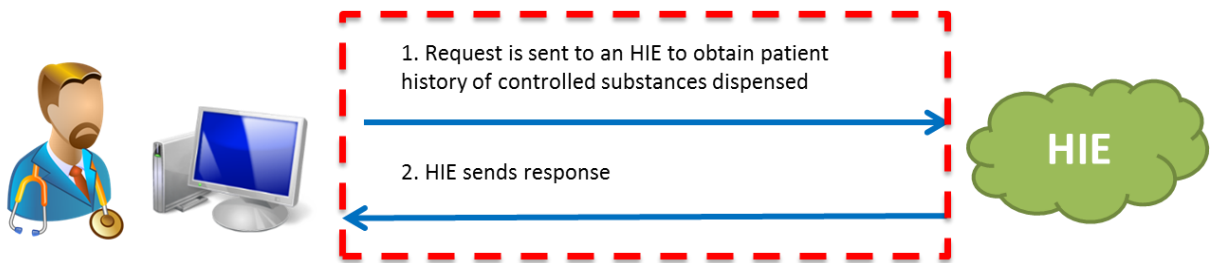


Figure 10: Scenario #3, User Story #1

User Story #2 – Pharmacist queries PDMP through a Pharmacy Intermediary prior to dispensing a PDMP reported controlled substance to a patient

A trigger event occurs, such as a patient arrives at the pharmacy to have a prescription filled or a prescription is sent to the pharmacy for dispensing. The pharmacist authenticates to the Pharmacy Dispensing system. After, the pharmacist sends a query to the Pharmacy Intermediary through the Pharmacy Dispensing system to obtain patient history of controlled substances dispensed. The Pharmacy Intermediary receives the query. The Pharmacy Intermediary sends the query response back to the Health IT system where the query originated. After receiving the query response, the pharmacist makes an informed decision of whether or not to dispense the medication based on the information received.

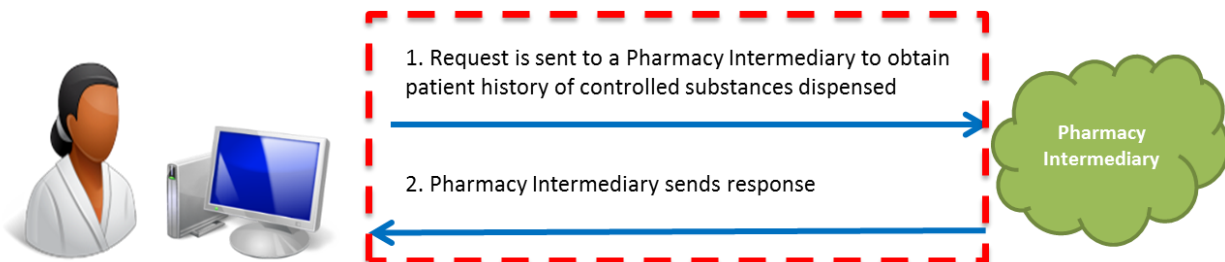
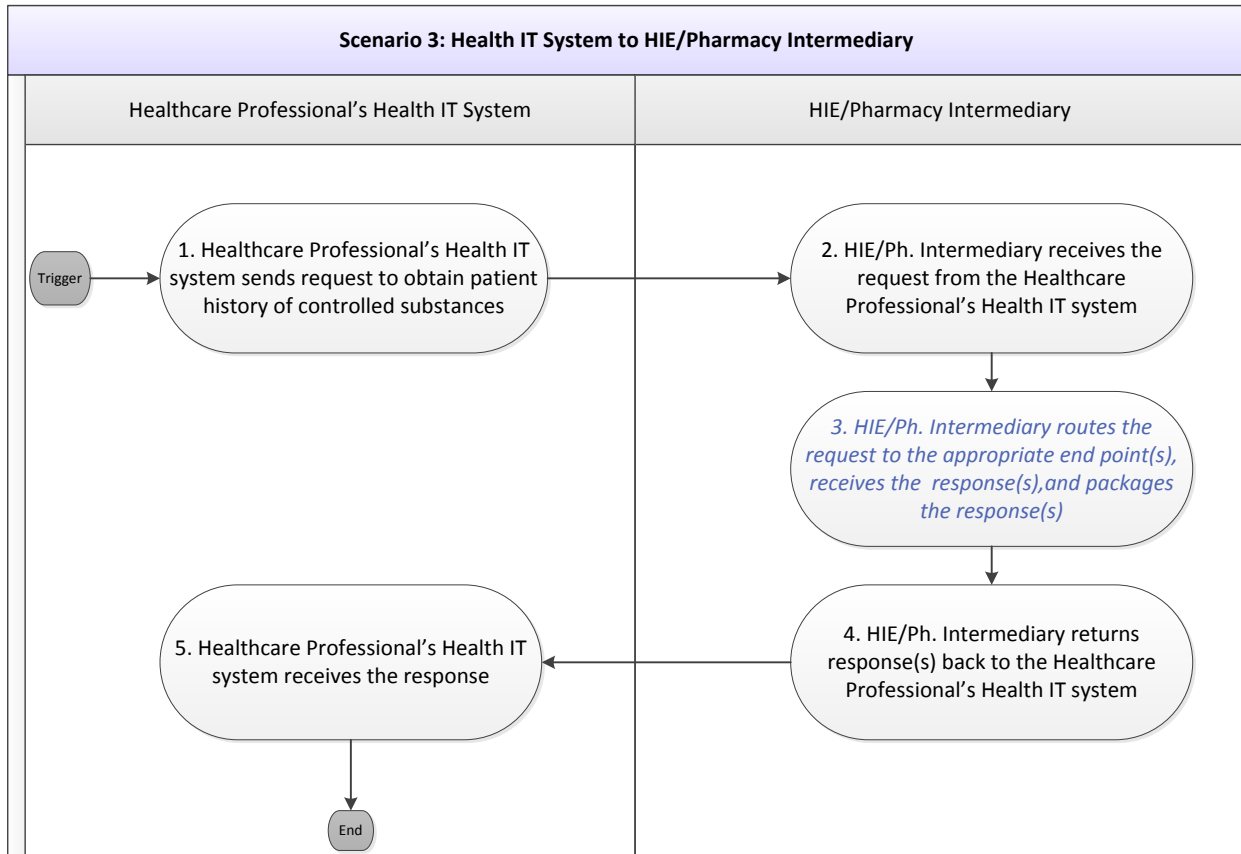


Figure 11: Scenario #3, User Story #2

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

10.2 Activity Diagram



Note: In step 3, the HIE/Ph. Intermediary interacts with a PDMP system to receive the information for the patient’s history of controlled substances; however, those transactions are not included in this scenario.

Figure 12: Activity Diagram Scenario #3

10C.2.1 Base Flow

Step #	Actor	Role	Event/Description	Inputs	Outputs
1	Healthcare Professional	Request Sender	Healthcare Professional’s HIT System sends request to obtain patient history of controlled substances	Healthcare Professional identifies patient of interest from his/her HIT System.	Patient history of controlled substances request initiated and sent in standard format and content specification

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

Step #	Actor	Role	Event/Description	Inputs	Outputs
2	HIE/Ph. Intermediary	Request Receiver	HIE/Ph. Intermediary receives the request for patient history of controlled substances through Healthcare Professional's HIT System	Patient history of controlled substances request	Patient history of controlled substances request
3	<i>HIE/ Ph. Intermediary</i>	<i>Request receiver</i>	<i>HIE/Ph. Intermediary routes the request to the appropriate end point(s), receives the response(s),and packages the response(s)</i>	<i>Patient history of controlled substances request</i>	<i>Patient history of controlled substances in standard format</i>
4	HIE/Ph. Intermediary	Response Sender	HIE/Ph. Intermediary returns response(s) to Healthcare Professional through his/her HIT system	Patient history of controlled substances	Patient history of controlled substances in standard format
5	Healthcare Professional	Response Receiver	Healthcare Professional receives response through his/her HIT System	Patient history of controlled substances	END

Table 9: Scenario #3, Base Flow

10C.3 Functional Requirements

10C.3.1 Information Interchange Requirements

Information Interchange Requirement	Initiating System	(describes action)	Information Interchange Requirement Name	Receiving System	(describes action)
IIR 01a.	Health IT System	Sends	Request for patient history of controlled substances	HIE/Pharmacy Intermediary System	Receives
IIR 02a.	HIE/Pharmacy Intermediary System	Sends	Response to patient history of controlled substances	Health IT System	Receives

Table 10: Scenario #3, Information Interchange Requirements

10C.3.2 System Requirements

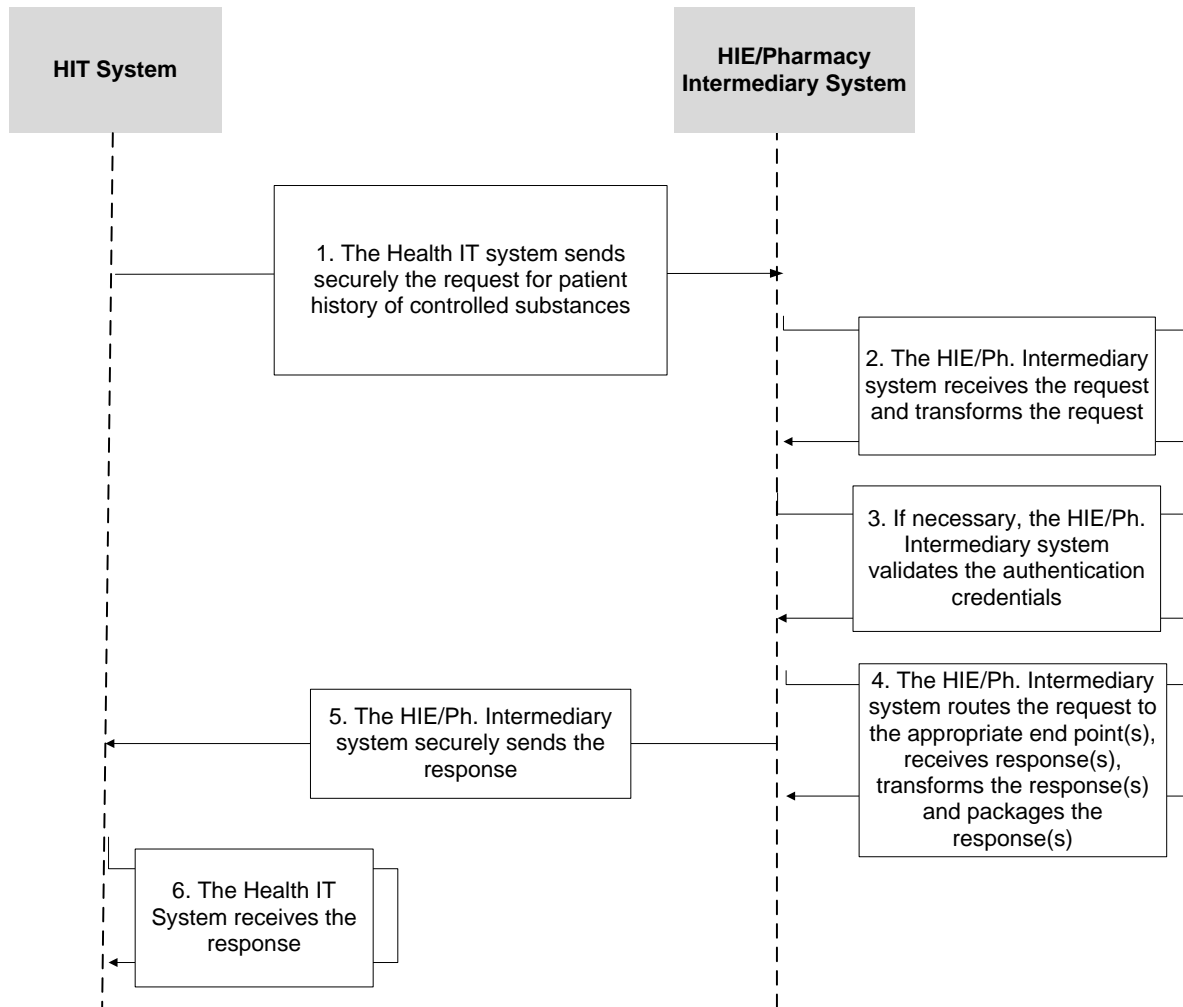
System	System Requirement
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**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

System	System Requirement
HIT System	<ol style="list-style-type: none"> 1. Generate a request for patient history of controlled substances 2. Assemble authentication, authorization and consent information for PDMP system validation 3. Package the request in a specified standardized format
HIE/Pharmacy Intermediary System	<ol style="list-style-type: none"> 1. Authenticate requesting application 2. Route query to appropriate PDMPs 3. Package PDMP response(s) specified standardized format 4. Transform request/response information from one format to another format recognized by PDMP and Health IT System

Table 11: Scenario #3, System Requirements

10C.4 Sequence Diagram



**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

Figure 13: Scenario #3, Sequence Diagram

11.0 Dataset Requirements

Note: These tables represent the perspectives of various stakeholders but have not been fully validated.

Request for History of Controlled Substances Data Elements

Category	Data Element	Definition	EHR	Pharmacy Dispensing System	Pharmacy Intermediary	HIE	Hub	PDMP
General								
	Request Date	Date of request	X		X	X	X	
	Request Timestamp	Time of request	X			X	X	
	State of Request	State where request was initiated	X		X		X	
	Requester Location	Name of the entity from which the Healthcare Professional sends the request (e.g. pharmacy name, hospital name, name of group practice, etc.)	X		X		X	
	Requested State(s) (if applicable)	State PDMPs that should receive request	X	X			X	
	Authenticator	Identifier for the authenticator	X			X		
	System Authentication	Identifier that authenticates the system	X		X		X	
	Initiating requestor's routing ID	Identifies the initiator (sender) for the medication history request	X		X	X		
	Responder ID	Identifies the responder for the medication history request			X	X	X	
	Message ID	Unique reference identifier for the transmission, generated from the sender of the request and echoed back in the response to link the response to the request	X		X	X	X	
	Requestor's Internal Patient ID	Either the MR number from the HIT or the patient visit number	X					
	"Start" date	Start date for medication history date range	X	X	X	X	X	X
	"End" date	End date for medication history date range	X	X	X	X	X	X

Table 12: General Request Data Requirements

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

Category	Data Element	Definition	EHR	Pharmacy Dispensing System	Pharmacy Intermediary	HIE	Hub	PDMP
Authorized User		Reports the Authorized User's name and basic information						
	First Name	Authorized User's first name	X		X			X
	Last Name	Authorized User's last name	X		X			X
	Generational Suffix (if applicable)	Authorized User's generational suffix	X					X
	1. Address Information - 1 [Required] 2. Address Information - 2 [Optional]	1. Address information 2. Additional address information	X		X			x
	City Address	City name	X		X			X
	State Address	U.S. Postal Service state code	X		X			X
	ZIP Code Address	U.S. Postal Service ZIP code	X		X			X
	Email address		X		X			X
	Phone number	Complete phone number, including area code	X		X			X
	Authentication credentials (DEA number, NCPDP/NABP Provider ID, National Provider Identifier, License Number, Delegate ID)	Identifier assigned to the authorized user	X	X	X	X		X
	Type of User	Specifies the role of the Healthcare Professional	X	X	X		X	X

Table 13: Authorized User Request Data Requirements

Category	Data Element	Definition	EHR	Pharmacy Dispensing System	Pharmacy Intermediary	HIE	Hub	PDMP
Patient		Reports the patient's name and basic						

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

	information						
First Name	First name of patient	X	X	X	X		X
Last Name	Last name of patient	X	X	X	X		X
1. Address Information - 1 [Required] 2. Address Information - 2 [Optional]	1. Address information 2. Additional address information	X	X	X	X		
City Address	City name	X	X	X	X		X
State Address	U.S. Postal Service state code	X	X	X	X		
ZIP Code Address	U.S. Postal Service ZIP code	X	X	X	X		
Phone Number	Phone number of patient	X		X	X		
Patient Gender	Gender of patient	X	X	X	X		X
Country	Country of residency	X		X	X		
Date of Birth	Date patient was born	X	X	X	X		X
Identification Qualifier of Patient Identifier	Code identifying the jurisdiction that issues identifier	X	X	X			
Identification Qualifier	Code to identify the type of ID	X	X	X			
Identification of Patient	Identification number for the patient (e.g. driver's license number, SSN, HIE Patient ID, etc.)	X	X	X	X		

Table 14: Patient Request Data Requirements

Response for History of Controlled Substances Data Elements

Category	Data Element	Definition	EHR	Pharmacy Dispensing System	Pharmacy Intermediary	HIE	Hub	PDMP
General								
	Response Date	Date of response	X		X	X	X	X
	Response Timestamp	Time of response	X			X	X	X
	Response Time	Time period covered by response	X				X	X
	State of Response	State where response was created	X				X	X
	Response Identifier	Identifier assigned to the response (may be same as request identifier)	X			X	X	X
	Message ID	Unique reference identifier for the transmission, generated from the sender of the request and echoed back in the response to link the response to the request	X		X	X	X	X
	Summary	Summary of response (number of prescribers and prescriptions for POI for the date range)						X

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

	Create Time	Time report is created				X		X
	Intended Recipient	Indicates the intended message recipient				X		X
	Status of Request	Whether or not the request has been approved or not approved				X		X

Table 15: General Response Data Requirements

Category	Data Element	Definition	EHR	Pharmacy Dispensing System	Pharmacy Intermediary	HIE	Hub	PDMP
Patient		Reports the patient's name and basic information						
	First Name	First name of patient	X	X	X	X		X
	Last Name	Last name of patient	X	X	X	X		X
	1. Address Information - 1 [Required] 2. Address Information - 2 [Optional]	1. Address information 2. Additional address information	X	X		X		X
	City Address	City name	X	X		X		X
	State Address	U.S. Postal Service state code	X	X		X		X
	ZIP Code Address	U.S. Postal Service ZIP code	X			X		X
	Country	Country of residency	X	X				
	Date of Birth	Date patient was born	X	X	X	X		X
	Identification Qualifier of Patient Identifier	Code identifying the jurisdiction that issues identifier	X	X				
	Identification Qualifier	Code to identify the type of ID	X	X				
	Identification of Patient	Identification number for the patient (e.g. driver's license number, SSN, etc.)	X	X		X		
	PDMP Patient Reference Number	PDMP system generated patient reference number	X	X				X
	Gender Code	Code indicating the sex of the patient	X	X		X		X
	Species Code	Differentiates a prescription for an individual from one prescribed for an animal	X	X				
	Phone Number	Complete phone number, including area code	X	X				

Table 16: Patient Response Data Requirements

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

Category	Data Element	Definition	EHR	Pharmacy Dispensing System	Pharmacy Intermediary	HIE	Hub	PDMP
Prescription Information		Identifies the basic components of dispensing of a given prescription order, including the date and quantity						
	Name of Drug	Derived from product ID, such as National Drug Code (NDC); It will be the generic ingredients as opposed to the brand name	X	X		X		X
	Strength	Derived from product ID, such as NDC	X	X		X		X
	Form	Derived from product ID, such as NDC	X	X		X		X
	Quantity Dispensed	Number of metric units dispensed in metric decimal format	X	X		X		X
	Days' Supply Dispensed	Calculated or estimated number of days the medication will cover	X	X		X		X
	Date written	Date the prescription was written (authorized)	X	X	X			X
	Refills Authorized	Number of refills authorized by the prescriber	X	X				X
	Refill Number	Number of the fill of the prescription	X	X	X			X
	Partial Fill	Prescription was only partially filled	X	X	X			X
	Prescription Number	Serial number assigned to the prescription by the pharmacy	X	X	X	X		X
	Date Prescription Filled	The date the prescription was filled at the pharmacy	X	X		X		X
	Date Prescription Sold/Dispensed	The date the prescription was sold/dispensed (dispensed is being used as defined by state law)		X				X
	Drug identifier	Identifier for drugs (Rxnorm, NDC code)		X		X		X
	Payment Method	The method used to purchase the prescription		X				X

Table 17: Prescription Response Data Requirements

Category	Data Element	Definition	EHR	Pharmacy Dispensing System	Pharmacy Intermediary	HIE	Hub	PDMP
Prescriber		Reports the prescriber of the prescription's information						
	First Name	Prescriber's first name	X	X		X		X
	Last Name	Prescriber's last name	X			X		X
	1. Address	1. Address information	X			X		X

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

	Information - 1 [Required] 2. Address Information - 2 [Optional]	2. Additional address information						
	City Address	City name	X			X		X
	State Address	U.S. Postal Service state code	X	X		X		X
	ZIP Code Address	U.S. Postal Service ZIP code	X			X		X
	Phone Number	Complete phone number, including area code	X	X				X
	DEA Number	Identifying number assigned to a prescriber or an institution by the DEA	X	X		X		X
	Authentication credentials (DEA number, NCPDP/NABP Provider ID, National Provider Identifier, License Number, Delegate ID)	Identifier assigned to the authorized user	X	x				X
	PDMP Prescriber Reference Number	PDMP system generated prescriber reference number						X

Table 18: Prescriber Response Data Requirements

Category	Data Element	Definition	EHR	Pharmacy Dispensing System	Pharmacy Intermediary	HIE	Hub	PDMP
Dispenser		Reports the pharmacy or the dispensing professional's information						
	Pharmacy or Dispensing Prescriber Name	Freeform name of the pharmacy or dispensing professional	X			X		X
	1. Address Information - 1 [Required] 2. Address Information - 2 [Optional]	1. Address information 2. Additional address information	X			X		X
	City Address	City name	X			X		X
	State Address	U.S. Postal Service state code	X			X		X

**Use Case Development and Functional Requirements for Interoperability
PDMP & Health IT Integration Use Case**

ZIP Code Address	U.S. Postal Service ZIP code	X			X		X
Phone Number	Complete phone number, including area code	X			X		X
DEA Number	Identifier assigned to the pharmacy by the DEA	X			X		X
NCPDP/NABP Provider ID	Identifier assigned to pharmacy by the NCPDP	X			X		X
National Provider Identifier (NPI)	Identifier assigned to the pharmacy by CMS	X	X		X		X
PDMP Dispenser Reference Number	PDMP system generated dispenser reference number		X				X

Table 19: Dispenser Response Data Requirements

12.0 Risks, Issues and Obstacles

- Ongoing commitment and participants that have helped develop this Use Case will be vital in harmonization.
- Some states are able to connect to a hub in order to obtain information, and only a few states have the ability to connect to an out of state PDMP directly.
 - Implementers are not expected to adopt all scenarios identified in the Use Case.
- If a patient’s history of controlled substances has not been reported to a state PDMP, it may be difficult for a Healthcare Professional to make a meaningful determination of whether or not a drug should or should not be prescribed or dispensed.
- State variability in policy may impact the ability to recommend standards dealing with privacy of patient data and the associated transmission of patient data.
- Given that each state has its own requirement for a PDMP, the solution that this Use Case defines may or may not adequately meet each state’s requirements.
- The standard(s) that we identify may not apply to the transactions identified in the Use Case.

Use Case Development and Functional Requirements for Interoperability PDMP & Health IT Integration Use Case

Appendices

Appendix A: Privacy Considerations

Prescription Drug Monitoring Programs (PDMPs) have been identified as a promising tool for use in the effort to reverse the prescription drug epidemic in the U.S.¹ This initiative seeks to improve interoperability of PDMP data among authorized participants, specifically between health information technology (HIT) systems and PDMP systems to better inform prescribers of the prescription history of patients at the point of care. However given the environment in which PDMPs and HIT systems have developed, specific challenges relating to privacy and security of individually identifiable data arise and must be addressed as either in or out of scope for this initiative.

The legal framework in which PDMPs and associated stakeholders operate is complex. Regulations governing PDMP access, data transmission and reporting vary by state and in some cases by organizational policy. In total, 49 states and D.C. have passed statutes to establish a Prescription Monitoring Program (PMP). Of these, 48 programs are collecting prescription data and providing authorized users access to that information.² Federal funding is available from the Harold Rogers PDMP grant, established in 2002 and administered by the Department of Justice (DOJ). The National All Schedules Prescription Electronic Reporting Act (NASPER), enacted in 2005, created a U.S. Department of Health and Human Services grant program for states to implement or enhance prescription drug monitoring programs.³ The intent of the law was to foster the establishment or enhancement of PDMPs that would meet consistent national criteria and have the capacity for the interstate exchange of information.⁴ States must meet specified use and disclosure limitations when implementing PDMPs funded under NASPER.⁵ Finally, in the case of HIT authorized users who are covered entities or business associates the Health Insurance Portability and Accountability (HIPAA) regulations for privacy and security apply and it is the responsibility of those entities to comply.

During the project charter development and consensus activities, PDMP/HIT Integration Initiative members (the community) provided comments on a variety of issues concerning the overall project scope⁶. Several commenters expressed their concerns about the use of PDMP data with respect to the privacy rights of individuals. This appendix is provided to help readers of this Use Case document better understand why community members' comments relating to existing or future privacy policies or regulations are outside the scope of the initiative.

The Standards and Interoperability (S&I) Framework facilitates a process whereby a narrowly focused yet broadly applicable interoperability challenge can be addressed. In this case, the challenge is to accelerate the development and adoption of standards to allow more seamless and timely access to PDMP information for those healthcare professionals who already have authorized access. The initiative

¹ http://www.healthit.gov/sites/default/files/fdasia1141report_final.pdf

² <http://www.namsdl.org/library/1DAC9EB2-1C23-D4F9-7463F51F7502F189/>

³ Codified at 42 USC § 280g-3.

⁴ http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm

⁵ 42 USC 280g-3 (f)

⁶ <http://wiki.siframework.org/PDMP+%26+Health+IT+Integration+Charter+and+Members#E2E>

Use Case Development and Functional Requirements for Interoperability PDMP & Health IT Integration Use Case

does not define or set privacy policy; it describes technical specifications to enable interoperable exchange of healthcare data according to existing policy. Although existing policies are often referenced in Use Case documents as examples of real-world workflows, these technical specifications are intended to be sufficiently policy agnostic so that they can survive and continue to support policies which evolve over time.

The community recognizes the important privacy and security considerations that states must make as they design, build, and implement their PDMPs and know that state approaches to this have varied in their effectiveness. However, this S&I Initiative is not empowered to create policy and was not formed to address the appropriateness or relative merits of any existing privacy or security policy for PDMPs. The S&I Framework does not have the authority to set policy for PDMPs. It does not have the authority to change federal law, nor does it have the authority to preempt 49 separate state laws concerning PDMPs. This project is focused on improving the technical standards used to communicate data from PDMPs to health IT systems *among states where they have already authorized this sharing of data.*

The specific security and privacy protection laws PDMPs fall under depend on several factors, including: The state agency the PDMP is housed in, its purposes for collecting, using, and disclosing data, and state-specific privacy legislation. In many cases, state PDMPs may not be covered by HIPAA because they do not fall under the regulatory definition for covered entities or business associates. Instead, they are subject to state privacy laws and the privacy and security protections outlined by the PDMP authorizing legislation. From the perspective of the EHR systems receiving PDMP information, any data they incorporate an EHR may become subject to the HIPAA Privacy Rule, including the access and correction provisions.

There are unique privacy and security risks inherent to the exchange of sensitive information from a PDMP to a Health IT system, including any intermediaries that may transport the information between the systems. This Use Case document is designed to inform the development of subsequent technical specifications or implementation guides and recognizes the importance for including the necessary specificity to ensure data is transported securely, without unnecessarily constraining implementers to the use of a specific technology to provide that security.

The appropriate level of security is always a risk-based decision by implementers. For this initiative and use case, it is imperative that pilots and reference implementations adequately address both user authentication and patient matching so that the right requester receives the right information about the right patient, without violating any existing security or privacy policy.

States currently have portals which allow authorized healthcare professionals access to this data and PDMP Integration only seeks to make this access easier and more streamlined for the authorized healthcare professionals. The potential increased frequency of this access provides an opportunity to learn how the pilots address the degree to which they inform patients of the information, collection, and use of PDMP data, which in turn affords an opportunity for further discussion about openness and transparency. It is important to note that while patient access to PDMP data is not in scope for this initiative, this work may lend itself to greater opportunities to inform patients about PDMPs.

Use Case Development and Functional Requirements for Interoperability PDMP & Health IT Integration Use Case

Appendix B: Previous Work Efforts

- Previous PDMP work efforts (January 2013-March 2013) can be found [here](#).

Appendix C: References

The initiatives general references can be found [here](#). The following is a list of useful artifacts for the community:

- [Project Charter](#): The page describes the overall project charter including the challenge statement, scope, deliverables and timelines.
- [PDMP & HITI Terminology](#): The page defines the terminology used for this initiative.
- [Initiative Parking Lot](#): This page highlights any items identified as parking lot items at any stage in this initiative