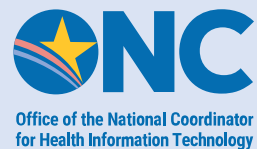


Auditing Guidance

Advancing PDMP-EHR Integration Project
PDMP-EHR Integration Toolkit



This document was developed by Accenture Federal Services as the contractor leading the Advancing Prescription Drug Monitoring Programs - Electronic Health Record (PDMP-EHR) Integration Project under contract #GS-35F-540GA order # HHSP233201800327G. The project team from Accenture Federal Services served as a contractor to the Office of the National Coordinator for Health Information Technology (ONC). ONC served as the implementer partner to the Centers for Disease Control and Prevention (CDC). Funding for this contract award was provided by the CDC.

The PDMP-EHR Integration Toolkit was developed based on lessons learned by the Accenture team through collaborations with PDMP-EHR integration technical demonstration sites and Clinical Decision Support Proofs-of-Concept sites that participated in the Advancing PDMP-EHR Integration Project from 2018 - 2021. The PDMP-EHR Integration Toolkit is supplemented by the Integration Framework.

The findings and conclusions in this document are those of the authors and do not necessarily represent the official position of, the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry, the Office of the National Coordinator for Health Information Technology, or the other organizations involved, nor does the mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

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Purpose

The Auditing Guidance translates learnings from the Office of the National Coordinator for Health Information Technology/Centers for Disease Control and Prevention (ONC/CDC) Advancing Prescription Drug Monitoring Program - Electronic Health Record (PDMP-EHR) Integration Project into general auditing tips relevant to query and response transactions for PDMP-EHR integrations. This is one of several documents within the PDMP-EHR Integration Toolkit.

The intended audience for this document is technical or administrative staff from health care systems who are planning to or already have integrated their EHR with their state PDMP. This document discusses the various audit log data sources, the data elements they commonly contain, and suggestions on how to map elements across the sources. Additionally, it provides example scenarios in which audit data might be useful to health care systems as they troubleshoot technical issues, monitor compliance, or evaluate progress against quality improvement goals. This document is not intended to be comprehensive of all possible auditing scenarios and the audience is encouraged to use it as they see fit for their auditing activities.



Background

The analysis of audit log data can help health care systems assess three key aspects of PDMP-EHR integration maintenance: troubleshooting, compliance, and quality improvement.

Within the context of PDMP-EHR integration, the most basic definition of auditing is the action of gathering and analyzing data on integration query requests originating in the EHR and the PDMP's return responses. Different entities may assign different definitions or objectives to auditing. The health care system and its EHR vendor, the state PMDP, and the integration vendor may each have their own unique audit logs that reflect different data elements of the same query request and response. If the integrated health care system uses a public data-sharing hub, that hub should have a consistent audit log for all of its users. The number of data sources relevant to the auditing process, the available data elements, and the different methods of auditing depend on the nature of your integration and the vendors involved.

Within the context of PDMP-EHR integration, the most basic definition of auditing is the action of gathering and analyzing data on integration query requests originating in the EHR and the PDMP's return responses.

General Guidance

This section provides a high-level summary of lessons learned and best practices for auditing, collected from six PDMP-EHR integration demonstration sites:

- Health care systems should have discussions with their state PDMP to establish necessary auditing responsibilities *prior to* PDMP-EHR integration.
- The health care system should discuss the frequency of uploading audit logs with the state PDMP and how readily available state PDMP audit logs are. The more readily available the audit logs from the state PDMP, the easier it is for the health care system to engage in robust troubleshooting, compliance, and quality improvement measures.

- The health care system should also discuss audit log content with their EHR and/or integration vendor to ensure essential data elements are collected and can be accessed by the health care system. The vendors’ audit logs may or may not be customizable. If the health care system sees a need to include more data in their audit logs, discuss the possibility of adding those data elements with the EHR and/or integration vendor during the planning phase of integration.
- Gathering and analyzing data on the integration query requests and PDMP responses can support health care systems with three key aspects of integration maintenance: 1) technical troubleshooting when query requests and responses don’t work as expected, 2) monitoring compliance by determining whether PDMP queries are conducted when expected, and 3) quality improvement efforts related to use of PDMP data. Table 3 in this document provides examples of how auditing this data can be beneficial.

Audit Log Sources

There are several different sources for audit logs a health care system may need to access for information regarding PDMP-EHR integration transactions including the EHR vendor’s audit log, the state PDMP’s audit log, the integration vendor’s audit log (if applicable), and the data-sharing hub’s audit log. A sample of possible data elements included in each of these entities’ audit logs is presented below. Data elements will vary depending on the relevant state and vendors involved in the integration. Data elements that appear in the audit logs may originate from different sources and standards. An analysis of these data elements can be used to support the troubleshooting, compliance, and quality improvement scenarios mentioned above.

In this report, “request” refers to a query originating from an integrated EHR, and “response” refers to the PDMP’s response to that query, sent back to the EHR. Please refer to the transaction diagrams in the [Appendix](#) for a visual representation of these terms. For an example of standard data elements involved in these transactions, refer to the [PMIX Glossary](#) in the Appendix.

Table 1. Audit Log Data Sources and Corresponding Data Elements

Audit Log Source	Description	Data Elements That May Be Included
EHR	This is the audit log provided by the health care system’s EHR vendor.	<ul style="list-style-type: none"> • Clinician Username • Request Time • Successfully Rendered/Viewed • Chart • Encounter
PDMP	This is the audit log provided by the state PDMP that the health care system sends queries to. It will contain data elements validating when the query was received by the PDMP.	<ul style="list-style-type: none"> • Requestor Username • Request Datetime • Action (internal categorization of query) • Filter (details of search carried by data-sharing hub) • Request Information <ul style="list-style-type: none"> ○ Licensee ○ Requesting Site ○ State ○ Response Type ○ Identifier

Audit Log Source	Description	Data Elements That May Be Included
Integration Vendor	This is the audit log provided by the health care system's integration vendor (if applicable). Data elements may vary by vendor.	<p>The data elements involved in auditing by an integration vendor may be dependent on the vendor. The health care system and the integration vendor, if applicable, will need to maintain proactive communication to achieve successful auditing.</p> <ul style="list-style-type: none"> • Created Time • Facility ID • Patient Identifying Information • Clinician Name • Clinician Drug Enforcement Agency Registration Number (DEA) • Clinician National Provider Identifier (NPI) • EHR Username • Status • Response Extensible Markup Language (XML) • Total Prescription Returned • State License Code • Processed Time
Data-Sharing Hub	This is the audit log provided by the public data-sharing hub. It will contain data elements validating when and where the query was received from the EHR by the data-sharing hub, and when and where the response was received from the PDMP.	<p>The data elements below reflect what is provided by the public data-sharing hub. These data elements are consistent among all audit logs for queries sent through the public data-sharing hub.</p> <ul style="list-style-type: none"> • Audit ID • Request ID • Requesting Site • Disclosing Site • Requestor • Role • DEA • NPI • Request Datetime • Response Datetime • Request Status

Mapping Data Elements Across Audit Log Sources

The auditor may need to compare a specific query transaction across multiple audit logs to analyze PDMP-EHR integration use holistically. The EHR system's audit log will lend the perspective of the request initiation: when the PDMP query was initiated, by whom, and for whom. The data-sharing hub's audit log will lend an intermediary perspective: when the request was sent to the PDMP, by whom (and additional identifying elements), from where, the success or failure of a response generated from the PDMP, and when the response was sent back to the EHR. The PDMP's audit log would lend another perspective indicating when the PDMP received the request, by whom, from where, what it includes, and whether the PDMP successfully generated the response. Note, the data elements among these audit logs can overlap with each other as they are influenced by the PMIX standards. This consistency facilitates traceability of a query transaction among all audit logs. While there is much overlap among the audit logs, one audit log may give a different header name to the same data element as another. Be aware of the meanings of all data elements in each audit log for successful transaction

mapping across audit logs. Please note that there may be slight differences in the timestamps of a specific transaction among the different audit logs due to technical delays, time zone differences, and synchronization discrepancies. Table 2 below shows which data elements may appear in multiple data sources and, therefore, may be used to map transactions and support cross-analysis of audit log data.

Table 2. Mapping Audit Log Data Elements Across Audit Log Sources

Data Element Name	Description ¹	Audit Log Sources			
		EHR	PDMP	Integration Vendor	Public Data-Sharing Hub
Audit ID	Unique identifier of the audit log.				X
Request ID	Unique identifier of the query request.				X
Chart	Unique identifier of the patient chart in the EHR.	X			
Requesting Site (also referred to as Facility ID)	Unique identifier of the health care system where the request originated.	X	X	X	X
Disclosing Site	This is the facility in which data are requested from. This data element is not relevant to PDMP-EHR integration queries.				X
Requestor (sometimes referred to as Clinician Username, Provider Username, or EHR Username)	Unique identifier of the clinician or delegate submitting the query request.	X	X	X	X
Role	Role of the clinician submitting the request.				X
DEA (sometimes referred to as Licensee)	DEA number of the clinician submitting the request.		X	X	X

¹ The data element descriptions are loosely derived from multiple PDMP-EHR integration standards and project observations. In order to efficiently compare the data elements among the four audit log examples, the descriptions are brief and generalized. Please refer to the data source of each audit log to obtain precise descriptions of the data elements.

Data Element Name	Description ¹	Audit Log Sources			
		EHR	PDMP	Integration Vendor	Public Data-Sharing Hub
NPI (sometimes referred to as Licensee)	NPI number of the clinician submitting the request.			X	X
State (or state License Code)	State in which the request originated.		X	X	
Patient Identifying Information	Patient information such as name, date of birth, address, etc., sourced from the EHR.			X	
Request Datetime	Date and time of the request (Pay attention to the format of the data element. It may be in UTC.).	X	X	X	X
Response Datetime	Date and time of the response (Pay attention to the format of the data element. It may be in UTC.).			X	X
Filter	This is an internal data element to some PDMP databases.		X		
Action	This is an internal multi-level element included in some PDMP databases that measures query action history such as logging into the database and successful rendering of the data.		X		
Response XML	This is the XML of the query response that is available for viewing.			X	
Successfully Rendered/Viewed (sometimes referred to as Status or Request Status)	This element details whether the query request/response was successfully created and sent. This is usually a binary data element.	X	X	X	X

When to Use Audit Log Data

The analysis of audit log data can help health care systems assess three key aspects of integration maintenance: troubleshooting, compliance, and quality improvement. Below is an example use case scenario for each of the three aspects to help illustrate when health care systems might want to use audit log data, noting which data elements could be helpful to that scenario. Please note that there are multiple methods to solve a given problem. The following examples are learnings from PDMP-EHR integration technical demonstration sites and are not comprehensive of all auditing possibilities.

Troubleshooting Scenario: The health care system queries the PDMP from within the integrated EHR but is not receiving a response from the PDMP.

To troubleshoot this issue, the health care system checks the EHR's audit log. The audit log does not show data within the transaction. The EHR is not receiving a response message. Therefore, the health care system contacts their state PDMP or Health Information Exchange (HIE) liaison. The state PDMP or HIE checks the data-sharing hub's audit log, which displays transaction data for the query request from the EHR and the return response from PDMP, and the "successfully rendered/viewed" data element is populated positively. This indicates that the data-sharing hub is receiving the query and the PDMP is sending a response back to the EHR through the data-sharing hub, however the EHR is blocking the response. At this point, the health care system knows to reach out to their EHR vendor to solve the issue.

Compliance Scenario: The health care system wants to validate a specific clinician is checking the PDMP report before prescribing opioids.

This scenario could be encountered if a health care system wants to conduct a check to validate whether a specific clinician routinely checks the PDMP before writing a prescription, or if a clinician has expressed desire to validate that their queries are being recorded correctly to be counted for state compliance requirements. To address this, the appropriate individual from the health care system can ask the state PDMP liaison to check the state PDMP's audit log. To find this information, the state PDMP liaison could search for the specific DEA number of the relevant prescriber and identify queries conducted at the time of the relevant patient visit to determine compliance. If the PDMP stores queries across different audit logs and does not locate the particular query instance in one audit log, it will need to check across other internal logs to locate the query. This scenario may not be applicable in states where state policy does not allow the PDMP to share compliance data with the health care system.

Quality Improvement Scenario: The health care system wants to assess whether clinicians are meeting organizational goals to check the PDMP beyond those required by the state.

Some health care systems have policies that require clinicians to check the PDMP report before prescribing benzodiazepines. This is in addition to state requirements that mandate clinicians check the PDMP before prescribing opioids.

In this scenario, a health care system has an internal policy that requires clinicians to check the PDMP report before prescribing benzodiazepines and has developed quality improvement goals to decrease how often benzodiazepines are prescribed without a PDMP query. The health care system has already confirmed their EHR vendor's audit log and prescription data log can help them assess whether clinicians are checking the PDMP before prescriptions for benzodiazepines are created. Therefore, they use their EHR audit log to internally monitor the health care system's progress against their quality improvement goals to query the PDMP before prescribing benzodiazepines. The health care system can extract records for the specific clinician's PDMP queries and benzodiazepine prescriptions and match the date and time for these transactions to determine the ratio of PDMP queries to benzodiazepine prescriptions.

Table 3 below further summarizes ways in which audit log data can be applied to each of the three aspects of maintenance.

Table 3. How to Apply Audit Data to Integration Maintenance Objectives

Objective	How to Apply Audit Data
Troubleshooting	<ul style="list-style-type: none"> • Identifying patterns of failed PDMP query and response transactions (specific date, specific clinician, etc.) • Determining system performance/timeout issues or trends
Compliance	<ul style="list-style-type: none"> • Evaluating clinician- or prescription-level data for compliance analysis, if required and allowed per state/health care system policies <ul style="list-style-type: none"> ○ For example, verifying whether the PDMP was queried for each patient encounter where controlled substances/opioids were prescribed • Providing data for analysis of prescribing patterns such as: <ul style="list-style-type: none"> ○ Frequency of PDMP checks ○ Time of PDMP checks (e.g., prior to, during, or after the encounter/prescription) • Validating appropriateness of the PDMP check <ul style="list-style-type: none"> ○ For example, determining whether a PDMP is being queried inappropriately for individuals who are not the clinician’s patients ○ Researching specific concerns about user access or activity
Quality Improvement	<ul style="list-style-type: none"> • Tracking the progress towards quality improvement goals in opioid and controlled substance prescribing <ul style="list-style-type: none"> ○ Note: The Quality Improvement and Care Coordination: Implementing the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain document states that “...clinicians should check the PDMP data frequently when prescribing opioids,” (The Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain, 2018). The health care system should determine how it defines “frequently” and communicate what that frequency is to prescribers. If you choose to audit the frequency, an analysis of the timestamp data header in the audit logs can distinguish how frequently a clinician is checking the PDMP. • Supplementing cost analyses for integration in a health care system, such as determining return on investment (ROI) for the health care system’s integration and related maintenance costs

Appendix

This appendix includes diagrams illustrating the transactions involved in querying the state PDMP (both with and without an optional integration vendor involved), and a glossary of data elements from the Prescription Monitoring Information eXchange (PMIX) standards. These items are included here to illustrate the context of the PDMP-EHR integrated query relevant to the auditing discussions in this document.

The transaction figures below illustrate the sequence through which a query is transferred from its point of origin in the EHR system, through the data-sharing hub, to the state PDMP, and the response is sent back to the EHR system. Many of the prescription drug monitoring databases included in these transactions use PMIX standards in their code. Therefore, many of the data elements in the audit logs mentioned above are also included in the PMIX glossary.

Figure 1. Transaction Diagram without Integration Vendor

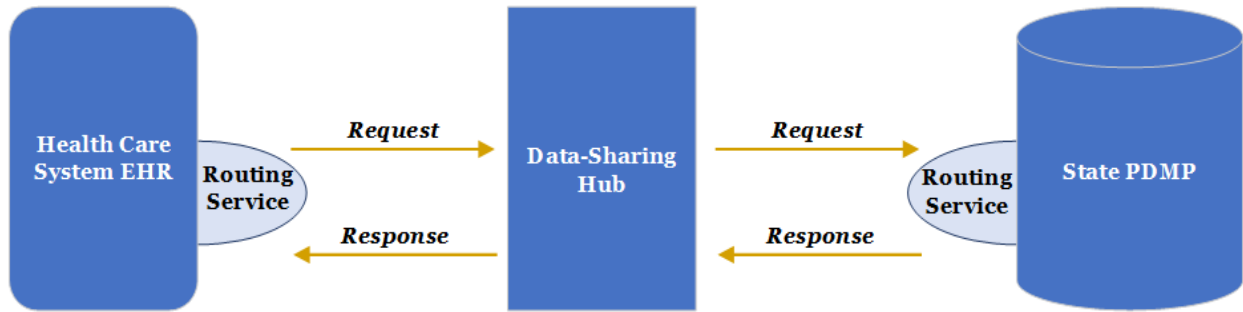
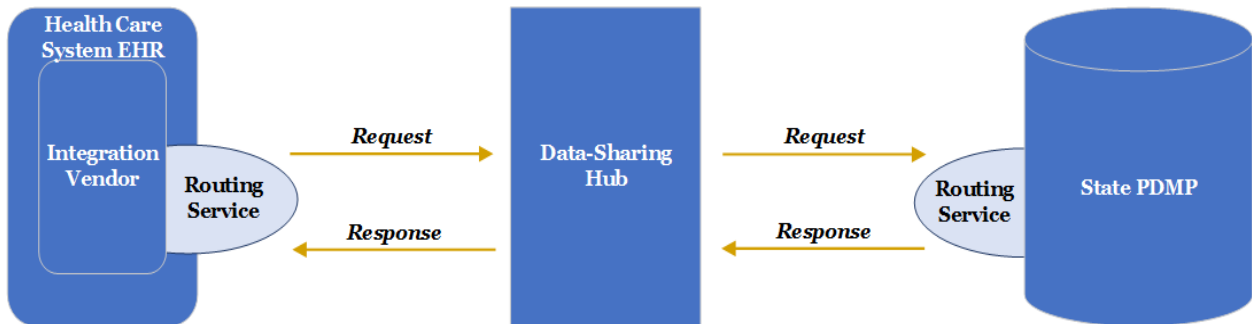


Figure 2. Transaction Diagram with Integration Vendor



PMIX Glossary ²

Data Type	PDMP Request Data Element	PMIX Data Element
Routing Information		
Request	Requestor	<pmix:Requestor>
	Requestor Role	<pmix:RequestorRole>
	Request ID	<pmix:RequestID>
	Request Date/Timestamp	N/A
Requestor Identifier	NPI Number	<nc:IdentificationID>
	DEA Number	<nc:IdentificationID>
Requesting Facility ID	DEA Number	<nc:IdentificationID>
	NCPDP Number	<nc:IdentificationID>
	NPI	<nc:IdentificationID>
Requesting Facility	Facility Name	<nc:OrganizationDoingBusinessAsName>
	State Code of Requesting Facility	<nc:LocationStateUSPostalServiceCode>
Message Body		
Patient	First Name	<nc:PersonGivenName>
	Last Name	<nc:PersonSurName>
	Date of Birth	<nc:PersonBirthDate>
Request Prescription Date Range	Start Date	<pmp:RequestPrescriptionDateRangeBegin>
	End Date	<pmp:RequestPrescriptionDateRangeEnd>

² (Prescription Monitoring Exchange Standards Organization, n.d.)

Data Type	PDMP Response Data Element	PMIX Data Element
Routing Information		
Response	Response Date/Timestamp	<pmp:ReportExecutionDate> <pmp:ReportExecutionTime>
	Response Prescription Date Range (Start Date)	<pmp:ReportDateRangeBegin>
	Response Prescription Date Range (End Date)	<pmp:ReportDateRangeEnd>
	Request ID	N/A
Message Body		
Patient	Patient First Name	<nc:PersonGivenName>
	Patient Last Name	<nc:PersonSurName>
	Patient Date of Birth	<nc:Date>
	Patient Gender	<j:PersonSexCode>
	Patient Street Address	<nc:StreetFullText>
	Patient City Address	<nc:LocationCityName>
	Patient State Code	<nc:LocationStateUSPostalServiceCode>
	Patient Zip Code	<nc:LocationPostalExtensionCod>
Patient Identifier	SSN	<nc:PersonSSNIdentification>
Prescription	Prescription Filled Date	<pmp:ReportDateRangeBegin> <pmp:ReportDateRangeEnd>
	Prescription Written Date	<pmp:PrescriptionWrittenDate>
	Prescription Number	<pmp:PrescriptionNumberText>
	Drug Name	<pmp:DrugProductNameText>
	Drug Strength	<pmp:DrugStrengthText>
	Dosage Form	<pmp:DrugUnitOfMeasureText>
	Drug Quantity	<pmp:DispensedQuantity>
	Days of Supply	<pmp:DaysSupplyCount>

Data Type	PDMP Response Data Element	PMIX Data Element
Routing Information		
	Refill Number	<pmp:DrugRefillNumberCount>
	Refills Authorized	<pmp:RefillsAuthorizedCount>
	Partial Fill Indicator	<pmp:PartialFillIndicator>
	Method of Payment	<pmp:MethodOfPaymentCode>
Drug	Product ID Qualifier	<pmp:DrugCPDProductIdentifier> <pmp:DrugDINProductIdentifier> <pmp:DrugHRIPProductIdentifier> <pmp:DrugNDCProductIdentifier> <pmp:DrugUPCProductIdentifier> <pmp:DrugUPNProductIdentifier>
	Product ID	<nc:IdentificationID>
Dispenser Organization	Dispenser Organization Name (Facility)	<nc:OrganizationDoingBusinessAsName>
	Dispenser Organization Street Address	<nc:StreetFullText>
	Dispenser Organization City Address	<nc:LocationCityName>
	Dispenser Organization State Code	<nc:LocationStateUSPostalServiceCode>
	Dispenser Organization Zip Code	<nc:LocationPostalCode>
	Dispenser Organization Phone Number	<nc:TelephoneNumberFullID>
Dispenser Organization (Pharmacy Identifier)	DEA Number	<nc:IdentificationID>
	NCPDP Number	<nc:IdentificationID>

Data Type	PDMP Response Data Element	PMIX Data Element
Routing Information		
	NPI Number	<nc:IdentificationID>
Prescriber	Prescriber First Name	<nc:PersonGivenName>
	Prescriber Last Name	<nc:PersonSurName>
	Prescriber Street Address	<nc:StreetFullText>
	Prescriber City Address	<nc:LocationCityName>
	Prescriber State Code	<nc:LocationStateUSPostalServiceCode>
	Prescriber Zip Code	<nc:LocationPostalCode>
Prescriber Identifier	DEA Number	<nc:IdentificationID>
	NPI Number	<nc:IdentificationID>
	State License Identifier	<nc:IdentificationID>
	State of License	<nc:IdentificationID>

References

1. Centers for Disease Control and Prevention. *Quality Improvement and Care Coordination: Implementing the CDC Guideline for Prescribing Opioids for Chronic Pain*. 2018. National Center for Injury Prevention and Control, Division of Unintentional Injury Prevention, Atlanta, GA.
2. *Prescription Monitoring Information Exchange (PMIX) Standards Organization*. (n.d.). Prescription Monitoring Information Exchange (PMIX) Standards Organization. Retrieved December 16, 2021, from <https://www.pdmpassist.org/PMIX>