Ease of Use   Fit with Workflow

Technical Impact

Clinical Impact   Driver Adoption
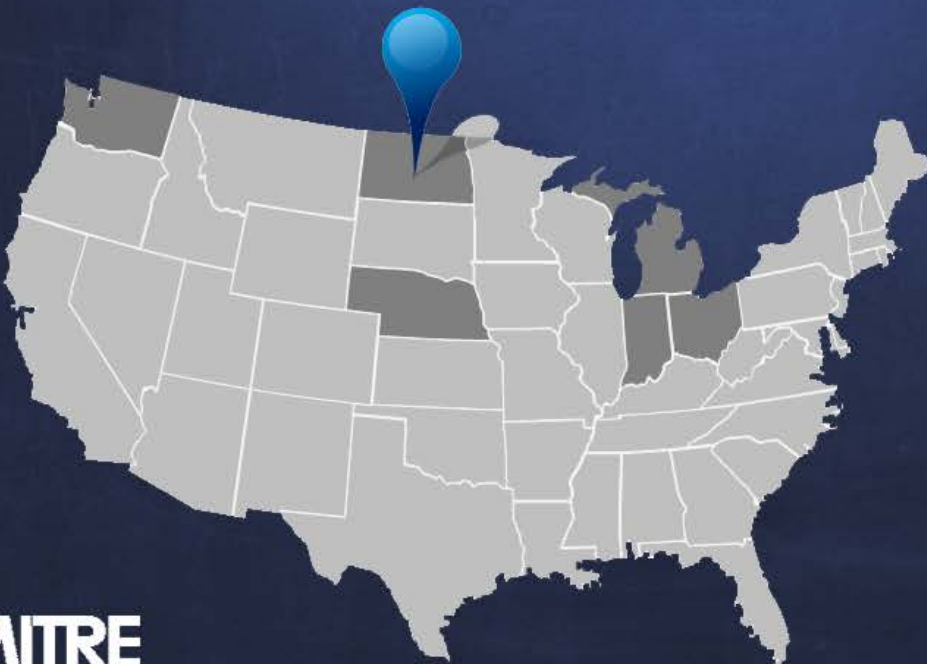
Optimization Factors

Enhancing Access to Prescription Drug Monitoring Programs Using Health Information Technology:

Linking the Indian Health Service Pharmacy to a Prescription Drug Monitoring Program: A Pilot Study

2012

The Office of the National Coordinator for
Health Information Technology

Substance Abuse and Mental Health Services Administration
✚SAMHSA

MITRE

Overview

Goal

The Fort Totten Indian Health Service (IHS) pilot demonstrated the value of health IT connectivity by:

- Automating the query to the state Prescription Drug Monitoring Program (PDMP), thereby eliminating a manual checking process by the dispenser (pharmacist)
- Making PDMP data more readily available during patient encounters within the pharmacy system
- Repurposing and leveraging an existing automated process used for insurance benefits checking

This pilot configuration showcased the workflow, ease of use, and added technical value of improved access to the PDMP in the pharmacy setting.

Pilot Design

The North Dakota pilot automated the query to the state PDMP by repurposing and leveraging an existing process for checking insurance eligibility. Parties participating in this pilot included:

- The pharmacy system (known as the Resource and Patient Management System, or RPMS) in place at the Fort Totten IHS Pharmacy (part of the Spirit Lake Health Center)
- The Emdeon benefits management switch (*Emdeon Connect*) and Rules Engine (*Emdeon Edit*)
- The North Dakota PDMP through the Prescription Monitoring Program InterConnect (PMPi) interstate data hub
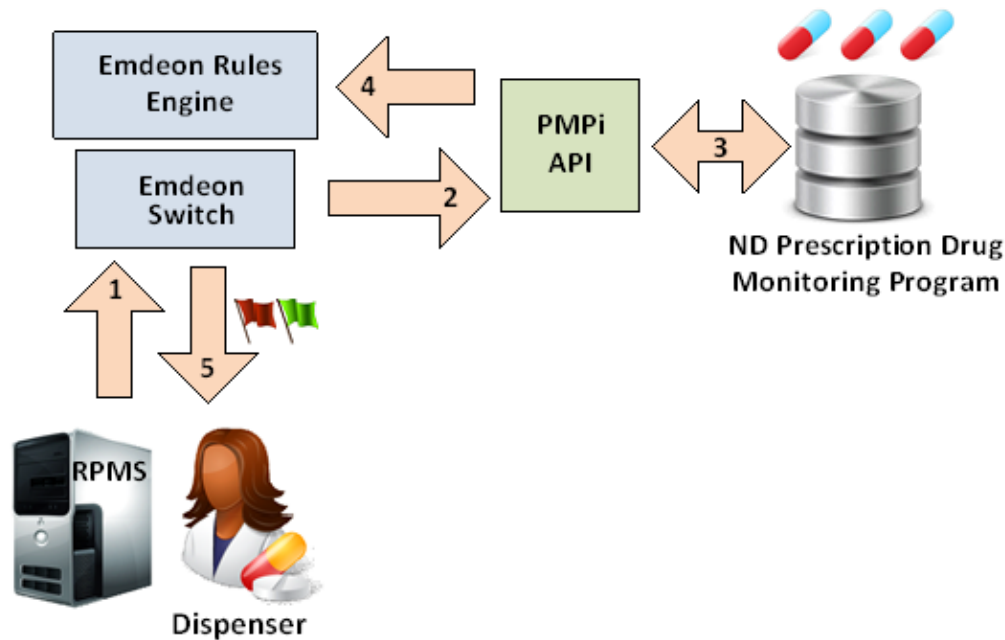
Figure 1. Pilot Workflow Diagram

Figure 1 shows the following steps of the pilot workflow:

1. For requests to fill prescriptions for scheduled drugs in RPMS, the dispenser manually triggers a specially tagged eligibility request message ("E1*"), which is passed to the Emdeon switch.

2. The switch uses the data in the message to generate a PDMP query, which is sent to the PMPi interface with instructions to query the North Dakota PDMP.

3. PMPi submits a query to the PDMP for that patient for 1 month (30 days) and receives the response.

4. PMPi sends the response to Emdeon, where the Emdeon rules engine analyzes the data and identifies patients potentially at risk using a previously established IHS threshold. This generates a single-digit response code ("flag").

5. The switch returns the response code to the RPMS system for use by the dispenser at the point of care. Based on the result, the dispenser follows specific procedures defined by IHS.

To identify patients potentially "at risk," *Emdeon Edit* calculated a response code by comparing the PDMP data to a set of rules and thresholds proposed by IHS (3/3/1—exceeding three prescribers or three pharmacies as the source of scheduled prescription drugs in a one month time-frame). Dispensers at Spirit Lake Health Center ran queries on patients filling prescriptions for all scheduled drugs plus Tramadol, an unscheduled drug which the state has determined must also be tracked by the PDMP.

Appendix A describes the pilot's technical considerations, including the list of participants. Appendices B and C discuss the operational and legal considerations, respectively.

Experiment

Pre-Pilot State

Within the Indian Health Service at Spirit Lake, most PDMP queries are requested by prescribers (as "consults"), not dispensers. However, it is the dispenser who performs the actual query and then enters the PDMP data and/or notes into the RPMS system, which the prescriber and dispenser share. Dispensers may also perform queries based on their own determination. Very few outsiders (those not directly connected with IHS) use this facility, and there are no cash payments at the pharmacy.

In the six-month window between January 1 and July 1, 2012, Spirit Lake Health Center performed 151 PDMP inquiries from this facility, 91% of which were "consults." All queries were conducted through the North Dakota PDMP web interface, which required manual login and patient data entry. When performing these manual queries, the pharmacy staff used a feature that allowed imperfect matches for both name and date of birth (DOB), and manually selected from the raw data on the state portal to derive a clear picture of that patient. This process may be prone to errors.

Hypotheses and Specific Methods

The following hypotheses in Table 1 directly relate to the six areas of interest that were the basis for evaluating the effectiveness of the pilots. Appendix D describes the evaluation methods in detail.

Table 1. Hypotheses and Intended Impacts

Area of Interest	Intended Impact
Ease of Use	Easier for dispenser staff to access the PDMP
Fit with Workflow	Improves pharmacy processes and is accessible at the proper place in the workflow
Technical Impact	Results in more pharmacy queries
Clinical Impact	Results in greater oversight of patients, with those most in need receiving the necessary additional attention
Driver of Adoption	Well accepted by the participants, and the pilot drives further adoption by other (IHS) sites or user groups (e.g., prescribers)
Optimization Factors	Has identifiable opportunities to improve

The pilot execution phase included 15 days for data collection. Table 2 defines the response codes delivered by the switch.

Table 2. Response Codes

Response Code	Meaning
A	"Green flag" – Patient not "at risk".
B	"Red flag" – Patient may be "at risk" and should be subjected to additional scrutiny.
C	Rules engine cannot determine if the patient is "at risk" or not. Examples: no patient matches, multiple patient matches, no data in that date range for an identified patient, web service errors, other circumstances
R	Timeout – Retry query as time permits.

Results

Table 3 lists the pilot patient query results. The pilot was deemed a success, though some opportunities for improvement remained. In particular, the query failure rate (Code C) was too high for optimal use, and more than 30% of queries resulted in timeouts on the first attempt. Table 4 addresses the pilot analysis results in light of the specific evaluation criteria outlined in Appendix D.   In particular, the very large increase in self-initiated queries showed definitively that enabling access through the switch provides major leverage for increasing use of PDMP data by dispensers.

Table 3. Pilot Results

Unique Patients	Code A	Code B	Code C
182	31	1	150

Table 4. Analysis Results

Area of Interest	Participating Dispenser Response
Ease of Use	75% believed that the pilot configuration made it easier to look up patients. 50% were satisfied with quality of the data itself.
Fit with Workflow	100% believed the manual request feature is both at the proper place in the workflow and superior to the previously used option for patient lookups.
Technical Impact	Queries initiated by dispensers showed a 112-fold increase on a per-week basis. All requests (including "consults") showed more than a 10-fold increase on a per-week basis.
Clinical Impact	50% were satisfied with data provided for clinical use. Further analysis was hindered by the fact that only one "red flag" patient was identified. No preventive action could be taken because this patient did not attempt to obtain scheduled drugs at the IHS pharmacy during the pilot.
Driver of Adoption	75% wished to continue to use this capability, and 100% would recommend it to their colleagues for adoption.

Optimization Factors	100% identified additional features or capabilities that would enhance this tool.

Discussion

A major issue for the pilot was the high frequency of code C responses (meaning the rules engine could not determine if the patient was "at risk"). Causes of a Code C include, but are not limited to:

- Match to multiple patients
- Match to no patients
- Single matched patient with no PDMP data in the 30-day time window
- Web service errors

The pharmacy system did not have the ability to identify which of the multiple causes of a Code C response was responsible for a particular patient. This was noted by all participants as a feature that should be addressed in a future iteration. As an added difficulty, IHS dispensers noted that correct DOB and a high degree of name variation are known problems in the data stored in the RPMS system. These issues are also seen in the state PDMP data. The dispensers have historically addressed this by configuring the query to allow close name matches and a multi-year window for DOB, and resolved the results by manual review. We note that some states perform clustering to ensure that these small variations (especially name) are addressed in a more systematic manner. IHS staff noted that they could request that clusters of these records be created by calling the state, though the process was somewhat onerous. In addition, it was discovered late in the pilot that there are subtle differences in query response types from a state PDMP versus the PMPi. It is believed that small differences between how the PMPi and the ND PDMP handle single-matched patients without data in the query time range caused many A responses to become C's. This could greatly complicate a multi-state query, necessitating very careful up-front analysis.

Many of the participants' suggestions centered on the issue of being able to better address ambiguous matches within the tool. Such a capability would be expected to increase the clinical value of enhanced PDMP access. The participants also expressed a number of other specific suggestions for improving PDMP access:

- A strong desire to explore alternative ways of accessing the data, including having the switch response offer an option for viewing the raw data. Some even suggested that the raw data should automatically display for all "red flag" patients. These options invoke some privacy concerns.
- Improvements to the method of access—passing both sign-on credentials and patient query information to the state web portal from within RPMS, and showing the results in a pop-up state web portal window.

- Reducing the threshold to 2/2/1 or always displaying the last prescription filled as means to better monitor recent patient activity.
- Allowing the switch to log more data to help in troubleshooting, though this too potentially raises privacy concerns.

Outcome and Next Steps

The tool will remain in use for the time being, and discussions are ongoing with IHS regarding future options, including improving functionality and expanding to multi-state queries. PMPi is already in place in some states with large IHS-served populations (e.g., Michigan, Arizona) and could provide considerable leverage for this expansion. Prescribers at IHS sites also use RPMS, and expansion of the switch-enabled query capability to this group represents another potential next step. Efforts to build on this program would be well-served by addressing the issues identified during this pilot, especially the slow response time and relatively high failure rate of queries.

Other Pilots

The Enhancing Access to PDMP project conducted five additional pilots in Fiscal Year 2012 which are available for review. The pilots encompass a variety of user groups, including dispensers (pharmacists) and prescribers (ambulatory and emergency department) as well as different technological solutions. These papers can be found at the Office of the National Coordinator for Health Information Technology (ONC) PDMP website: http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3870.

Appendix A. Technical Considerations

The following sections contain a detailed description of the pilot design, including participants and technologies.

Participants

The following parties participated in the pilot:

- **North Dakota Board of Pharmacy** (http://www.nodakpharmacy.com) – A state agency responsible for licensing pharmacies, issuing permits to operate pharmacies, and regulating prescription drug distribution within the state. It is the owner of the state PDMP and is based in Bismarck, ND.

- **United States Indian Health Service** (IHS, http://www.ihs.gov) – A division of the Department of Health and Human Services that provides health care to American Indians through 33 hospitals, 59 health centers, and 50 health stations. IHS headquarters are in Rockville, MD.

- **Spirit Lake Health Center** (http://www.ihs.gov/Aberdeen/index.cfm?module=ab_ao_hf_slsu) – A clinic and pharmacy that falls under the IHS Aberdeen Service Area. This facility is located on the Spirit Lake Sioux Reservation, Fort Totten, ND.

- **Emdeon** (http://www.emdeon.com) – A national benefits switch and related technology provider located in Nashville, TN. Emdeon provided the switch (*Emdeon Connect*) and rules engine (*Emdeon Edit*) components and made modifications to their systems necessary to support the pilot activities.

- **CAS Severn** (http://cassevern.com) – An established contractor and technology vendor to IHS, located in Laurel, MD. CAS Severn performed the necessary RPMS system modifications.

- **National Association of Boards of Pharmacy** (NABP, http://www.nabp.net) – The provider of the PMP InterConnect (PMPi) interstate data hub, based in Mount Prospect, IL.

- **Appriss** (http://www.appriss.com) – An established technology vendor to NABP, located in Louisville, KY. Appriss provided configuration management for the use of PMPi during the pilot.

Relevant Technologies and Tools

The following technologies and tools were vital components of the pilot.

Switch

National Council for Prescription Drug Programs (NCPDP) billing and eligibility claims are usually transmitted through a routing service ("switch"), which helps to ensure that the millions of submitted claims reach the correct payers and that the payers' responses make it back to the

originating party. For example, *Emdeon Connect* is a "third-party claims switching service" that provides full access to all third party processors in the United States. *Emdeon Connect* customers have access to *Emdeon ScriptView*, which allows users to view their transmitted and received claim data and responses. This information simplifies processor troubleshooting and historic claim research. This connectivity infrastructure is absolutely critical for modern pharmacy operation, and it served as the major connectivity and communication platform for the pilot. More details are available at
http://www.emdeon.com/resourcepdfs/EMDA1010333.pdf.

Rules Engine

A (Business) Rules Engine, or "Inference Engine," is software designed to derive answers from an existing base of knowledge to formulate new conclusions. These entities operate on a set of pre-defined rules that comprise statements describing specific business policies or procedures. For example, the *Emdeon Edit* rules engine provides financial, administrative, and legal compliance reviews on transactions that pass through the *Emdeon Connect* claims switching service ("Switch"). Rules applying thresholds to PDMP data, as accomplished through *Emdeon Edit*, were a vital to the pilot project. More details are available at
http://www.emdeon.com/resourcepdfs/EMDA1010338.pdf.

Prescription Monitoring Program InterConnect (PMPi) / Representational State Transfer (REST)

NABP's PMPi is a system that facilitates the secure sharing of data between state PMPs. The InterConnect rules engine allows each participating state full autonomy to enforce its own rules and policies of data access when sharing with other states. InterConnect does not house any data but serves as a conduit. PMPi uses the PMIX messaging specification developed by the Bureau of Justice Assistance. The system is implemented using a REST architecture, one optimized for distributed systems. PMPi serves as the application programming interface (API) for the ND PDMP in this pilot (seeing Emdeon as a state), a role which was not envisioned during the design or rollout of this hub. This may introduce additional complexities for multi-state pilots. Note that this API configuration was seen in three pilots. More details are available at http://www.nabp.net/programs/assets/PMPInterconnectFactSheet.pdf.

Resource and Patient Management System (RPMS)

RPMS is an integrated clinical and administrative management solution for healthcare facilities used by IHS. It provides a comprehensive clinical, financial, and administrative solution, and is used to efficiently manage programs, maximize revenue generation, and provide high-quality care for patients. RPMS was adapted from the Veterans Health Information System and Technology Architecture (VistA), which was originally developed by the United States Department of Veterans Affairs. More details are available at http://www.ihs.gov/rpms and http://linuxmednews.com/1183676336.

Extensible Markup Language (XML)

XML is an open standard for defining data elements on both web pages and business-to-business documents. XML uses a similar tag structure as Hypertext Markup Language (HTML),

but while the latter defines how elements are displayed, the former defines the contents of the elements. By providing a common method for identifying data, XML supports business-to-business transactions and has become a widely adopted format for electronic data interchange. XML serves as the basis for the Emdeon transactions with the ND PDMP.

Modifications to RPMS

The telecommunication standard used was NCPDP Version D.0. Only a few fields were modified from the standard E1 specification to implement the pilot transaction request.

For *Emdeon Connect* to recognize the transaction as a request for PDMP data, the following header fields were set to the following values:

- NCPDP Field 101 (BIN #): 610144
- NCPDP Field 104 (PCN): NDPMP

For *Emdeon Connect* to recognize where the request is coming from, the following header field is also required:

- NCPDP Field 201 (Service Provider Id): Set to North Dakota Pharmacy National Provider Identifier (NPI)

The following required patient record data was sent for the State of ND to match on the patient:

- NCPDP Field 304 (Date of Birth)
- NCPDP Field 310 (Patient First Name)
- NCPDP Field 311 (Patient Last Name)

The following required header fields were not modified but were sent:

- NCPDP Field 102 (Version): D0
- NCPDP Field 103 (Transaction code): E1
- NCPDP Field 109 (Transaction count): 1
- NCPDP Field 202 (Service Provider Id Qualifier): 01
- NCPDP Field 401 (Date of Service): Request date

The following data was sent, but not required:

- NCPDP Field 302 (Patient Medicare ID)
- NCPDP Field 305 (Patient Gender)
- NCPDP Field 325 (Patient ZIP code)

In response, the following fields are required to be sent back:

- NCPDP Field 112 (Transaction response status)
- NCPDP Field 504 (Message field)

In the standard E1 transaction response, there are only two status options: a status of 'A' (Active) or 'R' (Rejected) response. The standard E1 message field also contains a message string that needs to be parsed out into Primary, Secondary, and Tertiary Insurance information. For the PDMP response (E1*), the message field is no longer parsed. The E1* status display was modified to show just the fields of Request Date, Patient Name, Status Code, and Result text. The following response codes are allowed:

- 'A' – PDMP Check performed and no further evaluation required
- 'B' – PDMP Check performed and further evaluation suggested
- 'C' – PDMP Check NOT performed, manual evaluation required
- 'R' – Rejected for timeout issues

Modifications to Emdeon Components

Emdeon Switch

- No changes required to accept E1* transaction from RPMS

Emdeon Pre and Post-Editing System

- New edit configuration
  - Qualifier for store
  - Qualifier for "dummy" BIN
- Connection to Web Service
- Creation of E1* response back to pharmacy
- Creation of Reporting Data Object to populate Report table

Emdeon Web Service

- New Web Service created to communicate with PMPi
- XML creation based on Appriss technical specifications document
- Connection to PMPi for request and response from PMPi
- Encryption based on Appriss technical specifications document
- Disclosure report interrogation based on IHS 3/3/1 criteria

- Creation of Transaction Response Code back to Pre and Post-Edit System based on report interrogation

Testing and Deployment Issues

This pilot configuration had many parts and players, each with their own features and policies, which made testing challenging. In particular, the unwillingness of Health Information Designs (HID, host of the ND PDMP) to place test patients temporarily in the system introduced some difficulties. Adding to this was the fact that the E1* message was configured to take the patient information (in the form of a RPMS "chart ID" number) for the query from RPMS, so any test patients would need to be in that system or be entered into it for testing purposes. PMPi could point towards the test or production environments at HID, though there was concern that any difference between the two could be very problematic for the switch and rules engine. Finally, the Emdeon environment consists of either totally isolated or in-production systems, though the latter can be controlled by restricting access to a small time window and limiting to certain participating sites. The sum of these parameters necessitated the use of "limited production" testing, in which a production version was hosted at Emdeon for testing with the IHS test (and production) environments.

The most significant pitfalls identified in the testing, and continuing into deployment, related to query response time. First, the response time for the PDMP query through PMPi exceeded our initial estimate of 10 seconds. This necessitated the increase of the timeout limit to 30 seconds in *Emdeon Edit*. The times seen in the pilot are deemed by Emdeon as incompatible with typical switch traffic (often 2 seconds or less) and needed to be quarantined from the rest of the systems. Transaction time prevented the pilot from using billing (B) transaction and necessitated the use of the eligibility (E) one instead. Opinions differ, but some believe that the former is better placed in the workflow. Use of the billing transaction would also allow the checks to be run automatically rather than manually.

The cause of the pervasive query slowness was never fully determined, and Appriss claims that the actual PDMP + hub response time is not especially slow. During the pilot's second week, the response time was assessed as less than 2 seconds based on ND PDMP system timestamps, which is well below the Emdeon threshold. On Emdeon's side, the queries appeared to be much, much slower, as was noted in the high frequency of timeouts. The issue of this temporal difference was never reconciled. The second issue relates to the presence of a (previously unknown) second timeout trigger point within *Emdeon Connect*. This could not be reset just for the pilot (it is system-wide), and thus it was necessary to re-route pilot transactions to a system subdomain (i.e., not with the other switch traffic) where we could control this factor. This was also reset to 30 seconds. The RPMS default timeout, 60 seconds, was never an issue during the pilot. It was also noted that the PMPi interface sporadically lost recognition of the Emdeon web service. This de-authentication occurred for roughly 20% of the queries. Emdeon and Appriss jointly investigated this but were unable to come to a definitive conclusion as to the underlying cause.

Test patients were needed for all three response code types to ensure that the system was performing as desired. Emdeon created a set of fictitious test patients, but these could not be used due to HID's policies (i.e., no dummy patients in the production database). Instead, all test patients were current (real) patients of the Spirit Lake Health Center, including those for whom an unsolicited alert had been previously received by the pharmacy (as likely "red flag" candidates). However, it became clear that as the time window for the query was only 1 month, even likely candidate test patients had often fallen back into compliance. To complete testing, the limit was temporarily lowered to 1/1/1, allowing the team to obtain the first "red flag" (for an otherwise "green flag" patient). This result category was later confirmed for a real "red flag" patient. All test patients were subject to a ND PDMP manual query to ensure accuracy of the rules engine results, and all were determined to be correct on this basis. The logging tool built into RPMS was reset prior to the pilot execution phase to clear out the test data. The first week of pilot execution also contained a modest number of audits to ensure that the results were correct.

It was noted during execution that the standard workflow of the pharmacy uses a fairly loose query of the state PDMP web portal for both name (starts with) and DOB (2-year range). Subsequent pharmacist curation of the results narrows down the data that will be used to evaluate the patient's status. This would not be trivial to automate, but might instead be better achieved by clustering records in the state PDMP. Difficulties with clustering have been previously noted. Conversely, the switch query was more strict and required full matching of name and DOB. The differences between the results obtained by manual and automated lookups caused by this query difference was a source of considerable concern during execution.

One final concern relates to the nature of the *Emdeon Edit* analysis and how *Emdeon Edit* performs its role. The rules engine operates by counting the number of identifiers, including Drug Enforcement Agency (DEA) and NPI numbers affiliated with the prescribers and pharmacies. However, the present iteration does not normalize the data, so a patient with three opioid prescriptions (which require DEA numbers) from three different providers and one prescription for Tramadol from a fourth (which does not require a DEA number since it is not scheduled) would not be counted as having four prescribers by *Emdeon Edit*. This should be addressed at some future date.

User Interface

Figures A-1 to A-3 show examples of the response code views for all three expected patient response codes (not counting Code R).

Figure A-1. "Green Flag" (Code A) Patient Response in RPMS

Figure A-2. "Red Flag" (Code B) Patient Response in RPMS

```
Generate PMP chk for which patient?
███████████████████████████████████████████████

Transmitting PMP check, please stand by.....



Send report to device: HOME//   virtual

On:                AUG 20, 2012010:26:03
Patient Name:      ████████████████
Status:            c
Result:            PMP Check NOT performed, manual evaluation required
                   d



Generate PMP chk for which patient?



     AAC     IMPORT ENTRIES FROM AAC FILE
     APS     Benchmark Price Update Status
     ATFF    Auto-finish failure report
     AMP     Benchmark Price Manual Update
```
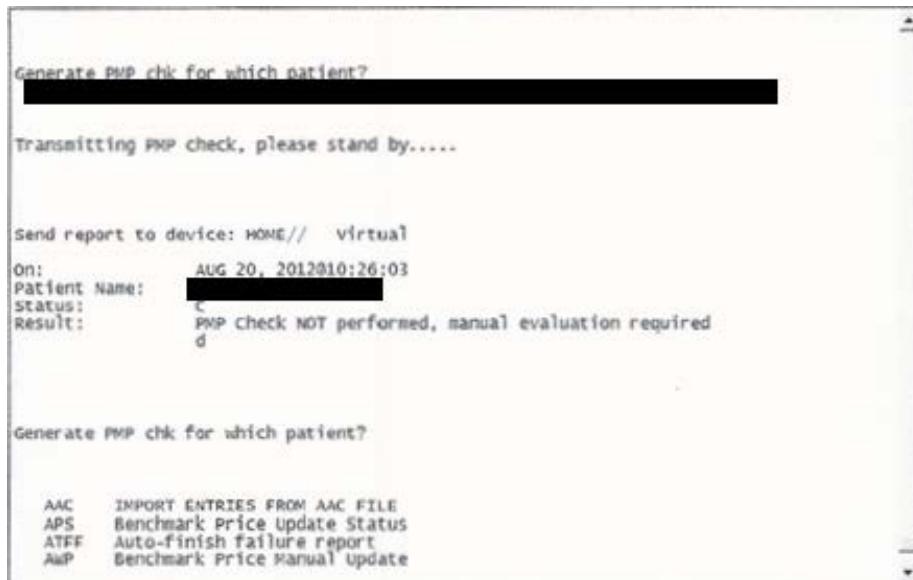
Figure A-3. Code C (Indeterminate) Patient Response in RPMS

Detailed Description of Workflow

The following list describes the specific, detailed steps that constitute the pilot workflow. Figure 1 shows a much simplified, higher-level view.

1. Dispensers in Fort Totten, ND had RPMS and existing connections to various infrastructure.

2. The dispenser made the decision to check the PDMP based on a patient's prescription for a controlled substance.

3. In RPMS, the dispenser used a new menu feature (developed as part of the project and available only to the dispenser) to manually create a specially tagged E1 message ("E1*").

   a. This tagging was through a Bank Identification Number (BIN) and Procedure Code System (PCS) code, which Emdeon calls a "dummy BIN." IHS and Emdeon created this code on their own.

   b. This was an NCPDP transaction and had patient first and last names and DOB.

      i. DOB was an issue, as more than one distinct DOB may be available in the system.

4. This E1* message was sent to the Emdeon Switch.

5. The Switch used the data in the message to format a query to PMPi, seeking ND data. This query was for the last month (time range).

6. The query was sent to PMPi.

7. PMPi processed the request in the ND PDMP.

8. The ND PDMP returned the standard data output for the query to PMPi (XML).

9. PMPi passed the output back to the Emdeon Switch.

10. An Emdeon Rules Engine (internal to Emdeon systems) analyzed the returned data using the 3/3/1 IHS threshold (exceeding 3 doctors or 3 pharmacies in 1 month [30 days] as the source of scheduled prescription drugs). The analysis generated one of four possible outcomes:

    a. A = Accept ("green flag")

    b. B = Patient of concern ("red flag")

    c. C = Query failed (e.g., lack of single match, no data, etc.). This result came without a detailed analysis by a rules engine, by definition.

    d. R = Query failed because of timeout.

11. Emdeon passed the result code back to the RPMS system through the E1 (E1*) channel (into the "response status segment field"). This was supplemented by a small amount of text in an appropriate text block.

    a. This was a "next step" message, consistent with IHS pharmacy operations views (see step 13).

12. Emdeon archived the E1* message but deleted the ND PDMP data from memory, as part of sensitivity to privacy.

13. The dispenser, having received training, took appropriate action at the point of care, as defined by IHS (see Appendix C).

Appendix B. Operational Considerations

Key Operational Assumptions

- Pilot site is limited to one pharmacy in Fort Totten, North Dakota (Spirit Lake Sioux Reservation), with existing switch (*Emdeon Connect*) connectivity.

- Dispensers and pharmacy techs at Spirit Lake Heath Center will participate "willingly" as a result of their employee status.

- Pilot will only request data only from the state in which the pharmacy resides, removing interstate data transfer and access issues.

- There will be an adequate number of patients seeking scheduled prescription drugs during the operational period to collect reasonable metrics (estimated at ~400 prescriptions per day total, with 20–40 of them for controlled substances or Tramadol).

- The RPMS system will provide the correct birthdays for patients (based on the patient registration package), and these will match those in the PDMP.

- The *Emdeon Edit* rules engine can effectively parse the PDMP data and analyze it according to the IHS thresholds using Emdeon-derived rules.

- The expected lag time for the PMPi/PDMP response is not too lengthy, which would result in excessive timeouts (initially a 10 second limit, **not met**).

- The desired threshold (3/3/1) will not trigger too many "red flag" responses, which would be the equivalent of a high false positive rate and would negatively impact workflow (**met, but the opposite ended up being an issue**).

- PMPi, IHS, and the North Dakota Board of Pharmacy will agree to all aspects of the pilot design, including the role of the switch.

- Consistent with the recommendations of the Business Agreements for Intermediaries Work Group, Business Associate Agreements (BAA) will be sufficient for conducting the pilot project. If not, the necessary agreements will not be overly difficult to craft or negotiate.

- While the Fort Totten facility is a 3-hour drive from Fargo and about a 2-hour drive from the closest alternative IHS site (Belcourt, ND), the (non-reservation) town of Devil's Lake is only a 10-minute drive away and has several pharmacies.

- All pharmacies report to the state, as do all mail order pharmacies that deliver to North Dakota.

- No patients classified as code A or B will show a changed code when queried multiple times.

Operational Advantages or Barriers

The State of North Dakota was very accommodating of all requests made during the pilot, as was Indian Health Service. The North Dakota PDMP has very current data, with daily to weekly reporting for many pharmacies, so practitioners can have great confidence that the data is not stale. Federal sites report weekly. The vast majority of prescriptions fulfilled at this pharmacy originated at the affiliated and co-located IHS clinic.

This pilot had a relatively large number of participating organizations and thus was intrinsically more susceptible to project interruptions caused by delays in any entity. The small population size served by the pilot facility (< 10,000) may have restricted the number of patients available for data collection. The aggressive development timeline, coupled with a hesitancy to allow the switch vendor to view the data (for privacy concerns), did not permit a thorough exploration of potential problems that could (and did) occur, nor the kind of detailed logging of intermediate results that would have made subsequent troubleshooting easier. The issue of legal agreements between parties with highly divergent responsibilities was sometimes very problematic from a timeline perspective (e.g., NABP and Emdeon), but not always (Emdeon and IHS). Extending the pilot (or second-generation) capability to multiple states would likely increase the complexity of the agreement structures needed, though having the new Emdeon-NABP agreement would perhaps reduce this somewhat.

Pilot Schedule

Table B-1 outlines the pilot schedule, normalized based on the 5-day work week because Spirit Lake Pharmacy is not open on weekends. The planning schedule also varied slightly between participants (e.g., CAS Severn joined later than Emdeon and had less planning and coding time).

Table B-1. Pilot Schedule

Task Name	Start	Finish	Duration
Planning	May 14, 2012	June 8, 2012	20 days
Coding, Testing, Deployment	June 11, 2012	August 14, 2012	47 days
Execution/Monitoring	August 15, 2012	September 5, 2012	15 days
Post-Pilot Analysis/Report	September 6,2012	September 14, 2012	12 days

Pilot Costs

Table B-2 shows the pilot costs. MITRE subcontracts are fixed price instruments. It is noted that no participants requested legal review costs for business (e.g., MITRE subcontract) and privacy-protection purposes (e.g., BAA or other agreements between Emdeon and IHS or NABP). Other expenses may also have been insufficiently enumerated in this list (e.g., anything done by IHS staff, including training and manual logging of activities resulting from a "red flag" response), and regional cost factors may likewise play a role in the quoted prices. Thus, the actual cost of reproducing this pilot elsewhere may be more or less than this amount, even when attempting to exactly replicate these circumstances.

Table B-2. Pilot Costs

Vendor	Services	Subcontract
Emdeon	Modifications to the switch system, generation of new business rules, testing, deployment, monitoring	$33,500
CAS Severn	Modifications to RPMS, testing, deployment, monitoring	$42,200
Appriss	Connectivity, configuration of PMPi interface for use by Emdeon, monitoring	$1,000/month

Appendix C. Legal Considerations

This section looks at the policy and regulatory considerations and obstacles, as well as the agreements implemented.

Policy and Regulatory Considerations

To successfully conduct the pilot on production systems, certain laws and policies need to be in place to support the pilot design. The following considerations were most applicable to this pilot:

- Policies for authentication: Standard PMPi and ND Board of Pharmacy rules apply and can be met.

- Dispensers are explicitly allowed to delegate to their staff the authority to view PDMP records. In such cases, the dispenser retains the responsibility to ensure that patent privacy is protected. (http://www.nodakpharmacy.com/PDMP-faq.asp#di)

- Dispensers, or their delegates, prospectively decide to create the E1* message. In this light, it is noteworthy that IHS policy does not allow pharmacy technicians to use the pilot query system, but they do have access to the state database.

- Prescribers and dispensers may both obtain access to the ND PDMP by state law (http://www.nodakpharmacy.com/PDMP-faq.asp#di), but at the IHS facility, only dispensers have access by policy.

- Agreements: Typical BAAs can be put into place between participants, or if not, the required agreement structure will not be onerous (**not met**).

- The federal/tribal vs. state issue will not impede the pilot. IHS will endeavor to follow relevant state policies, but is not strictly legally obligated to do so.

- As neither NABP nor the State of ND wanted Emdeon to store (even briefly) any actual PDMP result after the rules engine action, all results were purged from the system. This was not optimal from a logging and troubleshooting perspective, but better protected patient privacy.

- North Dakota requires daily reporting by all in-state facilities, but allows federal facilities up to 1 week to report. Veteran's Health Administration facilities do not report at this time. Out-of-state pharmacies that ship to North Dakota are required to report, but may request to do so as infrequently as monthly. (http://www.nodakpharmacy.com/PDMP-faq.asp#di)

Pharmacy Pilot Policies for Response Codes

IHS has implemented the following pharmacy operational policies at Spirit Lake Pharmacy regarding the response codes seen in the pilot.

- **Code A** – Process prescription as normal.
- **Code B** – "Red flag"
    - Log-in to ND PDMP with user credentials.
    - Conduct full query for past six months.
    - Utilize professional discretion to interpret report results.
    - If therapeutic duplication, overlapping fill dates, or morphine equivalents greater than >100mg per day—contact prescriber.
    - Record outcome of decision in manual tracking tool.
    - Enter the report into the RPMS system if advised that patient is at risk, consistent with state law (http://www.nodakpharmacy.com/PDMP-faq.asp#di).
- **Code C** – Consider manual query of PDMP database with expanded criteria and range search based on time available.
- **Code R** – Timeout failure. Retry as time permits.

Agreements Implemented

The following agreements were implemented as part of this pilot:

- PMPi-Emdeon Letter of Agreement (LOA)
- IHS-Emdeon Business Associate Agreement (BAA)
- IHS-Emdeon Data Exchange Agreement (DEA)
- IHS-Emdeon Data Release Agreement (DRA)
- IHS-Emdeon Business Partner Interconnection Security Agreement (BPISA)

There is also an existing NABP-ND Memorandum of Understanding (MOU), which was part of the state's entry into the PMPi community. This list does not include the subcontracts with The MITRE Corporation. The BPISA, in particular, may help ease any subsequent expansion of pilot-related activities.

Appendix D. Evaluation Methods

Evaluation Approach – Hypotheses and Specific Methods

The Federal Government and the MITRE Corporation conducted pilot studies, small-scale experiments, to test the feasibility of proposed workflows and evaluate their outcomes before investing resources in a full-scale, permanent implementation. These pilots provide valuable insights concerning time requirements, system challenges, and opportunities for process improvement—all of which can be addressed to improve final system design and performance success.

Evaluating the PDMP Pilots required a disciplined and consistent approach to examine the impact of the new or changed technical and clinical work process features toward achieving the following goals:

- **Workflow Logistics** – Providing the correct amount of appropriate information, in the proper condition, at the right place and time, in the necessary position/sequence

- **System Performance** – achieving desired outcomes

- **Predicting Implementation Success** – Extrapolating the results to a larger system

MITRE's systematic analytic approach effectively consolidated these objectives into a set of three consistent evaluation themes: usability, impact, and scalability. The PDMP Pilots varied from simple to more complex health IT connectivity configurations to the PDMP, so testing afforded the opportunity to examine the different facets of performance along a continuum of technical sophistication (see Figure D-1).
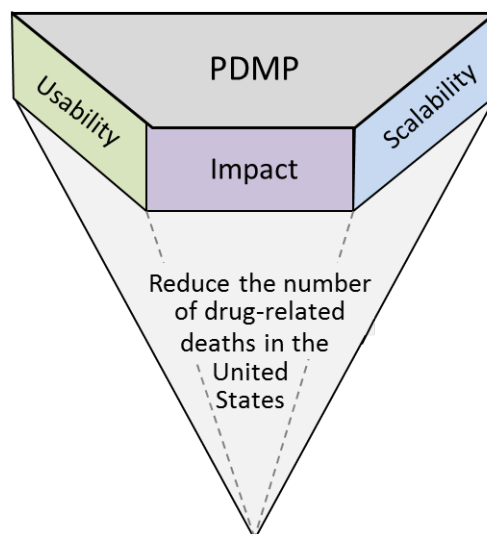

Figure D-1. Evaluation Themes

This appendix describes the three evaluation themes. Each theme and its accompanying areas of interest, with associated evaluation metrics, were the basis for evaluation of the PDMP pilots. Tables D-1 to D-3 provide details of how the pilot team evaluated each theme.

Usability

The primary focus of the usability theme is the user's perspective. The following areas of interest concern the optimization of the care delivery experience and the efficiency in performing work processes by leveraging and maximizing technical integration:

- **Ease of Use** – Promoting easier and more efficient ways to access to the PDMP prescription drug data than the previous method for providers and dispensers
- **Fit with Workflow** – Natural integration into existing clinical and health IT workflows for providers and dispensers

Table D-1. Usability Analysis Features

Area of Interest	Evaluation Metrics	Data Source
Ease of Use	% reporting PDMP data provided was of acceptable quality for use	Participant Feedback (Interview)
	% reporting PDMP data now easier to access (pilot versus prior methods)	Participant Feedback (Interview)
Fit with Workflow	% indicating proper integration with position in workflow	Participant Feedback (Interview)
	% indicating access to PDMP data was better than alternative option	Participant Feedback (Interview)

Impact

The impact theme is meant to validate that the connectivity method to the PDMP was achieved and ultimately resulted in a positive impact to clinical care outcomes (reducing the number of prescription drug related deaths). The following areas of interest assess the technical and clinical impact:

- **Technical Impact** – Resulted in maximizing connections to existing technologies and increased queries to the PDMP data
- **Clinical Impact** – Resulted in timely and meaningful PDMP prescription drug information, readily available at the time of decision-making, that positively impacted care delivery to the patient

Table D-2. Impact Analysis Features

Area of Interest	Evaluation Metrics	Data Source
Technical Impact	% change in PDMP queries (pilot versus prior)	Logged System Data
	Distribution of patients at threshold condition (at risk versus not at risk)	Logged System Data
Clinical Impact	% satisfied with data provided in pilot configuration for clinical use	Participant Feedback (Interview)
	% reporting change in treatment as result of better PDMP access	Participant Feedback (Interview), Manually Logged Data
	% change in prescriptions for controlled substance written or fulfilled (pilot versus prior)	Manually Logged Data

Scalability

The scalability theme assessed the capability of the new work processes to be widely applied and accommodate growth in the existing system of providers and dispensers. The following areas of interest assessed how well participants adopted the new process and the degree to which it improved the existing workflow:

- **Driver of Adoption** – Accepted by the participants so that pilot drove further adoption by other sites or user groups (e.g., providers), if applicable

- **Optimization Factors** – Generated identifiable improvement opportunities to increase the usefulness and timely availability of PDMP prescription drug information

Table D-3. Scalability Analysis Features

Area of Interest	Evaluation Metrics	Data Source
Driver of Adoption	% wishing to continue to use the new process	Participant Feedback (Interview)
	% willing to recommend the new process to their peers or colleagues	Participant Feedback (Interview)
Optimization Factors	% able to identify specific, actionable steps to further refine process	Participant Feedback (Interview)
	Distribution of specific suggestions for improvement	Participant Feedback (Interview)

Acronyms

API	Application Programming Interface
BAA	Business Associate Agreement
BIN	Bank Identification Number
BPISA	Business Partner Interconnection Security Agreement
DEA	Drug Enforcement Agency, Data Exchange Agreement
DOB	Date of Birth
DRA	Data Release Agreement
HID	Health Information Designs, Inc.
HTML	Hypertext Markup Language
IHS	United States Indian Health Service
LOA	Letter of Agreement
MOU	Memorandum of Understanding
NABP	National Association of Boards of Pharmacy
NCPDP	National Council for Prescription Drug Programs
NPI	National Provider Identifier
ONC	Office of the National Coordinator for Health Information Technology
PCS	Procedure Code System
PDMP	Prescription Drug Monitoring Program
PMPi	PMP InterConnect
REST	Representational State Transfer
RPMS	Resource and Patient Management System
VistA	Veterans Health Information System and Technology Architecture
XML	Extensible Markup Language