ACTION PLAN FOR IMPROVING ACCESS TO PRESCRIPTION DRUG MONITORING PROGRAMS THROUGH HEALTH INFORMATION TECHNOLOGY

Presented to

The Behavioral Health Coordinating Committee,

Department of Health and Human Services

through

The Pharmaceutical Abuse Subcommittee

bv the

Prescription Drug Abuse and

Health Information Technology Work Group

JUNE 30, 2011

PREFACE

This *Action Plan for Improving Access to Prescription Drug Monitoring Programs through Health Information Technology* (Action Plan) is the result of a collaborative process outlined in the U.S. Department of Health and Human Services (HHS) Behavioral Health Coordinating Committee (BHCC), Subcommittee Goals. The BHCC is an organized committee of diverse interests created to improve behavioral health. The BHCC formed five subcommittees to achieve this goal: 1) the Alcohol Subcommittee; 2) the Communications Subcommittee; 3) the IOM/Early Intervention Subcommittee; 4) the Pharmaceutical Abuse Subcommittee; and 5) the Primary Care Subcommittee.

The Pharmaceutical Abuse Subcommittee is responsible for five goals: 1) improve the federal surveillance capacity for pharmaceutical abuse; 2) reduce opioid-related drug deaths by increasing timely access to Prescription Drug Monitoring Program (PDMP) data by clinicians and pharmacists; 3) reduce the number of opioid overdose deaths by identifying and implementing effective secondary prevention strategies; 4) collaborate on the development of educational materials to address the appropriate use of prescription pharmaceuticals and reduce their misuse and abuse; and 5) implement standards for the Electronic Medical Record to increase the identification of pharmaceutical abuse routinely in medical care.

The Prescription Drug Abuse and Health Information Technology (HIT) Work Group was formed to address goal number two - reduce opioid-related drug deaths by increasing timely access to PDMP data by clinicians and pharmacists. The Work Group was tasked with establishing an action plan by June 30, 2011 for improving access to PDMPs, through health information technology and health information exchanges.

In accordance with the goals of the BHCC, the Prescription Drug Abuse and HIT Work Group included representatives from various agencies within HHS and the Bureau of Justice Assistance (BJA) within the Department of Justice (DOJ). A detailed list of Work Group members is included below:

Chairmen	**Organization**
Farzad Mostashari	Office of the National Coordinator for Health Information Technology (ONC)
Westley Clark	Substance and Mental Health Services Administration (SAMHSA)

Member	Organization
Jodi Daniel	ONC
Betsy Ranslow	ONC
Kate Tipping	ONC
Claudia Williams	ONC
Peter Banks	ONC
Geoffrey Gerhardt	ONC
Robert Mayer	SAMHSA
Nicholas Reuter	SAMHSA
Jinhee Lee	SAMHSA
Sarah Wattenberg	OASH
Wilson Compton	NIDA
Richard Denisco	NIDA
Len Paulozzi	CDC
Linda Degutis	CDC
Susan Queen	ASPE
Cindy Gunderson	IHS
Dale Slavin	FDA
Maureen Boyle	NIH
Andrew Morgan	CMS
Nancy Fisher	CMS
Catherine McNamee	BJA

The Work Group met 5 times in Washington, D.C. Numerous smaller working group sessions and conference calls were also held. Dates and durations of the full Work Group meetings are listed below:

Meeting Date	**Duration of Meeting**
4/6/2011	1 hour
5/11/2011	1.5 hours
5/25/2011	45 min
6/8/2011	1.5 hours
6/22/2011	1 hour

In order to gather feedback from key stakeholders including PDMP Administrators, State HIT Coordinators, practitioners, and policy makers, the Work Group convened a White House Roundtable on Prescription Drug Abuse and Health Information Technology on June 3, 2011. This meeting facilitated the development of the Action Plan detailed below.

INTRODUCTION

On April 19, 2011, the Administration released a comprehensive action plan, "Epidemic: Responding to America's Prescription Drug Abuse Crisis," to address the national prescription drug abuse epidemic. The 2011 Prescription Drug Abuse Prevention Plan expands upon the Administration's National Drug Control Strategy and includes action in four major areas to reduce prescription drug abuse: education, monitoring, proper medication disposal, and enforcement. The Plan calls for coordinated efforts by federal and state authorities.

The charge to the Prescription Drug Abuse and HIT Work Group parallels the monitoring directive of the Administration's Plan. Likewise, the Plan seeks to improve the quality and availability of data that is stored in PDMPs through HIT. The ambition is to provide clinicians and pharmacists with real-time information about patient's prescription drug histories from the PDMPs, which can reduce the risk of opioid-related drug abuse and deaths.

The Action Plan encourages collaboration across federal, state and local governments, State HIT Coordinators, State PDMP Administrators, providers, pharmacists, health care professionals' associations, and vendors to pilot ways to improve access to PDMP data through the use of HIT. Specifically, this Action Plan seeks to improve access to PDMP data in three distinct situations: 1) at the point of prescribing (outpatient), 2) at the point of dispensing, and 3) at the point of care in the Emergency Department.

BACKGROUND

Problem

Prescription drug abuse is the nation's fastest-growing drug problem. While there has been a marked decrease in the use of some illegal drugs like cocaine, data from the National Survey on Drug Use and Health (NSDUH) show that nearly one-third of people aged 12 and over who used drugs for the first time in 2009 began by using a prescription drug non-medically.[1]

Although a number of classes of prescription drugs are currently being abused, this Action Plan primarily focuses on the growing and often deadly problem of prescription opioid abuse. The number of prescriptions filled for opioid pain relievers - some of the most powerful medications available - has increased dramatically in recent years. From 1997 to 2007, the milligram per person use of prescription opioids in the U.S. increased from 74 milligrams to 369 milligrams, an increase of 402 percent.[2] In 2009, 257 million prescriptions for opioids were dispensed, reflecting a 48 percent increase since 2000.[3] Further, opiate overdoses, once nearly exclusively due to heroin use, are increasingly caused by abuse of prescription painkillers.[4] Opioid abuse now accounts for more deaths than cocaine and heroin combined.[5]

Over the past decade, prescription drug-induced deaths have approached motor vehicle deaths as the leading cause of all injury deaths.[6] Many of the deaths are of patients receiving very high doses (i.e. more than 100 mg of morphine equivalent doses) from multiple prescribers (who are likely unaware of each other).[7] According to the 2009 National Survey on Drug Use and Health, an estimated 5.3 million persons used opioids non-medically (in the past month) compared with 9 million medical users. "Medical users" (who receive their prescription drug as part of legitimate medical practice) seem to account for a large portion of the deaths, ranging from 34 percent in West Virginia, to 63 percent in Utah,[8] and 75 percent in Ohio.[9] Most of the prescriptions are being written in emergency departments (39 percent) and primary care offices (30 percent).[10]

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[1] *Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings*, SAMHSA (2010).
[2] Manchikanti L, Fellow B, Ailinani H, Pampati V. Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective. *Pain Physician*. 13:401-435. 2010.
[3] Based on data from SDI, Vector One: National. Years 2000-2009. Retrieved April 20,2011. Available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM217510.pdf
[4] *Unintentional Drug Poisoning in the United States*, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, July 2010.
[5] National Vital Statistics System. http://wonder.cdc.gov, multiple cause dataset
[6] Xu JQ, et al. Deaths: Final Data for 2007, National Vital Statistics Reports, 2010;58 (19)http://www.cdc.gov/nchs/data/nvsr/nvsr58/nvsr58_19.pdf
[7] West Virginia: Hall AJ, et all. JAMA 2008;300:2613-20; Ohio: Ohio Department of Health. www.healthyohioprogram.org/diseaseprevention/dpoison/drugdata.aspx
[8] Utah: Lanier W. 2010. CDC Epidemic Intelligence Service Conference
[9] Ohio: Ohio Department of Health. www.healthyohioprogram.org/diseaseprevention/dpoison/drugdata.aspx
[10] Raofi S, Schappert SM. Medication therapy in ambulatory medical care: United States, 2003–04 National Center for Health Statistics. Vital Health Stat 13(163). 2006.http://www.cdc.gov/nchs/data/series/sr_13/sr13_163.pdf

Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs (PDMPs), also referred to as Prescription Monitoring Programs (PMPs), are tools for reducing prescription drug abuse and diversion. They consist of statewide electronic databases which collect, monitor, and analyze electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. The data is used to support states' efforts in education, research, enforcement and abuse prevention. The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency (which varies by state).

States recognize the medical need for controlled substances and, therefore, PDMPs are designed not to interfere with appropriate, medical use. Prescription data is provided only to entities authorized by state law to access the program, such as health care practitioners, pharmacists, regulatory boards and law enforcement agencies (which vary by state).

There are currently 48 states with laws that authorize the establishment and operation of a PDMP. Thirty-five are operational (i.e. collecting data and distributing data to one or more authorized users). Legislation is pending in Missouri and New Hampshire. The District of Columbia has yet to introduce legislation authorizing a PDMP.

Current Status of PDMPs

The current status of state PDMPs vary. For most states, the PDMP is electronic and available online. Authorized users have direct access to the online system, and when requested, a report is generated within seconds to minutes. Some states also accept requests via fax. This process takes a bit longer, generally one to two days, as requester information must be authenticated. In other states with exclusively manual systems that can only be accessed by fax or U.S. mail, a report may take as long as 14 days.[11] For states with online systems, the authorized user must log onto a separate system to access the PDMP data through a web portal. Other states have the capability to send secure messages to providers and pharmacists if there is reason to believe that the patient may be obtaining prescriptions from multiple providers and pharmacists (unsolicited reports). Still other state PDMPs do not have the electronic capabilities or resources to perform these functions. This Action Plan is designed to leverage existing technology to provide access to PDMPs in real-time.

Funding

States receive funding from a variety of public/private sources to fund the PDMPs. There are two federal sources of funding for state PDMPs – the Harold Rogers Prescription Drug Monitoring Program and the National All Schedules Prescription Electronic Reporting Program (NASPER).

[11] Blumenschein K, Fink III J, Freeman P, James K, Kirsh K, Steinke D, Talbert, J. Review of Prescription Drug Monitoring Programs in the United States (June 2010). Retrieved April 6, 2011 from Kentucky Cabinet for Health and Family Services Official SiteWebsite: http://chfs.ky.gov/NR/rdonlyres/85989824-1030-4AA6-91E1-7F9E3EF68827/0/KASPEREvaluationPDMPStatusFinalReport6242010.pdf

The Harold Rogers Prescription Drug Monitoring Program (HRPDMP), administered by the Bureau of Justice Assistance (BJA), has awarded 146 grants to 47 states to support the planning, implementation, and enhancement of PDMPs since 2003. BJA has also created a robust Training and Technical Assistance (TTA) program to support states' efforts to establish PDMPs and engage in interstate data sharing. The current TTA providers are the Alliance of States with Prescription Monitoring Programs and the Center of Excellence at Brandeis University. The HRPDMP does not have legislative authorization, but has received an annual appropriation since its inception. Funding levels have averaged approximately $7 million per year, and in Fiscal Year 2011 the amount of funds available to support grant awards to states as well as TTA resources is approximately $5.8 million. The Administration's FY 2012 budget did not include funds in support of the HRPDMP.

NASPER was enacted in 2005 by Congress and directed the Secretary of Health and Human Services to provide grants to states to implement or to improve their PDMPs. NASPER authorization expired in 2010 however; grants were awarded in fiscal year 2009 and 2010. No funds were appropriated for NASPER in fiscal year 2011. However, funds are included in the Administration's proposed fiscal year 2012 budget. Bills have been introduced both in the House (H.R. 866, "National All Schedules Prescriptions Electronic Reporting Act of 2011" and H.R. 1925, "Prescription Drug Abuse Prevention and Treatment Act of 2011") and the Senate (S. 507, "Prescription Drug Abuse Prevention and Treatment Act of 2011") to reauthorize the program.

Reporting

States with PDMPs differ in how they operate. States with reactive PDMPs generate solicited reports only in response to a specific inquiry made by a prescriber, dispenser, or other party with appropriate authority. States with proactive PDMPs generate unsolicited reports. Many states do both solicited and unsolicited reporting. Unsolicited reports are automatically generated when certain thresholds, which might indicate abuse of a controlled substance, doctor shopping, or errant prescribing practices, are reached. For instance, under the NASPER system, the Substance Abuse and Mental Health Service Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) required unsolicited reports be sent to prescribers and pharmacies when an individual has filled six or more controlled substance prescriptions of the same drug class, from six or more different prescribers, or six or more different pharmacies in a state, within a one month period. SAMHSA included this requirement to address reports of low physician utilization of PDMPs. Although there is wide variation between states, in most states, less than 20 percent of the authorized physicians utilize the PDMP in their state. ONDCP believes all PDMPs should produce and disseminate unsolicited reports.

The Alliance of States with PMPs (Alliance) and the National Association of State Controlled Substances Authorities adopted the *Prescription Monitoring Program Model Act* (Model Act) in October 2002. The Alliance and the Center of Excellence prepared a revision to the Model Act in 2010 to provide a statutory framework for establishing and

operating a prescription monitoring program. The Model Act is a consensus document that reflects the best practices of the states that currently run PDMPs, as well as, the knowledge of other states that have a long standing interest in PDMPs. The Model State Prescription Drug Monitoring Law also includes a provision requiring unsolicited reporting. Of the most recent data collected from a survey of the Brandeis University Center of Excellence and the Alliance, 31 states are authorized to provide unsolicited reports, but only 19 are currently providing them. State laws vary in who can access the data – prescribers, pharmacists, law enforcement, and/or licensing entities.

Interstate Exchange

In addition to sharing information with authorized users for medical treatment decisions, states may have greater need for sharing prescription information with other states to prevent doctor shopping. In an effort to support interstate PDMP data sharing, BJA, the IJIS (Integrated Justice Information Systems) Institute, and the Alliance of States with Prescription Monitoring Programs have established the Prescription Monitoring Information Exchange (PMIX) Project. PMIX is supporting design and development of the technical infrastructure for interstate PDMP data sharing. The current design is based upon a centralized hub (PMIX hub) that will facilitate the exchange of information between states. Kentucky and Ohio, through a memorandum of understanding (MOU), recently demonstrated two exchanges (one originating in each state) of simulated patient data highlighting the success of the project. BJA is currently coordinating with other organizations that are proposing alternative technical solutions to confirm that they are compliant with the PMIX specifications to ensure that a nationwide data sharing framework is established.

The National Association of Boards of Pharmacy has also been working with state prescription monitoring program administrators to develop PMP InterConnect. PMP InterConnect is a communication hub that will, for participating PDMPs, facilitate the transfer of PDMP data across state lines to authorized users. Connecticut, Indiana, Kansas, Mississippi, North Dakota, Ohio, South Carolina, Virginia, and West Virginia have all signed MOUs which is the first step in participating with PMP InterConnect.

The Council of State Governments (CSG) is also working to facilitate interstate exchange. CSG, through its National Center for Interstate Compacts, has been involved in the development of the Prescription Drug Monitoring Program Compact. CSG drafted the interstate compact that would enable states to develop an interoperable system to share prescription data. The compact will be activated and have the force of law once six states adopt it. Legislative auditors in West Virginia recently endorsed the Prescription Monitoring Program Compact. Legislation is currently being considered by states. The Compact is gaining traction and the attention of policymakers.

HIE/HIT Landscape

Widespread adoption and meaningful use of health information technology (HIT) is one of the foundational steps in improving the quality and efficiency of health care. The appropriate and secure electronic exchange and consequent use of health information to improve quality and coordination of care is a critical enabler of a high performance health care system. HIT will play a major role in this initiative by providing the foundation for increasing connectivity and enabling patient-centric information to flow between the PDMP and the point of care.

Under the Health Information Technology for Economic and Clinical Health (HITECH) Act, the State Health Information Exchange (State HIE) Cooperative Agreement Program was created to rapidly build capacity for exchanging health information across the health care system both within and across states. All 50 states and six territories have received approval of their Strategic and Operational plans and are currently moving forward in the implementation stages of exchange. Recognizing that State HIEs could provide the infrastructure needed for monitoring prescription drug abuse, the State HIE Program is working with specific states on pilot projects that address the three areas of interest (Prescriber, Dispenser, and the Emergency Department) outlined in this Action Plan. The State HIE Program is convening a meeting in July 2011 to discuss in more detail.

Direct Project

The Direct Project is the set of standards and services that, with a policy framework, enable simple, directed, routed, scalable transport over the Internet to be used for secure and meaningful exchange between known participants in support of meaningful use. The Direct Project does not replace other ways information is exchanged electronically today, but it might enhance them. It supports simple use cases in order to speed adoption, but other methods of exchange might be suited for other scenarios. The Direct Project was designed to coexist with existing protocols for data exchange. It seeks to replace slow, inconvenient, and expensive methods of exchange (paper or fax) and provide a future path to advanced interoperability. The Direct Project facilitates the communication of many different kinds of content necessary to fulfill meaningful use requirements.

The Direct Project represents over 50 organizations and over 200 participants (including 20 states). These participants include EHR and PHR vendors, medical organizations, systems integrators, integrated delivery networks, federal organizations, state and regional health information organizations, organizations that provide health information exchange capabilities, and health information technology consultants. In addition, over 40 states have included Direct in their State HIE operational plans with the goal of enabling various services that will support meaningful use.

HIPAA

Many prescribers and dispensers who are the sources of the patient information for the PDMP are covered entities subject to HIPAA. We will ensure that the disclosures of individually identifiable health information addressed in this Action Plan are consistent with the requirements of the Privacy Rule.

ACTION PLAN

Rationale

Currently data is trapped within PDMPs, creating a situation in which information is not going where it needs to go in time for it to be of use. The purpose of this Action Plan is to make information flow more effectively, not to create "new" systems. The goal is to make the systems we already have become more valuable by connecting them.

The overall goal of the Action Plan is to collaborate with public and private stakeholders to develop ways to fix this problem. It is important to note that the pilots will build on the current PDMP program through existing technologies that will facilitate providing the PDMP data to the provider in "real time" in contrast to establishing new data sources. The aim is not to interfere with the current workflow of the provider but to have a "machine to machine" communication that does not necessitate action by the provider. This Action Plan lays out incremental steps to resolve issues leading to pilot demonstration projects in three distinct areas: Prescriber, Dispenser, and the Emergency Department.

Building on What Works

The Work Group examined models for achieving this goal that fit into the current workflow of either the provider or the pharmacist and leverage existing technology. The Work Group identified three variables relevant to integration into the current workflow: data access points, triggers, and intermediaries. The Work Group then identified existing health IT vehicles for each that might be leveraged to accomplish the goals. The constant is the data source, which is always the PDMP.

Data Access Point	Trigger	Intermediary
Outpatient Provider	Registration	None
• E-Rx	Insurance • Eligibility Check • Claims Check	HIEs: • State • Other
• EHR	E-Rx • Provider • Pharmacy	PMP Hubs: • PMIX • PMP Interconnect
• Emergency Department(ED)	Admission/Discharge/ Transfer (ADT) Transaction Standard	Networks: • Surescripts • Relay Health • Other
Dispenser	Other	Other

PILOTS

The Work Group envisions pilots in three areas: Prescriber, Dispenser, and the Emergency Department. An HIE could provide a variety of services that would enable PDMP querying and response in the following pilots (depending on the state and the maturity of the PDMP and HIE).

General

Pilot 1 Secure Message (Direct)/Unsolicited Report: PDMP regularly runs reports to identify patients at risk (patients that meet a certain threshold set by the state).

- The PDMP sends a secure message to the patient's providers/pharmacists which includes minimal patient information, but alerts the provider/pharmacist to check the PDMP and the link.

OR

- The PDMP sends a secure direct message to the patient's providers/pharmacists which includes the patient's scheduled drug history.

Prescriber

Pilot 2 Prescriber EHR Technology Enhanced:

A. When the patient is seen by the provider and the provider uses his/her EHR to electronically prescribe, the e-Rx (trigger) is routed to the switch for a claims check which would automatically send a query to the PDMP. The PDMP would return the patient's scheduled drug history back to the provider's EHR.

OR

B. A patient makes an appointment (in advance or walk-in) at the provider's office. A designated number of hours prior to the patient's appointment, an eligibility check is performed. The patient appointment/eligibility check goes through a switch (e.g. Surescripts) and that would trigger an automatic query of the PDMP. The PDMP would return the patient's drug history of scheduled drugs back through the switch which would then transfer the information to the provider's EHR.

Dispenser

Pilot 3 Dispenser (Pharmacist) Technology Enhanced: A patient drops off the paper prescription at the pharmacy or the controlled substance is electronically prescribed. Prior to dispensing the medication, the pharmacist performs a claims check. Cash prescriptions that do not require a claims check will get labeled with a unique code (Dummy BIN). The claims check will go through an existing switch (e.g. RelayHealth). The claims check acts as a trigger to query the PDMP. If there is a match, the PDMP will send the patient's scheduled drug history back through the switch to the pharmacist/pharmacy system.

Emergency Department

Pilot 4 ED Technology Enhanced: The patient checks-in to the Emergency Department and an Admission/Discharge/Transfer (ADT) message is created to track the patient's location in the hospital. The ADT message is the trigger that sends the query to the PDMP. The results of the PDMP query will be returned to the ED EHR system. **Because an ED provider is not assigned to the patient at the time the ADT triggers a query to the PDMP, the best case scenario would be for the ADT to enable an automatic query to the PDMP and the results to be returned to the ED EHR. The feasibility of this occurring is dependent on the state policy which will be researched by the assigned work group.*

Pilot 5 ED HIE Query: A patient is assigned to a provider in the ED. The provider queries the HIE for the patient care summary. Assuming the technical capability is there, this query automatically triggers a query to the PDMP. The PDMP returns the patient's scheduled drug history through the HIE to the ED provider.

WHITE HOUSE ROUNDTABLE ON HIT AND PRESCRIPTION DRUG ABUSE

On June 3, 2011 the Office of the Vice President of the United States, Office of National Drug Control Policy, Office of the National Coordinator for Health Information Technology, and the Office of Science and Technology hosted the White House Roundtable on HIT and Prescription Drug Abuse. Approximately three dozen leaders across public safety, healthcare and technology sectors met to address leveraging existing technology to improve access to PDMPs. Attendees at the White House Roundtable reviewed the Data Access Point/Trigger/Intermediaries chart and expanded upon the models developed by the Prescription Drug Abuse and HIT Work Group.

During the White House Roundtable discussion, leaders in the field expressed a great deal of interest and enthusiasm. Former competitors agreed to collaborate and work together to find solutions to leverage existing technology to improve access to PDMPs. As the discussion of the pilots advanced, meeting attendees identified key questions/issues in policy and/or technology, as described in the task list.

TASK LIST
1. Work Group charge: a. Harmonize data messaging and formatting standards for communicating with interstate data exchanges.
2. Work Group charge: a. Develop standards for the user interfaces and identify the PDMP data elements and format in which it will be presented in the EHR.
3. a. Develop standards for the user interfaces and identify the PDMP data and format in which it will be presented in pharmacy systems.
4. Work Group charge: In order to develop standard for PDMP/HIT pilots: a. Review state laws and current policies for PDMP use of intermediaries (with business agreements). b. Review state laws relative to the delegation by the pharmacist to the pharmacy and the physician to the hospital. c. Review current policies and practices for "Dummy BINs" (Batch ID Numbers) that will route pharmacy dispensing data, including cash payments and recommend policies for same. d. Reviewing current policies and practices relative to role based access to pharmacy and ED systems to ensure data is only available to authorized personnel and recommend policies for same.
5. Work Group Charge: a. Review current policies and practices for "Dummy BINs" (Batch ID Numbers) that will route pharmacy dispensing data, including cash payments and recommend policies for same.

TASK LIST
6. Work Group charge: In order to develop standard for PDMP/HIT pilots: a. Review current pharmacy chain policies and practices relative to delegating access to PDMP data, determine rationale for policy decisions that do not permit delegation and recommend policies for the same.
7. Work Group charge: In order to develop standard for PDMP/HIT pilots: a. Analyze current protocols for switch organizations to participate in routing queries between providers and PDMPs and pharmacies and PDMPs. b. Develop a model business agreement for switch organization data sharing.

The pilot studies detailed below represent variations of the five pilot areas discussed earlier. Following each pilot study description is the list of the tasks that are associated with the pilot. All pilot studies will involve designing the pilot, conducting the pilot and evaluating the pilot.

PILOT STUDIES AND SUPPORTING WORKGROUPS

Note: * = Work Group tasks that support multiple pilots but that only need to be developed once.

1. **Provider Pilot Study A**: PDMP, Direct, Provider EHR /Unsolicited Report

   Routing:

   - PDMP system identifies patients at risk and sends a message via Direct to all providers who have previously prescribed to the patient (patients at risk – minimal patient information) with link back to the PDMP (provider accesses PDMP for patient scheduled drug history).

   Supporting Work Group Tasks:

Work Group/Task	Task Description
1.a*	Harmonize data messaging and formatting standards for communicating with interstate data exchanges (enhances pilot).

2. **Provider Pilot Study B**: Provider EHR, Switch, PDMP/Solicited Report

   Routing:

- Patient makes an appointment or visits the doctor. When appointment/visit is logged into the provider's EHR it triggers an eligibility check via a Switch, which triggers a drug history (switch) and PDMP query
- PDMP returns patient at risk – scheduled drug history via the Switch

Supporting Work Groups Tasks:

Work Group/Task	Task Description
1.a*	Harmonize data messaging and formatting standards for communicating with interstate data exchanges (enhances pilot).
2.a*	Develop standards for the user interfaces and identify the PDMP data elements and format in which it will be presented in the EHR.
4.a*	Review state laws and current policies for PDMP use of intermediaries (with business agreements).
7.a*	Analyze current protocols for switch organizations to participate in routing queries between providers and PDMPs.
7.b*	Develop a model business agreement for switch organization data sharing.

3. **Provider Pilot Study C:** Provider EHR, Switch, HIE, PDMP/Solicited Report

Routing:

- Patient makes an appointment or visits the doctor. When appointment/visit is logged into the provider's EHR it triggers an eligibility check via a Switch, which triggers a drug history (switch) and PDMP query via an HIE.
- PDMP returns patient at risk – scheduled drug history via the HIE and the Switch.

Supporting Work Groups:

Work Group/Task	Task Description
1.a*	Harmonize data messaging and formatting standards for communicating with interstate data exchanges (enhances pilot).
2.a*	Develop standards for the user interfaces and identify the PDMP data elements and format in which it will be presented in the EHR.
4.a*	Review state laws and current policies for PDMP use of intermediaries (with business agreements).
7.a*	Analyze current protocols for switch organizations to participate in routing queries between providers and PDMPs.
7.b*	Develop a model business agreement for switch organization data sharing.

4. **ED Pilot Study A:** PDMP, Direct, ED EHR /Unsolicited Report

Routing:

- PDMP system identifies patients at risk and sends a message via Direct to all ED providers that have previously prescribed to the patient (patients at risk – minimal patient information) with link back PDMP (provider accesses PDMP for patient scheduled drug history).

Supporting Work Groups:

Work Group/Task	Task Description
1.a*	Harmonize data messaging and formatting standards for communicating with interstate data exchanges (enhances pilot).
4.b*	Review state laws relative to the delegation by the physician to the hospital.

5. **ED Pilot Study B:** ED EHR, Admission, Discharge and Transfer (ADT) Message, PDMP/Solicited Report

Routing:

- The patient checks-in to the ED and an ADT message is created. The ADT triggers a query to the PDMP.
- PDMP returns a patient at risk - scheduled drug history to ED EHR.

Supporting Work Groups:

Work Group/Task	Task Description
1.a*	Harmonize data messaging and formatting standards for communicating with interstate data exchanges (enhances pilot).
2.a*	Develop standards for the user interfaces and identify the PDMP data elements and format in which it will be presented in the EHR.
4.b*	Review state laws relative to the delegation by the physician to the hospital.
4.d*	Reviewing current policies and practices relative to role based access to ED systems to ensure data is only available to authorized personnel and recommend policies for same.

6. **ED Pilot Study C:** ED EHR, Admission, Discharge and Transfer (ADT) Message, HIE, PDMP/Solicited Report

Routing:

- The patient checks-in to the ED and an ADT message is created. The ADT triggers a query to the PDMP via the HIE.
- PDMP returns patient at risk - scheduled drug history to ED EHR via the HIE.

Supporting Work Groups:

Work Group/Task	Task Description
1.a*	Harmonize data messaging and formatting standards for communicating with interstate data exchanges (enhances pilot).
2.a*	Develop standards for the user interfaces and identify the PDMP data and format in which it will be presented in the EHR.
4.a*	Review state laws and current policies for PDMP use of intermediaries (with business agreements).
4.b*	Review state laws relative to the delegation by the physician to the hospital.
4.d*	Reviewing current policies and practices relative to role based access to ED systems to ensure data is only available to authorized personnel and recommend policies for same.

7. **ED Pilot Study D:** ED Manual Query Terminal, HIE, PDMP/Solicited Report

Routing:

- Patient is assigned to a provider, provider accesses existing manual query terminal to access the patient care summary from the HIE, the patient care summary query triggers a PDMP query by the HIE to the PDMP.
- PDMP returns a patient at risk - scheduled drug history through the HIE to the ED manual query terminal.

Supporting Work Groups:

Work Group/Task	Task Description
1.a*	Harmonize data messaging and formatting standards for communicating with interstate data exchanges (enhances pilot).
2.a*	Develop standards for the user interfaces and identify the PDMP data and format in which it will be presented in the EHR.
4.a*	Review state laws and current policies for PDMP use of intermediaries (with business agreements).

8. **Pharmacy Pilot Study A:** PDMP, Direct, Pharmacy System /Unsolicited Report

Routing:

- PDMP system identifies patients a risk and sends a message via Direct to all Pharmacists who have previously dispensed to the patient (patients at risk – minimal patient information) with link back PDMP (pharmacies can query PDMP for full information).

Supporting Work Groups:

Work Group/Task	Task Description
1.a*	Harmonize data messaging and formatting standards for communicating with interstate data exchanges (enhances pilot).

9. **Pharmacy Pilot Study B:** Pharmacy system, Switch, PDMP/Solicited Report

Routing:

- Pharmacy system receives an electronic prescription (e-Rx) which triggers a claims check via a switch; the claims check triggers a query to the PDMP (if the patient is paying with cash, interfaces with a "Dummy BIN").
- PDMP returns the patient at risk - scheduled drug history via the switch.

Supporting Work Groups:

Work Group/Task	Task Description
1.a*	Harmonize data messaging and formatting standards for communicating with interstate data exchanges (enhances pilot).
3.a*	Develop standards for the user interfaces and identify the PDMP data and format in which it will be presented in pharmacy systems.
4.a*	Review state laws and current policies for PDMP use of intermediaries (with business agreements).
4.b*	Review state laws relative to the delegation by the pharmacist to the pharmacy.
4.d*	Reviewing current policies and practices relative to role based access to pharmacy systems to ensure data is only available to authorized personnel and recommend policies for same.
5.a*	Review current policies and practices for "Dummy BINs" (Batch ID Numbers) that will route pharmacy dispensing data, including cash payments and recommend policies for same.
6.a*	Review current pharmacy chain policies and practices relative to delegating access to PDMP data, determine rationale for policy decisions that do not permit delegation and recommend policies for same.

IMPLEMENTATION

The Work Group understands that the development of this Action Plan brings with it a responsibility for their respective agencies to apply resources, consistent with their agency scope and goals, to implement the Plan.

Various agencies within HHS and DOJ currently fund efforts related to PDMPs and preventing prescription drug abuse. Work Group members acknowledged possible agency resources to support the implementation of the Action Plan:

Item	**Lead**
Policy Tasks	BJA (Training and Technical Assistance)
Technology Tasks	SAMHSA/ONC
Pilots	SAMHSA/ONC
Evaluation	ASPE/ +or- CDC

- Support for the proposed work groups to complete the tasks identified in the Task List and to launch the pilots is being solicited from participating agencies by ONC.
- Additional resources are being sought through alternative channels.

The Work Group also intends to aggressively contact state PDMPs, HIEs, health care professionals' associations, vendors, and other stakeholders to identify pilot participant volunteers and potential funding for pilot sites.

The success of this Action Plan will require effective coordination within HHS, between HHS and DOJ, and between HHS and external stakeholders. A synchronized effort will involve consistent communication between all the agencies involved.

TIMELINE

Once sufficient resources are identified, and a contract can be awarded, the following draft timeline will be instituted (but is subject to change since no contract has been awarded to date):

Contract Awarded:	Award date
Work Group Convening:	Within 8 weeks of effective date of contract (EDOC)
Work Group Products:	Within 5 months of EDOC
Pilot launched:	Within 6 months of EDOC
Pilots completed:	Within 12 months of EDOC

CONCLUSION

The Department of Health and Human Services (HHS) has a long and proud history in steadily and substantially improving the health and welfare of all Americans. Despite this progress, prescription drug abuse continues to take a significant toll on human life.

The Work Group focused its efforts on the development of an Action Plan. This endeavor provided an opportunity to gather various federal agencies and allow them to bring their resources and expertise to bear on this critical issue. The work is not complete, but will continue

to require the concerted and focused effort of all involved, for the end result of helping to prevent prescription drug-related deaths. The members of the Work Group recognize that the keys to success include collaboration, incremental steps, and building on the technology that already exists. They are committed to making this collaborative Action Plan succeed.