The Statewide Health Information Exchange

Technology to Support a Prescription Drug Monitoring Program

MARYLAND HEALTH CARE COMMISSION

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Abstract

The use of prescription drugs has increased exponentially over the last two decades. Since 1999, the abuse, misuse, and overdose of prescription drugs have risen. Each year more than 20,000 persons in the U.S. die from drug overdoses.[1] Millions of prescriptions written every year give people access to a wide range of prescription drugs. This has ushered in tremendous advances in medicine and, at the same time, the need for prescription drug monitoring programs (PDMP) that are proactively paired with aggressive prevention, drug treatment, and appropriate enforcement components. The *National Drug Threat Assessment 2005* notes that in the late 1990's legitimate commercial production and dispensing of narcotic pharmaceuticals increased sharply, making more of these drugs available for illegal diversion. Today, opiates are the most common source of drug overdose deaths in the nation.[2] A PDMP can be a valuable part of a comprehensive statewide health information exchange (HIE) initiative for states to consider.

In June 2008, the Advisory Council on Prescription Drug Monitoring was authorized (Chapter 276, Acts of 2008) to study the establishment of a prescription drug monitoring program that electronically collects and stores data concerning monitored prescription drugs.[3] PDMPs are designed to help prevent and detect the diversion and abuse of pharmaceutically controlled substances, particularly at the retail level where no other automated information collection system exists. The risks to privacy and security, and the cost of implementing and operating a PDMP differ from one state to another. These factors are mostly influenced by the policies that are developed to govern the use, collection, and storage of the information and the technology that is deployed to

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[1] Association of State and Territorial Health Officials, *Prescription Drug Overdose: State Health Agencies Respond*, 2008.
[2] Ibid.
[3] House Bill 525 *Advisory Council on Prescription Drug Monitoring – Study*, 2008, Maryland General Assembly.

support such a system. An efficient approach to deploying a PDMP in Maryland is to include this function as a service (Use Case) under the statewide HIE currently under implementation.

After several years of planning, Maryland began the implementation of a statewide HIE in August 2009. The statewide HIE, which is being built on sound privacy and security principles, is well positioned to assist legitimate prescribers by providing them with data to determine if, or ensure that, consumers are not receiving controlled substances from multiple prescribers, doctor shopping, or over-utilizing controlled substances. The statewide HIE is capable of allowing providers to access data that verifies consumers have not previously filled a prescription, or are not visiting numerous pharmacies with similar prescriptions from multiple physicians. Appropriately authorized and authenticated providers who use the statewide HIE could have access to data before prescribing or dispensing controlled substances. The data could be a strong deterrent to criminal activity related to controlled substance abuse. Key benefits associated with a PDMP Use Case include improved access to timely and accurate information in a private and secure environment, and minimal costs and workflow disruption to pharmacies.

Health Information Exchange

Driven by the opportunities to improve health care quality and reduce health care spending, Maryland is consistent with many other states in its effort to develop a statewide HIE. The statewide HIE is sufficiently flexible, built upon sound policy, and includes a privacy approach that is protective yet not prohibitively user access restrictive. The infrastructure is designed to deliver essential consumer information to authorized providers at the time and place of care that helps assure appropriate, safe, and cost-effective care; stores and transmits sensitive health information privately and securely; allows consumer access to important elements of their clinical record to help engage consumers in their own care; ensures a means for the consumer to exercise appropriate control over the flow of private health information, both as a matter of right and as a means of assuring trust; provides a secure method of transmitting administrative health care

transactions; and can gather information from the health care system to research efficiency and cost-effectiveness of care, to measure quality and outcomes of care, and to conduct biosurveillance and post-marketing surveillance of drugs and devices.

Developing a Use Case to support a PDMP is achievable over the next three to five years. Once the statewide HIE's core infrastructure is in place, Use Cases such as PDMP can be added based on a funding mechanism required to support the service.[4] Maryland's approach to building a statewide HIE is consistent with the *American Recovery and Reinvestment Act of 2009* (ARRA). On February 17, 2009, the President signed ARRA into law. The statute includes The *Health Information Technology for Economic and Clinical Health Act of 2009* (the HITECH Act) that sets forth a plan for advancing the appropriate use of health information technology to improve the quality of care and establishes a foundation for health care reform.

In the fall, the Office of the National Coordinator for Health Information Technology (ONC) will approve funding for up to 50 state grant applications to improve and expand HIE services in a manner defined by the ONC that improves the quality and efficiency of health care. Maryland is one of many states to submit an application for advancing the implementation of a statewide HIE and is eligible to receive up to $9 million in funding. The state anticipates the potential funding from ARRA will speed implementation of the statewide HIE. The statewide HIE will use potential grant funds to expand the number of Use Cases implemented over the next four years. Initial funding by the state is limited and is not expected to enable full deployment of the statewide HIE.

The statewide HIE infrastructure will enable connectivity regionally and nationally; ensure financial sustainability; and serve as the foundation for transforming health care in Maryland. The architecture is capable of connecting with approximately 47 acute care hospitals, 7,914 physician

[4] Use Cases are services in a system developed through analysis of the requirements into a set of possible sequences of interactions between systems and users in a particular environment and related to a particular goal.

practices, and 1,628 pharmacies throughout Maryland.[5] The infrastructure will eventually connect with other HIEs regionally and nationally. The governance of the statewide HIE will guide the development of finance, technical infrastructure, business and technical operations, and legal/policy implementation. The statewide HIE provides a mechanism for authorized individuals to perform sophisticated analytics and reporting for public health, biosurveillance, and other appropriate secondary uses of the data.

The State Designated HIE

The Chesapeake Regional Information System for our Patients (CRISP) is a not-for-profit membership corporation whose organizational members are Erickson Retirement Communities, Erickson Health Information Exchange, Johns Hopkins Medicine, MedStar Health, and University of Maryland Medical System. The CRISP coalition grew out of conversations among the members exploring opportunities for cooperation to improve the availability of electronic health information. The statewide HIE governance is composed of the Board of Directors, Advisory Board, and Policy Board established by the Maryland Health Care Commission (MHCC). Among other things, the Board of Directors has accountability for the statewide HIE, will ensure that the policies developed by the Policy Board connected with the MHCC are implemented, and will take the recommendations from their Advisory Board under consideration. The governance model is designed for flexibility to ensure that the organization can respond to market changes and eventually support data sharing with the Nationwide Health Information Network (NHIN).

More than 25 other-related stakeholder organizations have pledged support to the CRISP effort. In August, the MHCC has entered into a three year agreement with CRISP to implement the statewide HIE. CRISP will receive $10 million through Maryland's all-payor rate setting system to fund the statewide HIE implementation. Absent any additional funding, the statewide HIE expects to become sustainable for a narrowly defined set of Use Cases within roughly five years. The key to

[5] Information on hospitals obtained from the Health Services Cost Review Commission, physician data from the Maryland Board of Physicians, pharmacy data provided by the Maryland Board of Pharmacy.

achieving sustainability is a series of assumptions about the fees that various participants are willing to pay for services offered through the statewide HIE, and how fast those services are deployed and subsequently adopted by the user community.

Technology Design

The statewide HIE consists of a hybrid technology that combines a federated or distributed model, keeps the health information at its source facilities or with providers, and uses the HIE as the conduit for sharing. It provides consumers with an option to request that their information be held in a Health Record Bank (HRB) or Personal Health Record (PHR) account controlled by the individual. The statewide HIE serves as a secure and trusted conduit rather than a centralized repository that provides a roadmap for properly routing information to the appropriate location. The statewide HIE will maintain a central master patient index (MPI) and a separate registry (Registry) of the record's location within the system. The use of hybrid technology enables the centralization of records in an HRB/PHR that is directed by the consumer. This model does not constitute a centralized record, but rather directory information that allows records to be identified and located throughout the distributed system. A hybrid model is generally less threatening to providers and consumers because it is less disruptive to existing, trusted relationships between consumers and their providers, and raises fewer regulatory issues in today's privacy and security focused regulatory environment.

The statewide HIE will integrate with HRB and PHR applications that meet appropriate technology standards, and allow consumers to have access to and control over their health information. PHR documentation may be generated directly from the records of health care providers or entered by the consumer. Providers are not likely to assign the same value to records from a PHR since consumers may alter the information, yet PHRs allow consumers virtually complete control over their own information and how this information is shared.

The design allows consumers the freedom to either participate or not participate in the HIE, as well as enable consumers to have the right to be informed of their provider's access to and use of the HIE to access their data. Consumers will also have the capability to opt-out of participation entirely. Providers will not have the ability to exchange data of consumers that choose to opt-out of the HIE. The statewide HIE will inform consumers of their right not to participate through an intensive public awareness campaign and the consumer's rights related to it.

The infrastructure incorporates standards consistent with that of emerging national technology. The statewide HIE will only implement technology that meets federally endorsed standards and integration protocols that bridge proprietary boundaries. As a core technology principle, this ensures that the statewide HIE is not vulnerable to vendor selection issues or risks, and is also compatible with HIEs developed in other states and the federal initiative.

Deployment of Use Cases is gradual and growth is based on an incremental strategy that is built from individual Use Cases that have a demonstrated need and with evident clinical value to consumers and providers. The alternative, which imposes significant challenges, is the implementation of an HIE that immediately seeks to provide widespread exchange of all health information to providers. A leading implementation challenge is to avoid setting such high initial technological and user acceptance thresholds that the statewide HIE is unable to deliver on its broad promise to improve health care quality. The initial Use Cases under development include: medication history in the emergency department, laboratory results delivery, and hospital discharge summaries to hospitals and emergency departments.

The statewide HIE intends to benefit all Marylanders. Amid the inherent challenges of HIE, uninsured and underserved populations will not be overlooked. The MHCC will ensure that resources and focus remain directed to these components of the overall HIE effort, as it represents an important part of the solution and a key part of the quality, access, and cost challenges in health care.

Policy Development

A Policy Board established by the MHCC[6] will develop policies governing the statewide HIE. The separation of responsibilities assures a strong role for the public in both policy development and operational oversight. Members of the Policy Board have been selected to assure expertise, breadth of stakeholder representation, and a strong consumer voice in establishing the policies essential to building trust. Policies developed by the Policy Board will enable and foster information sharing within the state and eventually across state borders.

Operations of the statewide HIE will occur under the direction of the Advisory Board. In general, services are rendered with the agreement, amounting to consent from the consumer whose information is being exchanged. As a baseline process, the statewide HIE will notify consumers about its existence and the consumer's ability to opt-out of all exchange participation, meaning that they will have the choice to prohibit all of their health information from flowing through the HIE. The notice will describe the statewide HIE, its purpose and its functions. In effect, opting out will be the equivalent of placing one's self on a do not call or global suppression list. However, some information will remain in the statewide HIE for consumers that choose to opt-out. Depending upon the Use Case and associated data, additional consumer consent protocols will be deployed over and above the full HIE opt-out.

In practice this means that the statewide HIE will include all consumers by default unless they request not to be included. For those consumers that participate, the statewide HIE will be available for a variety of purposes, some of which will require additional consumer consent or authorization under the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) Administrative Simplification Provisions and the *Maryland Confidentiality of Medical Records Act*

[6] Requirement for a Policy Board was identified in the Maryland Health Care Commission and Health Services Cost Review Commission Request for Application for *A Consumer-Centric Health Information Exchange for Maryland*. April 15, 2009.

(MCMRA), and some of which will operate without explicit patient approvals.[7] For instance, under most circumstances, a hospital emergency department will ask verbal approval from any consumer capable of indicating consent before they use the statewide HIE to query external sources for health information.

Privacy

In some areas, Maryland privacy laws are more stringent then HIPAA requirements. Maryland law covers health care providers and facilities on original disclosures of information, and includes everyone on re-disclosure. Providers holding protected health information need to become familiar with both federal and state law to determine which legal rule or principle governs the disclosure of the information. Stringent requirements around access, authentication, audit, and authorization will be put in place to ensure the appropriate use of the system; how usage of the system is governed; how users are accurately and appropriately identified; and how records of that usage are captured, stored, and utilized for various audit purposes. Access to the statewide HIE is based on defined roles with each participating entity. Users are assigned access constraints and allowances based upon their designated roles. The statewide HIE will implement procedures to regularly review records of system activity, and will use audit logs, access reports, and security incident tracking reports to audit user activity. The statewide HIE will store the audit logs in a central location, which will include detailed information about the type of data that was accessed, who accessed the data, and when this information was accessed. The audit log will not store the actual health information.

The Policy Board will establish access levels in a manner to achieve a balance between complexity, usability and administrative overhead. Authorized individuals will have the ability to view and save select data for the purposes of treatment, while others may only have the ability to view data in the statewide HIE. The management of authentication services through the statewide

[7] Maryland's Confidentiality of Medical Records Act, codified at Health-General § 4-301 *et seq*., has been operative since 1991.

HIE is similar to access. The statewide HIE will use single factor authentication initially and eventually adopt a more stringent approach through two factor authentication. Consumers requesting access to their health record will continue to request this information from their treating provider. These providers will maintain the notice of privacy practices and provide for an accounting of disclosures.

Security

The statewide HIE will ensure the confidentiality, integrity, and availability of electronic consumer information. Complying with the HIPAA Security Rule requires significant time and effort on the part of the statewide HIE. Adherence to the standards provides basic assurances to the protection of electronic health information.[8] The Advisory Board is tasked with defining additional security rules that need to be implemented. Vendor technology partners are required to demonstrate that their solutions meet or exceed the security requirements. Participation agreements stipulate that users comply with the HIPAA requirements. The statewide HIE will maintain an inventory of electronic health information. The flow of electronic health information will be easily tracked throughout the statewide HIE.

State Laws

The MCMRA is substantively consistent with HIPAA with regards to implicit consent and the other HIPAA issues discussed in the preceding section.[9] Under this Act, an individual's health information may be exchanged among health care providers with only implicit consent for treatment purposes. In 2007, the Maryland Attorney General issued an opinion related to the MCMRA which addressed the requirement of a patient opt-in versus opt-out policy in an electronic

[8] Department of Health and Human Services, Office of the Secretary, 45 CFR Parts 160, 162, and 164. Health Insurance Reform: Security Standards. Federal Register / Vol. 68, No. 34 / Thursday, February 20, 2003 / Rules and Regulations.
[9] Office of the Attorney General, Maryland Health Care Commission, Department of Health and Mental Hygiene, the State Advisory Council on Medical Privacy and Confidentiality, with assistance from the Maryland State Bar Association Health Law Section HIPAA Subcommittee.

health records system.[10] According to this opinion, a consumer does not have a right under the Act to opt-out of an HIE, to receive services from a provider while insisting that the medical records related to that service be excluded from the HIE. The Attorney General went on to conclude that the disclosure of health record information solely for purposes of clinical care and payment and to the technical personnel needed to keep the system operational is permitted without the authorization of the consumer. The MCMRA does not prohibit an HIE from operating on the basis that participating providers must make all of a consumer's health records available through the HIE. However, because the law does not dictate the appropriate policy, an important caveat to the interpreted allowance is that making a consumer's health records available does not imply those records are stored within the HIE.

In the opinion, the Attorney General concluded that the MCMRA would permit an HIE in which health records are held by certain providers and referenced in the MPI facilitating other providers access to the records as needed without the authorization of the consumer.[11] This indexing function is a critical element of the approach in Maryland. Provider workflow considerations and management of a consumer's right to participate or not to participate are also of considerable concern in creating a consent policy. If consumer participation rights were managed on a provider-by-provider, encounter-by-encounter basis, then providers would bear a significant, and potentially prohibitive, technical and workflow burden establishing processes for obtaining and tracking consent.

The Current Environment

States that currently have a PDMP require the electronic transfer of data to a centralized source. Early systems, similar to the one deployed in Nevada, relied on physicians and pharmacies

[10] Medical Records – Application of Maryland Medical Records Confidentiality Act, To A Possible Statewide "Health Information Exchange" Mechanism. Information available online at http://www.oag.state.md.us/Opinions/2007/92oag107.pdf.
[11] Ibid.

faxing requests to the PDMP and waiting for hardcopy reports in the mail.[12] The overall approach and specifics of these systems and the data that is collected and reported varies by state. For the most part, the standalone system approach has been successful to help identify patients who might be abusing prescription drugs. This process requires pharmacists to upload data using a File Transfer Protocol (FTP) to exchange and manipulate files over the Internet. FTP is built on the client-server architecture and utilizes separate control and data connections between the client and server application. PDMPs that use FTP to transfer data are often faced with a number of critical challenges in managing the program: the cost to obtain and pay for disk space on an FTP server; most systems do not have automatic backup capability; FTP connections are unreliable and frequently time out; files can be corrupted during FTP transfer without user knowledge; most FTP software is not encrypted; and FTP servers do not normally use data mirroring.[13]

The typical pharmacy management software solution does not automatically produce reports that states can use for prescription drug monitoring. These systems require configuring by vendors to produce reports on specific controlled substances in a manner consistent with state defined data elements. Requiring pharmacies to generate reports that can be sent through an FTP application or on media to a contractor is burdensome to pharmacies given the volume of work they routinely manage. The existing approach calls into question the expectation around real time, which is often defined by states in reporting regulations. Compiling these data into a database by a centralized source is time consuming and delays its availability. From the initial transaction to when the data is available for analysis can be several weeks.[14] Enforcement of pharmacies to consistently comply with the reporting requirements presents another entirely unique set of challenges.

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[12] *Optimum Technology Announces New Prescription Monitoring Program for the State of Nevada*. Information available online at: http://www.otech.com/company/news/101904.asp.
[13] Perkins, Donovan, *Considerations in Secure Data and Information Exchange Protocols between Banks and Corporations*. Available online at: http://www.acuprint.com/articles/transporterconsiderations.html.
[14] Lambert, David, Ph.D., *Impact Evaluation of Maine's Prescription Drug Monitoring Program*, Muskie School of Public Service, University of Southern Maine, Portland Maine, March 2007.

An Ideal Use Case

The statewide HIE provides a suitable technology framework to support a Maryland PDMP. The statewide HIE is interoperable and eliminates the need to manually collect data from pharmacies and prescribers. A flexible infrastructure enables the statewide HIE to deploy technology designed to carve out pharmacy transaction data at different points for insured and wholesale transactions. The impact of the PDMP through the statewide HIE on the pharmacies is minimal; today insured data is routinely sent electronically to payers and pharmacy benefit managers. Wholesale transactions are manually entered into the pharmacy information system and saved at the point of service. The most basic way to capture wholesale transactions is to require that pharmacies treat wholesale transactions as they do today with third party payers, and electronically transmit them to the statewide HIE with a self-pay identifier in the electronic file. The statewide HIE can coalesce and securely store the data in an independent database where only appropriately authenticated individuals would have access to the data. It is conceivable that a statewide HIE can have data available for analysis within minutes from when a transaction is processed by the pharmacy.

Sound policy relating to privacy and security of the data will need to be established prior to implementing this Use Case. Architecting the Use Case around well thought out policy will ensure trust amongst the users that the data is appropriately used by individuals who have authorization to access the data, and the circumstances whereby the data can be used. The statewide HIE Policy Board could serve as the body that develops policy or could oversee an independent PDMP Advisory Board, consisting of a wide-range of stakeholders, which would make recommendations to the Policy Board about the appropriate use of the data. Among other things, policies need to take into consideration the present circumstances in neighboring states. Eventually, the statewide HIE will harmonize data sharing activities with bordering states. Interstate collaboration will ensure that states implement HIEs that enable appropriately authorized pharmacy data to move securely

across state borders. Implementing policies through the statewide HIE allows for standardized monitoring and reporting on the success of the program and allows the ability to make policy changes more rapidly.

Establishing policy to protect the privacy and security of data ensures that consumers with access to their information through the statewide HIE receive notification that information related to prescriptions for certain classes of drugs is reported to the state. Consumers will also have the ability to access and contest the accuracy and completeness of their data. The privacy and security and the integrity of the data in a PDMP are appropriately safeguarded by the statewide HIE. The statewide HIE is also well positioned to verify the accuracy of information through audit logs and conduct penetration testing to validate the adequacy of the security protections. Penetration testing is a method of evaluating the security of the HIE by simulating an attack from a malicious source.

The cost of implementing and operating a standalone PDMP differs among states due to many variables. The average cost to start a PDMP using the traditional client-server model is approximately $350,000 with annual operating costs that range from $100,000 to nearly $1 million.[15] Cost variations are affected by the frequency of data collection, the use of a third party vendor, the number of prescriptions written and filled in a state, the number of controlled substances monitored, and human resources required to support the program. The exact cost for implementing a Use Case for the statewide HIE to support a PDMP is not known. Until policies related to this Use Case are developed, it is not possible for the state to determine the financial impact of tasking the statewide HIE with this responsibility.

A PDMP managed through the statewide HIE increases efficiencies in monitoring of pharmacy data, allows for standardized and custom reporting, enables access to data in real time with minimal impact to pharmacies, and increases privacy and security protection of the data.

[15] U.S, Department of Justice, Drug Enforcement Administration, Office of Diversion Control: http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm.

Implementing a PDMP via the statewide HIE is consistent with the expectations for a PDMP system described by the Office of the Attorney General in their report on the prescription drug abuse in Maryland.[16] The statewide HIE provides an efficient approach to implementing a system that prevents abuse, trafficking, and diversion of controlled substances, and it can also help inform providers and the public of trends in the use and abuse of prescription drugs.

[16] *PRESCRIPTION FOR DISASTER, The Growing Problem of Prescription Drug Abuse in Maryland*, State of Maryland Office of the Attorney General, September 2005.