Electronic Prescription Records System Workgroup

WORKGROUP DISCUSSION ITEMS/GRIDS

KEY THEMES AND CONCEPTUAL IDEAS FOR CONSIDERATION

TASK: The Maryland Health Care Commission (MHCC) is tasked with convening a workgroup of interested stakeholders to conduct a health information technology policy study that assesses the benefits and feasibility of developing an electronic system (or statewide repository) for health care providers to access complete patient prescription medication history. This pertains to information on non-controlled dangerous substances, not CDS Schedule II-V drugs that are already made available through the Prescription Drug Monitoring Program (PDMP). Refer to the Workgroup Charter for more information.

APPROACH: Discussion items that follow are in part, specified in law (Chapter 435)[1] and serve as a guide for workgroup deliberations. Discussion items have been simplified and are intended to be thought-provoking and help narrow the focus on specific components of a statewide repository using information gathering grids. Reflecting on workgroup discussions, including information gathered in the grids, identification of key themes and conceptual ideas will guide development of informal draft recommendations. In general, terms have the following meaning:

Benefit: Value derived from producing or consuming a service

Barrier/Challenge: A circumstance or obstacle (e.g. operational, economic, political, budgetary, etc.) that hinders or prevents progress

Solution: An idea aimed at solving a problem or managing a difficult or complex situation

Key Theme: A key takeaway statement that summarizes quadrants of the grid and can be used to formulate potential recommendations

Note: The discussion items/grids are a means to spur objective thinking about the feasibility of developing a statewide repository. Key themes and conceptual ideas take into consideration concepts identified in the grids. This is not an exhaustive list nor does it represent consensus among the workgroup. This document serves as a working draft for framing key elements of draft recommendations.

[1] Required by House Bill 115, *Maryland Health Care Commission – Electronic Prescription Records System – Assessment and Report*, passed during the 2018 legislative session (Chapter 435). For more information, visit: mhcc.maryland.gov/mhcc/pages/home/workgroups/workgroups_hit_electronic_prescription.aspx.

Discussion Item 1: Capability of the State-Designated Health Information Exchange (HIE), the Chesapeake Regional Information System for our Patients (CRISP) to make available patient prescription medication history

1A. Expanding use of existing CRISP infrastructure (availability, process integrity, and operating effectiveness) to make available non-CDS data	
BENEFITS *(VALUE ADD/PERCEIVED)* ● CDS dispensers already required to report Schedule II-V drugs to the PDMP through CRISP (COMAR 10.47.07) ● A high percentage of pharmacists are registered and trained on the CRISP system, minimal training required beyond awareness building of non-CDS data availability ● Leverage aspects of existing CRISP infrastructure used for CDS	**BARRIERS & CHALLENGES** *(OBSTACLES/POTENTIAL ISSUES)* ● Partitioning CDS and non-CDS data within CRISP ● The technical impact of reporting non-CDS data at once versus a gradual phased in reporting approach (estimated ten-fold increase in data) ● Increased privacy and security protections ● Upfront and ongoing costs ● Identifying a minimally disruptive strategy to accommodate non-CDS data
SOLUTIONS *(FOR USING CRISP TO MAKE NON-CDS DATA AVAILABLE THROUGH THE PDMP)* ● A phased in approach for non-CDS reporting ● Other vendor(s)/data repositor(ies) for non-CDS data ● Adequate load testing of the system prior to implementation ● Appropriate penetration testing	
KEY THEMES • Leverage aspects of existing CRISP infrastructure used for CDS, including PDMP registration and training ○ Small number of pharmacies (<100 just dispending non-CDS) • Mandate and policies for non-CDS in a model that uses one or more vendors to collect and expose prescription data • Need sustainable funding model for upfront and ongoing costs • Phased in approach for non-CDS (also see Grid 3A)	
PARKING LOT ● Funding source(s) to support up-front and ongoing costs ● Elements of a phased in reporting approach for CRISP ● Identify loopholes with potential for creating gaps that make information not clinically useful	

Discussion Item 2: Required enhancements to the State-Designated HIE to ensure it can continue meeting other State mandates, including operating an effective PDMP

2A. Enhancing CRISP to support new and existing State mandates

BENEFITS *(VALUE ADD/PERCEIVED)*

- Established infrastructure and PDMP processes
- Increased value of the State-Designated HIE
- Expand use cases for improving care coordination
- Enhance patient matching algorithms

BARRIERS & CHALLENGES *(OBSTACLES/POTENTIAL ISSUES)*

- Obtaining legislative authority (compliance and enforcement; identification of a bill sponsor)
- Funding source(s) up-front and ongoing to support non-CDS data, including additional cost for privacy and security
- Patient education/consent
- Policy requirements to change and manage non-CDS data reporting and patient consent
- Identifying a reasonable and minimally disruptive implementation timeline
- Implementing a streamlined workflow across various vendors

SOLUTIONS *(FOR SUPPORTING NEW SERVICES)*

- State mandate to require reporting of non-CDS data
- A chartered stakeholder workgroup to identify policy and technology solutions to support a phased implementation approach
- Develop a sustainable funding model that spreads investment and maintenance costs across users
- Provider value and communication strategy

KEY THEMES

- Need sustainable funding model for upfront and ongoing costs
- Outreach and education
- Value-add service/enable innovative use cases for non-CDS data
- Phased in approach for non-CDS (also see Grid 3A)
- Legislation for non-CDS (as opposed to voluntary) to ensure consistency in reporting, use of industry standards, and in managing program costs
    - Dispensers are the ideal source for reporting non-CDS; preference is to send data (both CDS and non-CDS in one batch)

PARKING LOT

Discussion Item 3: Resources required for individual health care practitioners, health care facilities, prescription drug dispensers, and pharmacies to provide the information collected in a statewide repository of prescription medication information; resources required to ensure health care practitioners and prescription drug dispensers can maximize the benefit of using the system to improve patient care

3A. Investing new resources for reporting non-CDS data

BENEFITS *(VALUE ADD/PERCEIVED)*

- A more complete patient medication record available through CRISP
- Improved medication reconciliation (patient safety) and care coordination
- Opportunity to use existing vendor(s) and standards in the market that collect and make prescription information available, including prescriptions paid for with cash
- Leverage existing workflows for consulting the PDMP
- Potential for improving patient outcomes by addressing comorbid conditions that affect opioid use disorder and chronic pain syndromes beyond mental or behavioral health diagnoses

BARRIERS & CHALLENGES *(OBSTACLES/POTENTIAL ISSUES)*

- Start-up cost and implementation timeline for pharmacies
- Outreach and education to new and existing users
- Identifying a new reporting process for non-CDS, independent from the current PDMP infrastructure, including vendor(s) and standard(s)
- Ensuring data gets in the right place in existing clinical workflows
- Potential functionality and workflow challenges if medication reconciliation within EHR (e.g., view-only mode; duplication of data/alerts, etc.)
- Potential contractual issues with different health care organizations types when sharing information
- Burden on dispensers that have limited resources to expand reporting of non-CDS (e.g., local health departments)

SOLUTIONS *(FOR INVESTING RESOURCES)*

- Naming standard(s) in law, if needed, to ensure prioritization in the industry
- Developing an online training program to address implementation and reporting, among other things
- A phased in implementation process
- Mandate to facilitate contractual issues with data sharing

KEY THEMES

- Mandate and policies for a non-CDS vendor neutral model that encourages competition and ensures data gets to the right place in existing workflows
- Phased in approach for non-CDS through pilot projects with certain provider/pharmacy types or by county (not drug classification)
    - Reasonable and minimally disruptive implementation timeline
    - Amnesty period for certain dispensers with limited resources (e.g., local health departments); exemptions should not be prematurely defined
- Integrate cannabis dispensing information in the model
- Consider functionality for end-users to provide feedback/corrections to data in the repository
- Outreach and education

PARKING LOT

- Reporting of medical cannabis
- Alternative resources exist that have the large majority of this data (e.g., Surescripts, Change Healthcare, etc.)
- Explore other loopholes in medication reconciliation and potential solutions (e.g., awareness of medications discontinued by providers, medication history correction functionality, etc.)

Discussion Item 4: Feasibility of ensuring data in the system is used only by health care practitioners to coordinate the care and treatment of patients

4A. Existing system requirements – access, use, and disclosure	
BENEFITS *(VALUE ADD/PERCEIVED)* ● Mandatory registration and use of the PDMP ○ CDS prescribers and pharmacists in Maryland were required to register with the PDMP by July 1, 2017 (includes physicians, physician assistants, nurse practitioners, nurse midwives, dentists, podiatrists, and veterinarians)[2] ○ Beginning July 1, 2018, CDS prescribers must consult a patient's PDMP data before prescribing an opioid or benzodiazepine and every 90 days during the course of treatment with CDS; pharmacists must review a patient's PDMP data prior to dispensing any CDS drug if they reasonably believe the patient seeks the drug for non-medical use ● Prescribers and pharmacists may delegate PDMP access to staff working in the same practice or facility ● CRISP has: ○ Role-based access controls to prevent misuse and security violations ○ AI to track and monitor user access to patient records ○ Privacy and security audits conducted at least annually ○ Established governance structure in place ○ EHNAC accreditation and HITRUST certification	**BARRIERS & CHALLENGES** *(OBSTACLES/POTENTIAL ISSUES)* ● Developing policies regarding access, use, and disclosure or non-CDS data ● Modifying existing participation agreements
SOLUTIONS *(FOR MAINTAINING AND ENHANCING CURRENT PROCESSES)* ● Identifying minimum criteria for vendor(s) to ensure privacy and security ● Establish policies for non-CDS prescription data handling practices (e.g., data sharing) ● Expand user tracking of the PDMP	

[2] Other authorized users include law enforcement (with subpoena), health occupations licensing board (with administrative subpoena), MDH agencies (if there is an existing investigation), patients (for their own prescription history), other state PDMPs, and the PDMP Technical Advisory Committee. De-identified data may be made available for research, public education and reporting purposes.

KEY THEMES
• Vendor criteria for non-CDS and connecting to the PDMP • Vendor neutral infrastructure that encourages competition and ensures data gets to the right place in existing workflows • Rely on existing policies for misuse of data
PARKING LOT

Discussion Item 5: Scope of health care providers that would report prescription medication information in the system, including any specific exemptions; scope of prescription medication information that should be collected in the system, including any specific exemptions

5A. Exclusion of certain providers and non-CDS data elements to be reported	
BENEFITS *(VALUE ADD/PERCEIVED)* ● Confidentiality protections for consumers (e.g., behavioral health) ● Allay patient privacy concerns/need to adopt technology	**BARRIERS & CHALLENGES** *(OBSTACLES/POTENTIAL ISSUES)* ● Determining which providers and non-CDS data elements are exempt from reporting ● Responsibility to apply filters (dispenser or CRISP) ● Incomplete data could decrease utility of the repository ● Impact of limited information available to treating providers ● Creates doubt and places a burden on providers to engage patients to identify a complete list of medications ● Potential impact on patients
SOLUTIONS *(FOR DETERMINING PROVIDERS THAT SHOULD BE EXCLUDED)* ● Phased approach to implementation ● Engage stakeholders in establishing non-CDS exemptions	
KEY THEMES • Implications of incomplete data • Exemptions based on need (not convenience) to ensure patient safety	
PARKING LOT ● Reporting of hospital in-patient data ● Reporting of drugs used to treat co-occurring infectious diseases ● Reporting of emergency room, surgical centers, compounding pharmacies, first responders, and other circumstances where immediate administration to the patient occurs	

Discussion Item 6: Potential for development or use of systems other than CRISP for access to patients' prescription medication history

6A. Public application programming interface (API) for vendors

BENEFITS *(VALUE ADD/PERCEIVED)*

- Enables third party developers to advance functionalities and/or innovative uses for the data
- Increase use of data by vendors where the data is built into the workflow

BARRIERS & CHALLENGES *(OBSTACLES/POTENTIAL ISSUES)*

- Patient matching/various vendor MPIs
- Oversight of open API management
- Over 90% of EMRs have already adopted the necessary screens and backend data pipes to pull patient medication history within the provider workflow

SOLUTIONS *(FOR ENABLING/MANAGING A PUBLIC API)*

- Designate an entity required to provide oversight to the terms and use of the API, including criteria and corrective actions for misuse

KEY THEMES

- Vendor neutral technical infrastructure that encourages competition and supports innovative use cases
- Leverage existing market solutions to collect and expose non-CDS data
- Mandate and policies for a non-CDS

PARKING LOT

Discussion Item 7: Privacy protections required for the system, including the ability of consumers to choose not to share prescription data and ensure the prescription data is used in a manner that is compliant with State and federal privacy requirements, including 42 31 U.S.C. § 290dd–2 and 42 C.F.R Part 2

7A. Existing State and federal privacy protections	
BENEFITS *(VALUE ADD/PERCEIVED)* ● Floor for privacy protections and individual rights established by HIPAA/HITECH ● Maryland HIE regulations (COMAR 10.25.18) expand upon federal requirements to enhance privacy and security protections when electronic health information is made available by an HIE	**BARRIERS & CHALLENGES** *(OBSTACLES/POTENTIAL ISSUES)* ● Determining the appropriate balance between consumer privacy protections and a treating provider's needs in care delivery for complete medication history ● Addressing potential opt-outs (e.g., all in or all out; by diagnosis or classification of drugs; provider type, etc.) ● Managing the opt-out process, including how incidental disclosures should be handled ● Consumer notification
SOLUTIONS *(FOR ENHANCING PRIVACY PROTECTIONS)* ● Consumer awareness campaign on the pharmacy reporting requirements and value to care delivery ● Assessing lessons learned from other states that have similar reporting requirements	
KEY THEMES • Outreach and education (see Grid 7B) • Policies for non-CDS data handling practices, including complaints and remediation plans • Ensure patient safety by defining exemptions based on need (not convenience) (see Grid 5A) • Management of opt-out process (see Grid 7B)	
PARKING LOT ● Legislation	

7B. Consumers' control on who can access their non-CDS data

BENEFITS *(VALUE ADD/PERCEIVED)*

- Consumer engagement
- Consumer autonomy to opt-out/choose if they want to share their medication history for non-CDS drugs
- Perceived confidentiality

BARRIERS & CHALLENGES *(OBSTACLES/POTENTIAL ISSUES)*

- Reduced value of a system that does not include all non-CDS data
- Patient education/understanding
- Determining if all or certain types of non-CDS data should be included in the opt-out function
- Impact on care delivery, such as errors that can impact cost and patient health outcomes
- Messaging that is appropriate and inclusive of consumer's language, culture, etc.

SOLUTIONS *(FOR ENABLING CONSUMER CONTROL OF THEIR NON-CDS DATA)*

- A strategy that builds toward full reporting of non-CDS information where some consumer control exceptions are included in the design and where information is limited under certain situations
- Develop consumer education strategy

KEY THEMES

- Patient ability to opt-out (all in or all out)
- Management of opt-out process
- Outreach and education
- Implications of not having access to the data during care delivery

PARKING LOT

- Feasibility study to determine what percentage of patients will opt in/opt out - High % of opt out will make system clinically not useful

Discussion Item 8: Standards for prohibiting use of the data in the system by a person or an entity other than a health care practitioner, including any exceptions for use of the data with identifying information removed for bona fide research

8A. Limiting use of non-CDS data to treatment, payment, and health care operations	
BENEFITS *(VALUE ADD/PERCEIVED)* ● Limits secondary use of non-CDS data ● Builds consumer confidence ● Limits access to the information based on defined access rights	**BARRIERS & CHALLENGES** *(OBSTACLES/POTENTIAL ISSUES)* ● Identifying an appropriate oversight authority ● Engaging stakeholders to develop governing policies ● Building consumer awareness – messaging
SOLUTIONS *(FOR LIMITING USE OF NON-CDS DATA)* ● Expand PDMP user training to include best practices pertaining to the use of non-CDS data ● Establish an appropriate level of user audits ● Develop policies governing access, use, and disclosure ● Develop policies for use of non-CDS data, including complaint handling procedures and remediation plans	
KEY THEMES • Policies for non-CDS data handling practices, including complaints and remediation plans (see Grid 7A) • Oversight authority to ensure privacy protections for the system • Outreach and education	
PARKING LOT ● Oversight authority	

8B. Use of non-CDS data for research purposes

BENEFITS *(VALUE ADD/PERCEIVED)*

- Existing regulation (COMAR 10.25.18.10) outlines requirements for accessing, using, or disclosing data through an HIE for secondary use
- Value to population health studies (health outcomes, patterns of health determinants, interconnected policies and interventions)
- Public health benefit (disease monitoring, prevention, eradication)

BARRIERS & CHALLENGES *(OBSTACLES/POTENTIAL ISSUES)*

- Who decides on the permitted use cases for non-CDS data
- Ensuring non-CDS data is appropriately de-identified when released
- Obtaining patient authorization and managing the approval process

SOLUTIONS *(TO USE NON-CDS DATA FOR RESEARCH PURPOSES)*

- Electronically capturing the patients' authorization during the encounter where non-CDS drugs are prescribed
- A phased in approach to using non-CDS data in research where further assessment of the challenges and identifying solutions can occur
- Establish data sharing policies for non-CDS data for research purposes

KEY THEMES

- Oversight authority
- Policies for non-CDS data handling practices (see Grid 6A)
- Enable innovative use cases for population health using non-CDS data

PARKING LOT

- Oversight authority
- Addressing social determinants of health across health care and other services