



November 29, 2023

The Honorable Bill Ferguson
President of the Senate
H-107, State House
100 State Circle
Annapolis, MD 21401

The Honorable Adrienne A. Jones
Speaker of the House of Delegates
H-101, State House
100 State Circle
Annapolis, MD 21401

Re: HB1127/CH0296, 2022 - Public Health - State Designated Exchange - Health Data Utility Report (MSAR #14244)

Dear President Ferguson and Speaker Jones,

HB1127/CH0296, 2022 - Public Health - State Designated Exchange - Health Data Utility Report, required the State-designated exchange to operate as a health data utility for the State and provide data, as allowed by law, to individuals and organizations involved in the treatment and care coordination of patients and to support public health goals. The bill also requires that after dispensing a “noncontrolled prescription drug,” a dispenser must submit prescription information to the State-designed exchange.

By January 1, 2024, the Maryland Health Care Commission (MHCC), Maryland Department of Health (MDH), and the State-designated exchange must submit a report to the General Assembly that identifies ongoing revenue sources to fund the activities under the bill. Please find attached the report that addresses the responsibilities of the State-designated exchange and identifies the ongoing revenue sources to fund the activities set out in accordance with *HB1127/CH0296*.

We appreciate your consideration. If you have any questions or if we may provide you with any further information, please do not hesitate to contact me at ben.steffen@maryland.gov or 410-764-3566 or Ms. Tracey DeShields, Director of Policy Development and External Affairs, at tracey.desields2@maryland.gov or 410-764-3588.

Sincerely,

Ben Steffen,
Executive Director

cc:

The Honorable Wes Moore, Governor
The Honorable Joseline A. Pena-Melnyk, Chair, House Health and Government Operations Committee
The Honorable Pamela Beidle, Chair, Senate Finance
The Honorable Laura Herrera Scott, Secretary, Maryland Department of Health
Craig Behm, CRISP
Marie Grant, Assistant Secretary, Health Policy, Maryland Department of Health
House Health and Government Operations Committee
Senate Finance Committee
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Nicole Majewski, Chief, Health Information Technology, MHCC
Tracey DeShields, Director of Policy Development and External Affairs, MHCC



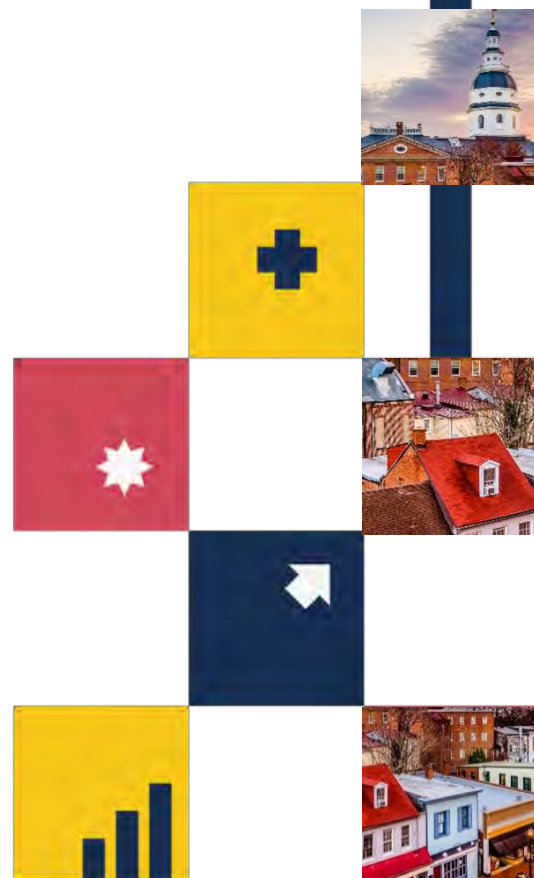
2021 and 2022 Legislation – CRISP Funding Update

Briefing Paper

July 2023

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Introduction

In 2021 and 2022, the Maryland General Assembly passed four bills in support of advancing use of health information technology (“health IT”) statewide. State law requires the Maryland Health Care Commission (“MHCC) to submit a report to the legislature by January 1, 2024 on the sources to fund the activities; this report satisfies the legislative requirement. Health IT makes it possible for authorized health care providers to securely store, share, and analyze electronic health information.¹ Leading elements of health IT include electronic health records (“EHRs”), health information exchange (“HIE”), and telehealth. In general, the laws expand the role of the State-Designated HIE (or “CRISP”)² through clinical and public health reporting; strengthen consumer control around sharing their personal health information; authorize CRISP to operate as a health data utility (“HDU”) for certain purposes; and align the HIE definition with federal policy. In support of the legislation, CRISP is planning to implement various pilots around Quarter 1 2024. The laws and highlights of them are included below.

- Chapter 790/Chapter 791 of the 2021 Laws of Maryland, *Public Health - State Designated Exchange – Clinical Information*: Aims to facilitate a State health improvement program, mitigate a public health emergency, and improve patient safety by requiring nursing homes, on request by the Maryland Department of Health (“MDH”), to electronically submit clinical information to CRISP and requiring electronic health networks (“EHNs”) to provide electronic health care transactions to CRISP for clinical and public health purposes (see Appendix A for a copy of the law).
- Chapter 798 of the 2021 Laws of Maryland, *Health Information Exchanges – Electronic Health Information – Sharing and Disclosure*: Requires the State-Designated HIE to develop and maintain a centralized consent management utility (“CMU”) allowing persons to opt-out from having their personal health information shared or disclosed by all HIEs operating in the State; CRISP will provide individuals’ opt-out status to HIEs upon request and block disclosures of those that have opted out (see Appendix B for a copy of the law).
- Chapter 296 of the 2022 Laws of Maryland, *Public Health – State Designated Exchange – Health Data Utility*: Establishes an HDU operated by CRISP and requires dispensers to submit information to CRISP on non-controlled prescription drugs (“non-CDS”); the HDU will make select information available to providers involved in the treatment and

¹ The Office of the National Coordinator for Health Information Technology, *Health IT: Advancing America’s Health Care*. Available at: www.healthit.gov/sites/default/files/pdf/health-information-technology-fact-sheet.pdf.

² CRISP is a 501(c)(3) independent non-stock Maryland membership corporation.



care coordination of patients and health officials to support public health interventions and promote health equity; CRISP must convene a Consumer Advisory Council to bring consumer perspectives into HIE services provided by CRISP (see Appendix C for a copy of the law).

- Chapter 718 of the 2022 Laws of Maryland, *Health Information Exchanges – Definition and Privacy Regulations*: Alters the definition of an HIE to align with federal policy, which will be reflected in regulations developed by MHCC that govern the privacy and security of protected health information obtained or released through an HIE (COMAR 10.25.18); the new definition addresses fragmentation that impedes delivery system transformation and ensures that HIEs are capable of connecting to diverse stakeholders (see Appendix D for a copy of the law).

Background

The MHCC promotes diffusion of health IT in the State. Health – General Article §19-143, Annotated Code of Maryland (2009) charged MHCC and the Health Services Cost Review Commission (“HSCRC”) with designating a statewide HIE.³ CRISP was competitively selected in August 2009 to serve as the State-Designated HIE. The State-Designated HIE is responsible for building and maintaining the technical infrastructure and ensuring an efficient and effective data management strategy to support secure statewide exchange of electronic health information. A State Designated HIE Designation Agreement (“SDA”) sets forth conditions for CRISP; changes to the SDA are considered as needed with redesignation occurring about every three years.⁴

Health Data Utility

CRISP has established a robust and secure HIE infrastructure allowing authorized users to electronically access and share patient health information.⁵ Designated authority and broad governance are key attributes of CRISP that support functions of an HDU that enables complex use cases using clinical and non-clinical data.⁶ As Maryland’s HDU, CRISP leverages its HIE infrastructure with advanced technical capabilities to combine, enhance, and

³ An HIE facilitates access to and retrieval of clinical data to provide safer and more timely, effective, and equitable patient-centered care.

⁴ The MHCC executed SDAs with CRISP in 2009, 2013, 2016, 2019, and 2022.

⁵ In 2022, CRISP launched CRISP Shared Services to assist member organizations in achieving economies of scale, pooling innovation efforts and implementing best practices. More information is available at: www.crispsharingservices.org.

⁶ Functions of an HDU include, but are not limited to, expansive multi-stakeholder governance with a mix of public and private sector stakeholders and transparent decision-making processes through advisory committees and other stakeholder workgroups (e.g., finance, privacy, and security, consumers).



exchange electronic data across health care for treatment, care coordination, quality improvement, and public health purposes. CRISP supports multi-stakeholder needs by enabling complex and evolving use cases, using clinical and non-clinical data, while ensuring privacy and security of data that exceed minimum standards established by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)⁷ and comply with State regulations.

Maryland was the first state to enact legislation designating HDU authority to CRISP. The law recognizes CRISP’s role statewide and ability to operate an HDU. This includes:

- Collecting, aggregating, and analyzing clinical information, public health data, and health administrative and operations data to assist State agencies in the evaluation of public health interventions and health equity;
- Communicating data between public health officials and health care providers to advance disease control and health equity; and
- Enhancing and accelerating interoperability of health information throughout the State.

Nursing Homes

Nearly all 225 nursing homes in Maryland have adopted a nationally recognized EHR of which nearly 80 percent use PointClickCare. CRISP in collaboration with three post-acute care associations (Health Facilities Association of Maryland, LeadingAge Maryland, and LifeSpan Network) and a health IT vendor (Real Time Medical Systems) launched a *Nursing Facility Connectivity Program* (“program”) in September of 2022. The program is designed to integrate nursing homes EHRs with CRISP; as of March 2023, approximately 49 percent of nursing homes in the State had integrated with Real Time Medical Systems.^{8, 9} Clinical data from nursing home EHRs will be used to improve public health reporting and surveillance; promote disease prevention; and expand communication between providers and public health officials.

Consumer Advisory Council

Consumers provide valuable insight into matters related to sharing electronic health information and opportunities to effectively address potential concerns. CRISP established

⁷ Health Insurance Portability and Accountability Act of 1996. Pub. L. No. 104-191, § 264, 110 Stat.1936.

⁸ MHCC, *CRISP Quarterly Report*, May 12, 2023. Available at: mhcc.maryland.gov/mhcc/pages/hit/hit_hie/documents/HIE_CRISP_Quarterly_Report.pdf.

⁹ Real Time Medical Systems was competitively selected by CRISP to assist with data integration.



a Consumer Advisory Council (“Council”) to identify privacy issues and advise on efforts to educate consumers on the benefits of data sharing.¹⁰ The Council will provide guidance to CRISP in developing policies that foster transparency and enable equitable information sharing attuned to consumer needs and expectations.

Electronic Health Networks

A provision in HIPAA aims to reduce administrative burdens in health care by making possible the standardized electronic transmission of administrative and financial transactions using standard record formats, code sets, and identifiers. EHNs are intermediaries between payers and providers for electronically exchanging administrative and financial data.¹¹ EHNs enable providers to exchange administrative transactions, such as claims and authorizations, with payers in a secure way that safeguards protected health information. Data available from EHNs will support care management and analytics use cases, population health initiatives, and other value-based care activities.

Noncontrolled Prescription Drugs Repository

Dispensers¹² are required by law to submit to CRISP information on non-CDS drugs dispensed in Maryland. Access to non-CDS dispense information, coupled with existing information on dispenses of controlled dangerous substances available from the Maryland Prescription Drug Monitoring Program (“PDMP”),^{13, 14} can prevent medication discrepancies that lead to interrupted or inappropriate drug therapy or result in adverse drug events (“ADEs”). Annually, ADEs cause approximately 1.3 million emergency department visits, and about 350,000 patients are hospitalized nationally for further treatment of ADEs.^{15, 16, 17}

¹⁰ More information is available at: www.crisphealth.org/consumer-advisory-council.

¹¹ As of June 2023, 29 EHNs are MHCC-certified EHNs. The list is available at:

mhcc.maryland.gov/mhcc/Pages/hit/hit_ehn/hit_ehn_certified.aspx.

¹² Dispensers include anyone authorized by law to dispense prescription drugs to a patient, or the patient’s agent, in the State as defined by §12-101 Health Occupations Article.

¹³ Chapter 166, *Public Health – Prescription Drug Monitoring Program*.

¹⁴ The PDMP is required to monitor the dispensing of prescription drugs that contain Schedules II, III, IV, or V controlled dangerous substances as defined Under Title 5, Subtitle 4 of the Criminal Law Article, Annotated Code of Maryland.

¹⁵ Centers for Disease Control and Prevention. *Adverse Drug Events in Adults*. April 6, 2023. Available at: www.cdc.gov/medicationsafety/adult_adversedrugsafety.html.

¹⁶ Maryland Health Care Commission. *2022 Position Paper*. Available at: www.mgaleg.maryland.gov/cmte_testimony/2022/hgo/1Jw57Y8O46v2cCenDhCrf7yGKdYsu7EF0.pdf.

¹⁷ Daniel Morhaim, MD. *Position Paper – HB1127 Favorable with Amendments*. Available at: www.mgaleg.maryland.gov/cmte_testimony/2022/hgo/1M-BgVYkRrijjZSWzNVmzzMxp9oEsIJ52.pdf.



Comprehensive medication history improves patient safety and bolsters public health initiatives.

Consent Management Utility

Privacy is a growing concern among consumers and policy makers. Strengthening privacy protections and regulatory oversight can help increase consumer trust.¹⁸ Today, processes for consumers choosing to opt-out or opt back into an HIE vary and require completion of separate forms for each HIE operating in Maryland. A total of 16 HIEs have registered with MHCC (as of June 2023).¹⁹ Many consumers recognize the need for and benefit of electronically sharing their health information; however, they also want and expect to easily control who has access to the electronic health information. CRISP will minimize privacy concerns by implementing a CMU that allows consumers to file one form to opt-out from having their electronic health information shared among MHCC registered HIEs. The CMU will help minimize concerns consumers often raise about privacy and security.

HIE Definition

HIEs emerged more than a decade ago as a result of federal legislation, the Health Information Technology for Economic and Clinical Health (“HITECH”) Act (2009). HITECH provided funding for the establishment of HIEs by states or state-designated entities to support electronic data sharing. HIEs build secure and robust connections to enable the exchange of data from disparate information systems operated by providers, payers, technology vendors, and government agencies. Alignment of Maryland’s statutory definition of an HIE and the federal definition supports use of standards that promote interoperability, eliminating information silos that hinder electronic information exchange.²⁰

Regulations

Maryland Health-General Article §4-302 (2011) requires MHCC to adopt regulations for the privacy and security of protected health information exchanged through an HIE.

¹⁸ Gupta R, Iyengar R, Sharma M, et al. Consumer Views on Privacy Protections and Sharing of Personal Digital Health Information. *JAMA Netw Open.* 2023;6(3):e231305. doi:10.1001/jamanetworkopen.2023.1305

¹⁹ The list of registered HIEs is available at:

mhcc.maryland.gov/mhcc/Pages/hit/hit_hie/hit_hie_registration.aspx.

²⁰ Interoperability with respect to health information technology enables the secure exchange of electronic health information and allows for access, exchange, and use of electronically accessible health information for authorized use. Title 42 – The Public Health and Welfare, § 300ii–2, page 1,575 available at:

www.govinfo.gov/content/pkg/USCODE-2020-title42/pdf/USCODE-2020-title42-chap6A-subchapXXVIII-sec300jj.pdf.



Development of regulations are informed by stakeholders and balance the need for increased data sharing while ensuring privacy and security of electronic protected health information. In June of 2023, MHCC sought stakeholder comments on preliminary draft amendments to COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information*; amendments support the four bills passed by the Maryland General Assembly in 2021 and 2022²¹ and align with federal health IT policy.

Costs and Funding Sources

The projected cost for CRISP to implement legislation passed by the Maryland General Assembly is about \$8 million annually.²² Funding is available under an existing financial agreement (“agreement”) between CRISP, HSCRC, and MDH. The agreement leverages operations and maintenance (“O&M”) funding through the Centers for Medicare & Medicaid Services (“CMS”) Medicaid Enterprise System (“MES”).²³ Health data collection and management systems operated and maintained by CRISP on behalf of the State are eligible for ongoing O&M funding at a 75 percent federal match; the remaining amount is provided by HSCRC through hospital assessments and MDH grants. The table below represents broad funding categories needed to support the requirements in law.

CRISP Funding Allocation Categories	
Operations	Amount (millions)
Public Health Efforts (including Data Analytics)	\$2.2
Encounter Notification Service (ENS)	\$2.4
Other General Infrastructure Components (i.e., MS Azure)	\$2.4
Development of New Use Cases	\$1
Total	\$8

²¹ See Appendix A, B, C, and D for copies of the legislation.

²² CRISP FY 2024 budget is approximately \$38 million.

²³ CRISP’s technical infrastructure is certified MES technology. Certification ensures that vendors meet CMS guidelines that align with Medicaid Information Technology and Architecture and the standards and conditions for Medicaid information technology.



CRISP Funding Allocation Categories	
Operations	Amount (millions)
<i>Note: Sources for funding are a mix of MES, MDH, HSCRC, and user fees.</i>	

Appendix A

Chapter 790 of 2021 Laws of Maryland

(House Bill 1022)

AN ACT concerning

Public Health – State Designated Exchange – Clinical Information

FOR the purpose of requiring a nursing home, on request of the Maryland Department of Health, to electronically submit clinical information to the State designated exchange for a certain purpose; authorizing the State designated exchange to provide certain information to certain individuals and entities in a certain manner; providing that information submitted under a certain provision of this Act may be combined with other data maintained by the State designated exchange for a certain purpose under certain circumstances; providing that certain information submitted by a nursing home may only be used for a certain purpose and may not be used for any other purpose; requiring an electronic health network to provide certain transactions to the State designated exchange for certain purposes; prohibiting an electronic health network from charging a certain fee to a health care provider, health care payor, or ~~of~~ the State designated exchange; requiring the State designated exchange to develop and implement certain policies and procedures; authorizing the Maryland Health Care Commission to adopt certain regulations; altering the purposes to which certain regulations



adopted by the Commission are required to limit the scope of certain information; ~~providing~~ requiring that certain regulations adopted by the Commission ~~may~~ limit redisclosure of certain information and restrict certain data in relation to the exchange of certain information; requiring the Department to identify and seek certain funding; requiring the Commission to report to the Governor and the General Assembly on or before a certain date; defining certain terms; making stylistic changes; and generally relating to the State designated exchange and the sharing of clinical information.

BY repealing and reenacting, with
amendments, Article – Health –
General
Section 4–302.3
Annotated Code of Maryland
(2019 Replacement Volume and 2020 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY
OF MARYLAND,

That the Laws of Maryland read as follows:

**Article – Health
– General**

4–302.3.

(a) (1) In this section the following words have the meanings indicated.

(2) “ELECTRONIC HEALTH CARE TRANSACTIONS” MEANS HEALTH CARE TRANSACTIONS THAT HAVE BEEN APPROVED BY A NATIONALLY RECOGNIZED HEALTH CARE STANDARDS DEVELOPMENT ORGANIZATION TO SUPPORT HEALTH CARE INFORMATICS, INFORMATION EXCHANGE, SYSTEMS INTEGRATION, AND OTHER HEALTH CARE APPLICATIONS.

(2) (3) “ELECTRONIC HEALTH NETWORK” MEANS AN ENTITY

INVOLVED:



(I) INVOLVED IN THE EXCHANGE OF ELECTRONIC HEALTH CARE TRANSACTIONS BETWEEN A PAYOR, HEALTH CARE PROVIDER, VENDOR, AND ANY OTHER ENTITY; AND

(II) CERTIFIED BY THE MARYLAND HEALTH CARE COMMISSION.

~~(3)~~ **(4) “NURSING HOME” HAS THE MEANING STATED IN § 19-1401 OF THIS ARTICLE.**

[(2)] ~~(4)~~ (5) “Standard request” means a request for clinical information from a health information exchange that conforms to the major standards version specified by the Office of the National Coordinator for Health Information Technology.

[(3)] ~~(5)~~ (6) “State designated exchange” means the health information exchange designated by the Maryland Health Care Commission and the Health Services Cost Review Commission under § 19-143 of this article.

(b) This section applies to:

(1) Except for the State designated exchange, a health information exchange operating in the State; and

(2) A payor that:

(i) Holds a valid certificate of authority issued by the Maryland Insurance Commissioner; and

(ii) Acts as, operates, or owns a health information exchange.

(c) An entity to which this section applies shall connect to the State designated exchange in a manner consistent with applicable federal and State privacy laws.

(d) When a standard request for clinical information is received through the State designated exchange, an entity to which this section applies shall respond to the request to the extent authorized under federal and State privacy laws.



(e) A consent from a patient to release clinical information to a provider obtained by an entity to which this section applies shall apply to information transmitted through the State designated exchange or by other means.

(F) (1) ON REQUEST OF THE DEPARTMENT, A NURSING HOME SHALL SUBMIT ELECTRONICALLY CLINICAL INFORMATION TO THE STATE DESIGNATED EXCHANGE TO FACILITATE THE OBJECTIVES STATED IN PARAGRAPH (3) OF THIS SUBSECTION.

(2) IN ACCORDANCE WITH STATE AND FEDERAL LAW AND TO FACILITATE THE OBJECTIVES STATED IN PARAGRAPH (3) OF THIS SUBSECTION, THE STATE DESIGNATED EXCHANGE MAY PROVIDE THE INFORMATION SUBMITTED UNDER PARAGRAPH (1) OF THIS SUBSECTION TO:

- ~~(I)~~ A HEALTH CARE PROVIDER;
- ~~(II)~~ AN AUTHORIZED HEALTH INFORMATION EXCHANGE USER;
- ~~(III)~~ A HEALTH INFORMATION EXCHANGE AUTHORIZED BY THE MARYLAND HEALTH CARE COMMISSION;
- ~~(IV)~~ A FEDERAL OFFICIAL; AND
- ~~(V)~~ A STATE OFFICIAL.

(3) (I) IF APPROVED BY THE MARYLAND HEALTH CARE COMMISSION, THE INFORMATION SUBMITTED UNDER PARAGRAPH (1) OF THIS SUBSECTION MAY BE COMBINED WITH OTHER DATA MAINTAINED BY THE STATE DESIGNATED EXCHANGE TO FACILITATE:

- ~~(I)~~ **1. A STATE HEALTH IMPROVEMENT PROGRAM;**
- ~~(II)~~ **2. MITIGATION OF A PUBLIC HEALTH EMERGENCY; AND**



~~(III)~~ **3. IMPROVEMENT OF PATIENT SAFETY.**

(II) THE INFORMATION SUBMITTED BY A NURSING HOME UNDER PARAGRAPH (1) OF THIS SUBSECTION MAY BE USED ONLY TO FACILITATE THE OBJECTIVES STATED IN SUBPARAGRAPH (I) OF THIS PARAGRAPH AND MAY NOT BE USED FOR ANY OTHER PURPOSE, INCLUDING LICENSING AND CERTIFICATION.

(G) (1) AN ELECTRONIC HEALTH NETWORK SHALL PROVIDE ~~ADMINISTRATIVE~~ ELECTRONIC HEALTH CARE TRANSACTIONS TO THE STATE DESIGNATED EXCHANGE FOR THE FOLLOWING PUBLIC HEALTH AND CLINICAL PURPOSES:

(I) A STATE HEALTH IMPROVEMENT PROGRAM;

**(II) MITIGATION OF A PUBLIC HEALTH EMERGENCY;
AND**

(III) IMPROVEMENT OF PATIENT SAFETY.

(2) AN ELECTRONIC HEALTH NETWORK MAY NOT CHARGE A FEE TO A HEALTH CARE PROVIDER, HEALTH CARE PAYOR, OR TO THE STATE DESIGNATED EXCHANGE FOR PROVIDING THE INFORMATION AS REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION.

(3) THE STATE DESIGNATED EXCHANGE SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES TO IMPLEMENT PARAGRAPH (1) OF THIS SUBSECTION THAT ARE CONSISTENT WITH REGULATIONS ADOPTED BY THE MARYLAND HEALTH CARE COMMISSION.

[(f)] (H) The Maryland Health Care Commission:

(1) May adopt regulations for implementing the connectivity to the State designated exchange required under this section; and

(2) Shall seek, through any regulations adopted under item (1)



of this subsection, to promote technology standards and formats that conform to those specified by the Office of the National Coordinator for Health Information Technology.

[(g)] (I) (1) The Maryland Health Care Commission may adopt regulations [specifying] **THAT:**

(I) SPECIFY the scope of clinical information to be exchanged under this section; **AND**

(II) PROVIDE FOR A UNIFORM, GRADUAL IMPLEMENTATION OF THE EXCHANGE OF CLINICAL INFORMATION UNDER THIS SECTION.

(2) Any regulations adopted under paragraph (1) of this subsection shall limit the scope of the clinical information to purposes that [promote]:

(i) [Improved] **IMPROVE** access to clinical records by treating clinicians; or

(ii) [Uses] **PROMOTE USES** of the State designated exchange important to public health agencies.

(3) REGULATIONS ADOPTED UNDER PARAGRAPH (1) OF THIS SUBSECTION ~~MAY~~ SHALL:

(I) LIMIT REDISCLOSURE OF FINANCIAL INFORMATION, INCLUDING BILLED OR PAID AMOUNTS AVAILABLE IN ELECTRONIC CLAIMS TRANSACTIONS;

(II) RESTRICT DATA OF PATIENTS WHO HAVE OPTED OUT OF RECORDS SHARING THROUGH THE STATE DESIGNATED EXCHANGE OR A HEALTH INFORMATION EXCHANGE AUTHORIZED BY THE MARYLAND HEALTH CARE COMMISSION; AND

(III) RESTRICT DATA FROM HEALTH CARE PROVIDERS THAT POSSESS SENSITIVE HEALTH CARE INFORMATION.



[(h)] (J) This section does not:

(1) Require an entity to which this section applies to collect clinical information or obtain any authorizations, not otherwise required by federal or State law, relating to information to be sent or received through the State designated exchange;

(2) Prohibit an entity to which this section applies from directly receiving or sending information to providers or subscribers outside of the State designated exchange; or

(3) Prohibit an entity to which this section applies from connecting and interoperating with the State designated exchange in a manner and scope beyond that required under this section.

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) The Maryland Department of Health shall identify and seek appropriate funding to implement Section 1 of this Act.

(b) On or before January 1, 2022, the Maryland Health Care Commission shall report to the Governor and, in accordance with § 2–1257 of the State Government Article, the General Assembly on:

(1) the availability of funding to implement Section 1 of this Act; and

(2) the sustainability of the technical infrastructure required to implement Section 1 of this Act.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2021.

Enacted under Article II, § 17(c) of the Maryland Constitution, May 30, 2021.



Appendix B

Chapter 798 of 2021 Laws of Maryland

(House Bill 1375)

AN ACT concerning

Health Information Exchanges – Electronic Health Information – Sharing and Disclosure

FOR the purpose of altering the laws with which certain regulations adopted by the Maryland Health Care Commission must comply; requiring that certain regulations adopted by the Maryland Health Care Commission require the State-designated health information exchange to develop and maintain a certain consent management application, subject to certain laws, and provide for certain penalties; providing requiring that, subject to certain laws, certain regulations may not prohibit certain sharing and disclosing of certain information or certain uses of allow certain entities to use electronic health information for certain purposes; excluding, rather than including, certain payors from the application of certain provisions of law governing health information exchanges; requiring, to the extent authorized under certain laws, certain health information exchanges and payors to transmit to the State-designated health information exchange certain clinical information in a certain manner under certain circumstances; requiring, rather than authorizing, the Commission to adopt certain regulations; altering the purposes for which certain regulations adopted by the Commission are required to limit the scope of certain clinical information; providing that the General Assembly recognizes certain information; requiring the Commission, in consultation with its Health Information Exchange Policy Board and other relevant stakeholders, to make a certain recommendation; requiring the Commission to report to certain committees of the General Assembly on or before a certain date; defining certain terms; altering certain definitions; making



conforming changes; and generally relating to health information exchanges.

**BY repealing and reenacting, with amendments, Article – Health – General
Section 4–301, 4–302.2(b), 4–302.3, 19–142, and 19–143(a)(2) and (f)(1)(ii)
Annotated Code of Maryland
(2019 Replacement Volume and 2020 Supplement)**

**BY repealing and reenacting, without amendments, Article – Health – General
Section 4–302.2(a)
Annotated Code of Maryland
(2019 Replacement Volume and 2020 Supplement)**

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

That the Laws of Maryland read as follows:

**Article – Health
– General**

4–301.

- (a) In this subtitle the following words have the meanings indicated.
- (b) “Common ownership” means ownership of a health care entity:
 - (1) By two or more health care providers;
 - (2) By two or more health care providers employed by a mutual employer for a wage, salary, fee, or payment to perform work for the employer;
 - (3) By health care organizations operating as an organized health care arrangement, as defined in 45 C.F.R. § 160.103;
 - (4) By a health care entity or health care entities that possess an



ownership or equity interest of 5% or more in another health care entity; or

(5) By affiliated providers operating under the same trade name.

(c) “Directory information” means information concerning the presence and general health condition of a patient who has been admitted to a health care facility or who is currently receiving emergency health care in a health care facility.

(d) “Disclose” or “disclosure” means the transmission or communication of information in a medical record, including an acknowledgment that a medical record on a particular patient or recipient exists.

(e) “Emergency” means a situation when, in the professional opinion of the health care provider, a clear and significant risk of death or imminent serious injury or harm to a patient or recipient exists.

(f) “General health condition” means the health status of a patient described in terms of “critical”, “poor”, “fair”, “good”, “excellent”, or terms denoting similar conditions.

(g) “Health care” means any care, treatment, or procedure by a health care provider:

(1) To diagnose, evaluate, rehabilitate, manage, treat, or maintain the physical or mental condition of a patient or recipient; or

(2) That affects the structure or any function of the human body.

~~(h) “HEALTH CARE OPERATIONS” HAS THE MEANING STATED IN 45 C.F.R. § 164.501.~~

~~{(h)}~~(i) (1) “Health care provider” means:

(i) A person who is licensed, certified, or otherwise authorized under the Health Occupations Article or § 13–516 of the Education Article to provide health care in the ordinary course of business or practice of a profession or in an approved education or training program; or



(ii) A facility where health care is provided to patients or recipients, including a facility as defined in § 10–101(g) of this article, a hospital as defined in § 19–301 of this article, a related institution as defined in § 19–301 of this article, a health maintenance organization as defined in § 19–701(g) of this article, an outpatient clinic, a medical laboratory, a comprehensive crisis response center, a crisis stabilization center, and a crisis treatment center established under § 7.5–207 of this article.

(2) “Health care provider” includes the agents, employees, officers, and directors of a facility and the agents and employees of a health care provider.

~~{(i)}~~ (1) “Health information exchange” means an entity that ~~provides~~

~~(i) DETERMINES, CONTROLS, OR HAS THE DISCRETION TO ADMINISTER A REQUIREMENT, A POLICY, OR AN AGREEMENT THAT AUTHORIZES, ENABLES, OR REQUIRES THE USE OF A TECHNOLOGY OR SERVICE; OR~~

~~(ii) PROVIDES or governs organizational and technical processes for the maintenance, transmittal, access, [or] disclosure, EXCHANGE, OR USE of electronic health care information [between]~~

~~1. BETWEEN or among UNAFFILIATED health care providers or entities [through an interoperable system] THAT ARE ENABLED TO EXCHANGE ELECTRONIC HEALTH INFORMATION WITH EACH OTHER; AND~~

~~2. FOR A TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS PURPOSE OR GOVERNS ORGANIZATIONAL AND TECHNICAL PROCESSES FOR THE MAINTENANCE, TRANSMITTAL, ACCESS, OR DISCLOSURE OF ELECTRONIC HEALTH CARE INFORMATION BETWEEN OR AMONG HEALTH CARE PROVIDERS OR ENTITIES THROUGH AN INTEROPERABLE SYSTEM.~~

(2) “Health information exchange” does not include:

(i) An entity composed of health care providers under



common **ownership; or**

(ii) If the organizational and technical processes it provides or governs are transactions, as defined in 45 C.F.R. § 160.103:160.103; or

1. A carrier, as defined in § 15–1301 of the Insurance Article;
2. A carrier’s business associate, as defined in 45 C.F.R. §
3. An administrator, as defined in § 8–301 of the Insurance **Article**.

~~{(j)}~~~~(k)~~ **(1) “Medical record” means any oral, written, or other transmission in any form or medium of information that:**

- (i) Is entered in the record of a patient or recipient;
- (ii) Identifies or can readily be associated with the identity of a patient or recipient; and
- (iii) Relates to the health care of the patient or recipient.

(2) “Medical record” includes any:

(i) Documentation of disclosures of a medical record to any person who is not an employee, agent, or consultant of the health care provider;

(ii) File or record maintained under § 12–403(c)(13) of the Health Occupations Article by a pharmacy of a prescription order for drugs, medicines, or devices that identifies or may be readily associated with the identity of a patient;

(iii) Documentation of an examination of a patient regardless of who:



1. Requested the examination; or
 2. Is making payment for the examination; and
- (iv) File or record received from another health care provider that:
1. Relates to the health care of a patient or recipient received from that health care provider; and
 2. Identifies or can readily be associated with the identity of **the patient of recipient**.

~~{(k)}~~~~(L)~~ (1) **“Mental health services” means health care rendered to a recipient primarily in connection with the diagnosis, evaluation, treatment, case management, or rehabilitation of any mental disorder.**

(2) **For acute general hospital services, mental health services are considered to be the primarily rendered service only if service is provided pursuant to Title 10, Subtitle 6 of this article or Title 3 of the Criminal Procedure Article.**

~~{(l)}~~~~(M)~~ **“Patient” means a person who receives health care and on whom a medical record is maintained.**

~~{(m)}~~~~(N)~~ **“Person in interest” means:**

- (1) An adult on whom a health care provider maintains a medical record;
- (2) A person authorized to consent to health care for an adult consistent with the authority granted;
- (3) A duly appointed personal representative of a deceased person;
- (4) (i) A minor, if the medical record concerns treatment to which the minor has the right to consent and has consented under Title 20, Subtitle 1 of this article; or



(ii) A parent, guardian, custodian, or a representative of the minor designated by a court, in the discretion of the attending physician who provided the treatment to the minor, as provided in § 20–102 or § 20–104 of this article;

(5) If item (4) of this subsection does not apply to a minor:

(i) A parent of the minor, except if the parent’s authority to consent to health care for the minor has been specifically limited by a court order or a valid separation agreement entered into by the parents of the minor; or

(ii) A person authorized to consent to health care for the minor consistent with the authority granted; or

(6) An attorney appointed in writing by a person listed in item (1), (2), (3), (4), or (5) of this subsection.

~~{(n)}~~~~(o)~~ **“Primary provider of mental health services” means the designated mental health services provider who:**

(1) Has primary responsibility for the development of the mental health treatment plan for the recipient; and

(2) Is actively involved in providing that treatment.

~~{(o)}~~~~(p)~~ **“Protected health information” means all individually identifiable health information held or transmitted by a covered entity or its business associate protected under the U.S. Department of Health and Human Services Privacy Rule.**

~~{(p)}~~~~(q)~~ **“Recipient” means a person who has applied for, for whom an application has been submitted, or who has received mental health services.**

~~(R)~~ ~~(Q)~~ **“STATE-DESIGNATED HEALTH INFORMATION EXCHANGE” MEANS THE HEALTH INFORMATION EXCHANGE DESIGNATED BY THE MARYLAND HEALTH CARE COMMISSION AND THE HEALTH SERVICES COST REVIEW COMMISSION UNDER § 19–143 OF THIS ARTICLE.**



4-302.2.

(a) The Maryland Health Care Commission shall adopt regulations for the privacy and security of protected health information obtained or released through a health information exchange.

(b) **(1)** The regulations adopted under subsection (a) of this section shall:

[(1)] (I) Govern the access, use, maintenance, disclosure, and redisclosure of protected health information as required by State or federal law, including the federal Health Insurance Portability and Accountability Act ~~and~~, the federal Health Information Technology for Economic and Clinical Health Act, THE FEDERAL 21ST CENTURY CURES ACT, AND TITLE 21, SUBTITLE 2A OF THIS ARTICLE; [and]

[(2)] (II) Include protections for the secondary use of protected health information obtained or released through a health information exchange;

(III) REQUIRE THE STATE-DESIGNATED HEALTH INFORMATION EXCHANGE TO DEVELOP AND MAINTAIN A CONSENT MANAGEMENT APPLICATION, SUBJECT TO STATE AND FEDERAL LAW, THAT:

3. ALLOWS A PERSON IN INTEREST TO OPT OUT OF HAVING ELECTRONIC HEALTH INFORMATION SHARED OR DISCLOSED BY A HEALTH INFORMATION EXCHANGE;

4. INFORMS THE PERSON IN INTEREST OF THE ELECTRONIC HEALTH INFORMATION THAT MAY BE SHARED OR DISCLOSED NOTWITHSTANDING THE CHOICE TO OPT OUT;

~~2~~ 3. REQUIRES THAT THE STATE-DESIGNATED HEALTH INFORMATION EXCHANGE PROVIDE A HEALTH INFORMATION EXCHANGE WITH THE OPT-OUT STATUS OF A PERSON IN INTEREST, ON RECEIPT OF AN ELECTRONIC REQUEST FROM THE HEALTH INFORMATION EXCHANGE FOR THE OPT-OUT STATUS OF THE PERSON IN INTEREST;



~~3~~ 4. REQUIRES A HEALTH INFORMATION EXCHANGE TO OBTAIN THE OPT-OUT STATUS OF A PERSON IN INTEREST FROM THE STATE-DESIGNATED HEALTH INFORMATION EXCHANGE BEFORE SHARING OR DISCLOSING THE ELECTRONIC HEALTH INFORMATION OF THE PERSON IN INTEREST;
AND

~~4~~ 5. EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, PROHIBITS A HEALTH INFORMATION EXCHANGE FROM SHARING OR DISCLOSING THE ELECTRONIC HEALTH INFORMATION OF A PERSON IN INTEREST IF THE PERSON IN INTEREST HAS OPTED OUT OF HAVING ELECTRONIC HEALTH INFORMATION SHARED OR DISCLOSED BY A HEALTH INFORMATION EXCHANGE; AND

(IV) PROVIDE APPROPRIATE PENALTIES FOR NONCOMPLIANCE WITH THE REGULATIONS, INCLUDING FINES THAT DO NOT EXCEED \$10,000 PER DAY AND THAT ARE DETERMINED BASED ON:

1. THE EXTENT OF ACTUAL OR POTENTIAL PUBLIC HARM CAUSED BY THE VIOLATION;
2. THE COST OF INVESTIGATING THE VIOLATION; AND
3. WHETHER THE PERSON COMMITTED PREVIOUS VIOLATIONS.

(2) THE REGULATIONS ADOPTED UNDER SUBSECTION (A) OF THIS SECTION ~~MAY NOT PROHIBIT:~~

~~(i) THE SHARING OR DISCLOSING OF INFORMATION THAT IS REQUIRED TO BE EXCHANGED UNDER FEDERAL LAW OR TITLE 21, SUBTITLE 2A OF THIS ARTICLE; OR~~

~~(ii) THE USE OF THE ELECTRONIC HEALTH INFORMATION FOR PURPOSES THAT ARE IMPORTANT TO PUBLIC~~



~~HEALTH FUNCTIONS OR HEALTH PLANNING ACTIVITIES OF THE DEPARTMENT, THE MARYLAND HEALTH CARE COMMISSION, OR THE HEALTH SERVICES COST REVIEW COMMISSION SHALL, SUBJECT TO STATE AND FEDERAL LAW, ALLOW THE DEPARTMENT, THE MARYLAND HEALTH CARE COMMISSION, AND THE HEALTH SERVICES COST REVIEW COMMISSION TO USE ELECTRONIC HEALTH INFORMATION FOR PLANNING ACTIVITIES AND PUBLIC HEALTH FUNCTIONS.~~

4-302.3.

- (a) [(1)] In this section [the following words have the meanings indicated.

(2) “Standard], “STANDARD request” means a request for clinical information from a health information exchange that conforms to the major standards version specified by the Office of the National Coordinator for Health Information Technology.

[(3) “State designated exchange” means the health information exchange designated by the Maryland Health Care Commission and the Health Services Cost Review Commission under § 19-143 of this article.]

- (b) This section applies to:

(1) Except for the [State designated] STATE-DESIGNATED HEALTH INFORMATION exchange, a health information exchange operating in the State; and

- (2) A payor that:

(i) Holds a valid certificate of authority issued by the Maryland Insurance Commissioner; and

(ii) Acts as, operates, or owns a health information exchange.

(c) An entity to which this section applies shall connect to the [State designated] STATE-DESIGNATED HEALTH INFORMATION exchange in a



manner consistent with applicable federal and State privacy laws.

(d) ~~(1)~~ When a standard request for clinical information is received through the [State designated] **STATE-DESIGNATED HEALTH INFORMATION** exchange, an entity to which this section applies shall:

(1) ~~respond~~ **RESPOND** to the request to the extent authorized under federal and State privacy laws.; **AND**

~~(2) TO THE EXTENT AUTHORIZED UNDER FEDERAL OR STATE PRIVACY LAW, AN ENTITY TO WHICH THIS SECTION APPLIES SHALL TRANSMIT TO THE STATE DESIGNATED HEALTH INFORMATION EXCHANGE THE CLINICAL INFORMATION SPECIFIED IN THE REGULATIONS ADOPTED IN ACCORDANCE WITH SUBSECTION (G) OF THIS SECTION TRANSMIT THE RESPONSE TO THE STATE-DESIGNATED HEALTH INFORMATION EXCHANGE IN THE MANNER SPECIFIED IN THE REGULATIONS ADOPTED UNDER SUBSECTION (G) OF THIS SECTION.~~

(e) A consent from a patient to release clinical information to a provider obtained by an entity to which this section applies shall apply to information transmitted through the [State designated] **STATE-DESIGNATED HEALTH INFORMATION** exchange or by other means.

(f) The Maryland Health Care Commission:

(1) ~~May~~ **SHALL** adopt regulations for implementing the connectivity to the [State designated] **STATE-DESIGNATED HEALTH INFORMATION** exchange required under this section; and

(2) Shall seek, through any regulations adopted under item (1) of this subsection, to promote technology standards and formats that conform to those specified by the Office of the National Coordinator for Health Information Technology.

(g) (1) The Maryland Health Care Commission ~~may~~ **SHALL** adopt regulations specifying the scope of clinical information to be exchanged **OR SENT** under this section.

(2) Any regulations adopted under paragraph (1) of this



subsection shall limit the scope of the clinical information to purposes that promote:

(i) Improved **TREATMENT, INCLUDING IMPROVED** access to clinical records by treating clinicians; [or]

(ii) Uses of the [State designated] **STATE-DESIGNATED HEALTH INFORMATION** exchange important to public health [agencies]; **OR**

(III) THE PROTECTION OF THE ELECTRONIC HEALTH INFORMATION OF A PERSON IN INTEREST WHO HAS OPTED OUT OF HAVING ELECTRONIC HEALTH INFORMATION SHARED OR DISCLOSED BY A HEALTH INFORMATION EXCHANGE.

(h) This section does not:

(1) Require an entity to which this section applies to collect clinical information or obtain any authorizations, not otherwise required by federal or State law, relating to information to be sent or received through the [State designated] **STATE-DESIGNATED HEALTH INFORMATION** exchange;

(2) Prohibit an entity to which this section applies from directly receiving or sending information to providers or subscribers outside of the [State designated] **STATE-DESIGNATED HEALTH INFORMATION** exchange; or

(3) Prohibit an entity to which this section applies from connecting and interoperating with the [State designated] **STATE-DESIGNATED HEALTH INFORMATION** exchange in a manner and scope beyond that required under this section.

19-142.

(a) In this Part IV of this subtitle the following words have the meanings indicated.

(b) “Carrier” means:

(1) An insurer;

(2) A nonprofit health service plan;



(3) A health maintenance organization; or

(4) Any other person that provides health benefit plans subject to regulation by the State.

(c) “Electronic health record” means an electronic record of health–related information on an individual that:

(1) Includes patient demographic and clinical health information; and

(2) Has the capacity to:

(i) Provide clinical decision support;

(ii) Support physician order entry;

(iii) Capture and query information relevant to health care quality; and

(iv) Exchange electronic health information with and integrate the information from other sources.

(d) (1) “Health benefit plan” means a hospital or medical policy, contract, or certificate issued by a carrier.

(2) “Health benefit plan” does not include:

(i) Coverage for accident or disability income insurance;

(ii) Coverage issued as a supplement to liability insurance;

(iii) Liability insurance, including general liability insurance and automobile liability insurance;

(iv) Workers’ compensation or similar insurance;

(v) Automobile or property medical payment insurance;

(vi) Credit–only insurance;

(vii) Coverage for on–site medical clinics;



- (viii) Dental or vision insurance;
- (ix) Long-term care insurance or benefits for nursing home care, home health care, community-based care, or any combination of these;
- (x) Coverage only for a specified disease or illness;
- (xi) Hospital indemnity or other fixed indemnity insurance; or
- (xii) The following benefits if offered as a separate insurance policy:
 1. Medicare supplemental health insurance, as defined in § 1882(g)(1) of the Social Security Act;
 2. Coverage supplemental to the coverage provided under Chapter 55 of Title 10, U.S.C.; or
 3. Similar supplemental coverage provided to coverage under an employer-sponsored plan.

(e) (1) “Health care provider” means:

- (i) A person who is licensed, certified, or otherwise authorized under the Health Occupations Article to provide health care in the ordinary course of business or practice of a profession or in an approved education or training program; or
- (ii) A facility where health care is provided to patients or recipients, including:
 1. A facility, as defined in § 10–101(g) of this article;
 2. A hospital, as defined in § 19–301 of this title;
 3. A related institution, as defined in § 19–301 of



this title;

4. An outpatient clinic;
5. A freestanding medical facility, as defined in § 19–3A–01 of this title;
6. An ambulatory surgical facility, as defined in § 19–3B–01 of this title; and
7. A nursing home, as defined in § 19–1401 of this title.

(2) “Health care provider” does not include a health maintenance organization as defined in § 19–701 of this title.

(f) “Health information exchange” [means a statewide infrastructure that provides organizational and technical capabilities to enable the electronic exchange of health information between health care providers and other health services organizations authorized by the Commission] **HAS THE MEANING STATED IN § 4–301 OF THIS ARTICLE.**

(g) “Management service organization” means an organization that offers one or more hosted electronic health record solutions and other management services to multiple health care providers.

(H) “STATE–DESIGNATED HEALTH INFORMATION EXCHANGE” MEANS THE HEALTH INFORMATION EXCHANGE DESIGNATED BY THE MARYLAND HEALTH CARE COMMISSION AND THE HEALTH SERVICES COST REVIEW COMMISSION UNDER § 19–143 OF THIS SUBTITLE.

[(h)] (I) (1) “State–regulated payor” means a carrier issuing or delivering health benefit plans in the State.

(2) “State–regulated payor” does not include a managed care organization as defined in Title 15, Subtitle 1 of this article.

19–143.



(a) (2) The Secretary, to align funding opportunities with the purposes of this section and the development and effective operation of the [State's] STATE-DESIGNATED health information exchange, may provide grants to the STATE-DESIGNATED health information exchange [designated under paragraph (1) of this subsection].

(f) On and after the later of January 1, 2015, or the date established for the imposition of penalties under § 4102 of the federal American Recovery and Reinvestment Act of 2009:

(1) Each health care provider using an electronic health record that seeks payment from a State-regulated payor shall use electronic health records that are:

(ii) Capable of connecting to and exchanging data with the STATE-DESIGNATED health information exchange [designated by the Commission under subsection (a) of this section]; and

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) The General Assembly recognizes that:

(1) the definition of “health information exchange” should be updated to accommodate changing technology, functionality, and innovation; and

(2) the definition of “health information exchange” in regulations adopted by the Office of the National Coordinator at 45 C.F.R. § 171.102 offers a model that the State could consider more closely aligning to, and definitions of “health information exchange” in other states and federal laws may also offer models for the State to consider.

(b) The Maryland Health Care Commission, in consultation with its Health Information Exchange Policy Board and other relevant stakeholders, shall make a recommendation on an updated statutory definition of “health information exchange” that addresses changing technology and functionality, the need to coordinate care, and the needs to address patient privacy and access.

(c) On or before December 1, 2021, the Maryland Health Care Commission shall report its recommendation made under subsection (b) of this



section to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2-1257 of the State Government Article.

SECTION ~~2~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2021.

Enacted under Article II, § 17(c) of the Maryland Constitution, May 30, 2021.



Appendix C

Chapter 296 of 2022 Laws of Maryland (House Bill 1127)

AN ACT concerning

Public Health – State Designated Exchange – Health Data Utility

FOR the purpose of requiring the State designated exchange to operate as a health data utility for the State for certain purposes; requiring ~~the Maryland Department of Health, dispensers, and certain nursing homes and electronic health networks~~ dispensers to provide certain data to the State designated exchange; requiring dispensers to submit certain prescription information to the State designated exchange; requiring the State designated exchange to establish a certain consumer advisory council; and generally relating to the State designated exchange operating as a health data utility.

BY adding to

Article – Health –

General Section 19–

145

Annotated Code of Maryland

(2019 Replacement Volume and 2021 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
MARYLAND,

That the Laws of Maryland read as follows:

Article – Health – General

19–145.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE
MEANINGS INDICATED.



(2) “DISPENSER” MEANS A PERSON AUTHORIZED BY LAW TO DISPENSE, AS DEFINED IN § 12-101 OF THE HEALTH OCCUPATIONS ARTICLE, A PRESCRIPTION DRUG TO A PATIENT OR THE PATIENT’S AGENT IN THE STATE.

(3) “NONCONTROLLED PRESCRIPTION DRUG” MEANS A PRESCRIPTION DRUG, AS DEFINED IN § 21-201 OF THIS TITLE, THAT IS NOT A CONTROLLED DANGEROUS SUBSTANCE DESIGNATED UNDER TITLE 5, SUBTITLE 4 OF THE CRIMINAL LAW ARTICLE.

~~(3)~~

(4) “STATE DESIGNATED EXCHANGE” HAS THE MEANING STATED IN § 4-302.3 OF THIS ARTICLE.

(B) THE STATE DESIGNATED EXCHANGE SHALL OPERATE AS A HEALTH DATA UTILITY FOR THE STATE.

(C) THE PURPOSES OF THE HEALTH DATA UTILITY INCLUDE ~~THE~~:

(1) THE COLLECTION, AGGREGATION, AND ANALYSIS OF CLINICAL INFORMATION, PUBLIC HEALTH DATA, AND HEALTH ADMINISTRATIVE AND OPERATIONS DATA TO ASSIST ~~HEALTH CARE AND PUBLIC HEALTH LEADERS~~ THE DEPARTMENT, LOCAL HEALTH DEPARTMENTS, THE COMMISSION, AND THE HEALTH SERVICES COST REVIEW COMMISSION IN THE EVALUATION OF PUBLIC HEALTH INTERVENTIONS AND HEALTH EQUITY;

(2) THE COMMUNICATION OF DATA ~~FROM~~ BETWEEN PUBLIC HEALTH OFFICIALS AND HEALTH CARE PROVIDERS TO ADVANCE DISEASE CONTROL AND HEALTH EQUITY; AND

(3) THE ENHANCEMENT AND ACCELERATION OF THE INTEROPERABILITY OF HEALTH INFORMATION THROUGHOUT THE STATE.

(D) ~~THE FOLLOWING ENTITIES~~ DISPENSERS SHALL PROVIDE DATA TO THE STATE DESIGNATED EXCHANGE:



~~(1) THE DEPARTMENT;~~

~~(2) NURSING HOMES REQUIRED TO PROVIDE DATA UNDER §
4-302.3~~

~~OF THIS ARTICLE;~~

~~(3) ELECTRONIC HEALTH NETWORKS REQUIRED TO
PROVIDE DATA UNDER § 4-302.3 OF THIS ARTICLE; AND~~

~~(4) DISPENSERS.~~

(E) (1) THE PURPOSE OF THIS SUBSECTION IS TO:

(I) AUTHORIZE INDIVIDUALS AND ORGANIZATIONS INVOLVED IN THE TREATMENT AND CARE COORDINATION OF PATIENTS TO ACCESS, AS LEGALLY AUTHORIZED, A PATIENT'S MEDICATION HISTORY, INCLUDING MEDICATIONS PRESCRIBED FOR THE PATIENT; AND

(II) ASSIST HEALTH CARE PROVIDERS, CARE MANAGERS, THE DEPARTMENT, AND PUBLIC HEALTH OFFICIALS LOCAL HEALTH DEPARTMENTS TO UNDERSTAND AND PROMOTE MATTERS OF HEALTH EQUITY AND TREATMENT EFFICACY.

(2) AFTER DISPENSING A NONCONTROLLED PRESCRIPTION DRUG, A DISPENSER SHALL SUBMIT PRESCRIPTION INFORMATION TO THE STATE DESIGNATED EXCHANGE.

(3) THE PRESCRIPTION INFORMATION SHALL BE SUBMITTED:

(I) BY ELECTRONIC MEANS;

(II) WITHOUT UNDULY INCREASING THE WORKLOAD AND EXPENSE ON A DISPENSER;

(III) IN A MANNER THAT MINIMIZES BURDEN AND



DUPLICATION BY BEING AS COMPATIBLE AS POSSIBLE WITH EXISTING FEDERAL STANDARDS FOR DATA SUBMISSION PRACTICES, INCLUDING TECHNOLOGY SOFTWARE OF DISPENSERS; AND

(IV) AS OTHERWISE REQUIRED BY REGULATIONS ADOPTED BY THE COMMISSION.

(4) THE STATE DESIGNATED EXCHANGE MAY NOT IMPOSE ANY FEES OR OTHER ASSESSMENTS ON DISPENSERS TO SUPPORT THE OPERATION OF THE EXCHANGE.

(5) THE STATE DESIGNATED EXCHANGE SHALL MAKE PRESCRIPTION INFORMATION SUBMITTED UNDER THIS SUBSECTION AVAILABLE FOR PURPOSES OF TREATMENT AND CARE COORDINATION OF A PATIENT.

(F) THE STATE DESIGNATED EXCHANGE ~~SHALL~~ MAY PROVIDE DATA, AS ALLOWED BY LAW, ~~TO INDIVIDUALS AND ORGANIZATIONS INVOLVED IN THE TREATMENT AND CARE COORDINATION OF PATIENTS AND TO PUBLIC HEALTH OFFICIALS TO SUPPORT PUBLIC HEALTH GOALS,~~ FOR PUBLIC HEALTH PURPOSES THAT MAY INCLUDE:

~~(1) UNDERSTANDING AND PROMOTING THE EQUITABLE AVAILABILITY TO PATIENTS OF~~ IMPROVING HEALTH EQUITY THROUGH ACCESS TO PRESCRIPTION MEDICATIONS, INCLUDING FOR THE TREATMENT OF INFECTIOUS DISEASE;

(2) ASSISTING PROGRAMS LED BY HEALTH CARE PROVIDERS, ~~CARE MANAGERS,~~ AND ~~PUBLIC HEALTH OFFICIALS IN IDENTIFYING THE DEPARTMENT,~~ LOCAL HEALTH DEPARTMENTS, THE COMMISSION, AND THE HEALTH SERVICES COST REVIEW COMMISSION TO IDENTIFY OPPORTUNITIES TO USE TREATMENTS MORE EFFECTIVELY, FOR QUALITY IMPROVEMENT, INCLUDING FOR STEWARDSHIP OF ANTIBIOTIC MEDICATIONS; AND

(3) ~~ANY ADDITIONAL PATIENT INTERVENTIONS AND~~



ACTIVITIES, INCLUDING CASE INVESTIGATION CONDUCTING CASE INVESTIGATIONS AND RELATED ACTIVITIES.

(G) INFORMATION SUBMITTED TO THE STATE INFORMATION EXCHANGE OR PROVIDED BY THE STATE INFORMATION EXCHANGE UNDER THIS SECTION SHALL BE SUBMITTED OR PROVIDED, TO THE EXTENT PRACTICABLE, IN AS NEAR TO REAL TIME AS POSSIBLE.

~~(G)~~(H) (1) THE COMMISSION, IN CONSULTATION WITH APPROPRIATE STAKEHOLDERS, SHALL ADOPT REGULATIONS TO CARRY OUT THIS SECTION.

(2) THE REGULATIONS SHALL TAKE INTO ACCOUNT CONSUMER PERSPECTIVE AND INCLUDE:

(I) THE SPECIFIC DATA REQUIRED TO BE PROVIDED UNDER SUBSECTION (D) OF THIS SECTION;

(II) THE SPECIFIC PRESCRIPTION INFORMATION REQUIRED TO BE SUBMITTED UNDER SUBSECTION (E) OF THIS SECTION;

(III) THE TIME FRAME FOR SUBMITTING PRESCRIPTION INFORMATION UNDER SUBSECTION (E) OF THIS SECTION;

(IV) THE ELECTRONIC MEANS AND MANNER BY WHICH PRESCRIPTION INFORMATION IS TO BE SUBMITTED UNDER SUBSECTION (E) OF THIS SECTION; ~~AND~~

(V) PRESCRIPTION INFORMATION SUBMISSION REQUIREMENTS THAT ALIGN WITH THE DATA SUBMISSION REQUIREMENTS ON DISPENSERS OF MONITORED PRESCRIPTION DRUGS UNDER TITLE 21, SUBTITLE 2A OF THIS ARTICLE; AND

(VI) IDENTIFICATION AND NECESSARY SUPPRESSION OF INFORMATION RELATED TO PROVIDERS OR MEDICATIONS THAT ARE DETERMINED TO HAVE SIGNIFICANT POTENTIAL TO CAUSE HARM.



(I) (1) THE STATE DESIGNATED EXCHANGE SHALL ESTABLISH A CONSUMER ADVISORY COUNCIL TO BRING THE PERSPECTIVES OF INDIVIDUALS AND ORGANIZATIONS WITH AN INTEREST IN PROTECTING CONSUMERS INTO THE DELIVERY OF SERVICES PROVIDED BY THE STATE DESIGNATED EXCHANGE.

(2) IN SELECTING MEMBERS, THE STATE DESIGNATED EXCHANGE SHALL CONSIDER DIVERSITY OF EXPERIENCE.

(3) THE CONSUMER ADVISORY COUNCIL ESTABLISHED UNDER PARAGRAPH (1) OF THIS SUBSECTION SHALL:

(I) CONSIST OF A MINIMUM OF SIX MEMBERS, INCLUDING AT LEAST FOUR CONSUMER REPRESENTATIVES AND TWO STAFF REPRESENTATIVES, AND MAINTAIN A RATIO OF CONSUMER REPRESENTATIVES TO NONCONSUMER REPRESENTATIVES OF AT LEAST TWO TO ONE;

(II) IDENTIFY AND REPORT CONSUMER PRIVACY CONCERNS TO SENIOR LEADERSHIP OF THE STATE DESIGNATED EXCHANGE;

(III) ADVISE ON EFFORTS TO EDUCATE CONSUMERS ON DATA EXCHANGE POLICIES, INCLUDING OPTIONS FOR CONSUMERS TO OPT OUT OF DISCLOSURE OF PROTECTED HEALTH INFORMATION;

(IV) MEET AT LEAST 3 TIMES EACH YEAR; AND

(V) ADOPT AND MAINTAIN A CHARTER TO BE POSTED ONLINE THAT INCLUDES THE PURPOSE, MEMBERS, AND MEETING SCHEDULE OF THE CONSUMER ADVISORY COUNCIL.

SECTION 2. AND BE IT FURTHER ENACTED, That on or before January 1, 2024, the Maryland Department of Health, the Maryland Health Care Commission, and the State designated exchange shall submit a report to the General Assembly, in accordance with § 2–1257 of the State Government Article,



that identifies ongoing revenue sources to fund the activities required under § 19–145 of the Health – General Article, as enacted by Section 1 of this Act.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2022.

Approved by the Governor, May 12, 2022.



Appendix D

Chapter 718 of 2022 Laws of Maryland

(House Bill 213)

AN ACT concerning

Health Information Exchanges – Definition and Privacy Regulations

FOR the purpose of altering the definition of a “health information exchange” as used in provisions of law governing the confidentiality of medical records; providing that regulations governing the privacy and security of protected health information obtained or released through a health information exchange may not prohibit the sharing and disclosing of information that is required to be exchanged or the use of electronic health information for certain purposes; and generally relating to health information exchanges.

BY repealing and reenacting, without amendments, Article – Health – General
Section 4–301(a) and 4–302.2(a)
Annotated Code of Maryland
(2019 Replacement Volume and 2021 Supplement)

BY repealing and reenacting, with amendments, Article – Health – General
Section 4–301(i) and 4–302.2(b)
Annotated Code of Maryland
(2019 Replacement Volume and 2021 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

That the Laws of Maryland read as follows:

Article – Health – General



4-301.

(a) In this subtitle the following words have the meanings indicated.

(i) (1) “Health information exchange”_means:

(I) ~~an~~ AN INDIVIDUAL OR entity that [provides or governs organizational and technical processes for the maintenance, transmittal, access, or disclosure] **DETERMINES, CONTROLS, OR HAS THE DISCRETION TO ADMINISTER ANY REQUIREMENT, POLICY, OR AGREEMENT THAT ALLOWS, ENABLES, OR REQUIRES THE USE OF ANY TECHNOLOGY OR ~~SERVICE SERVICES~~ FOR ACCESS, EXCHANGE, OR USE of electronic PROTECTED health care information:**

1. ~~between or among~~ AMONG MORE THAN TWO UNAFFILIATED ~~health care providers~~ INDIVIDUALS or entities [through an interoperable system] THAT ARE ENABLED TO EXCHANGE ELECTRONIC PROTECTED HEALTH INFORMATION WITH EACH OTHER; AND

2. THAT IS FOR A TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS PURPOSE, AS THOSE TERMS ARE DEFINED IN 45 C.F.R. § 164.501, REGARDLESS OF WHETHER THE INDIVIDUALS OR ENTITIES ARE SUBJECT TO THE REQUIREMENTS OF 45 C.F.R. PARTS 160 AND 164; OR

(II) A HEALTH INFORMATION TECHNOLOGY DEVELOPER OF CERTIFIED HEALTH INFORMATION TECHNOLOGY THAT DEVELOPS OR OFFERS HEALTH INFORMATION TECHNOLOGY, AS THAT TERM IS DEFINED IN 42 U.S.C. 300JJ(5), AND HAS ONE OR MORE HEALTH INFORMATION TECHNOLOGY MODULES CERTIFIED UNDER A PROGRAM FOR THE VOLUNTARY CERTIFICATION OF HEALTH INFORMATION TECHNOLOGY THAT IS KEPT OR RECOGNIZED BY THE NATIONAL COORDINATOR IN ACCORDANCE WITH 42 U.S.C. 300JJ-11(C)(5).

(2) “Health information exchange” does not include:

(i) An entity composed of health care providers under



common ownership IF THE ORGANIZATIONAL AND TECHNICAL PROCESSES THE ENTITY PROVIDES OR GOVERNS ARE FOR HEALTH CARE TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS PURPOSES, AS THOSE TERMS ARE DEFINED IN 45 C.F.R. § 164.501; [or]

(ii) ~~If the organizational and technical processes it provides or governs are [transactions, as defined in 45 C.F.R. § 160.103] FOR TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS PURPOSES, AS THOSE TERMS ARE DEFINED IN 45 C.F.R. § 164.501;~~

~~3.~~ (II) A carrier, as defined in § 15-1301 of the Insurance Article IF THE ORGANIZATIONAL AND TECHNICAL PROCESSES THE CARRIER PROVIDES OR GOVERNS ARE FOR HEALTH CARE TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS PURPOSES, AS THOSE TERMS ARE DEFINED IN 45 C.F.R. § 164.501;

[2. A carrier's business associate, as defined in 45 C.F.R. § 160.103; or]

[3.] ~~2.~~ (III) An administrator, as defined in § 8-301 of the Insurance Article, IF THE ORGANIZATIONAL AND TECHNICAL PROCESSES THE ADMINISTRATOR PROVIDES OR GOVERNS ARE FOR HEALTH CARE TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS PURPOSES, AS THOSE TERMS ARE DEFINED IN 45 C.F.R. § 164.501;

3. (IV) A HEALTH CARE PROVIDER, AS DEFINED IN SUBSECTION (H) OF THIS SECTION, IF THE ORGANIZATIONAL AND TECHNICAL PROCESSES THE HEALTH CARE PROVIDER PROVIDES OR GOVERNS ARE FOR HEALTH CARE TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS PURPOSES, AS THOSE TERMS ARE DEFINED IN 45 C.F.R. § 164.501;

~~(III)~~ (V) A CARRIER'S BUSINESS ASSOCIATE, AS DEFINED IN 45



C.F.R. § 160.103, IF THE ORGANIZATIONAL AND TECHNICAL PROCESSES PROVIDED OR GOVERNED BY THE BUSINESS ASSOCIATE ARE TRANSACTIONS, AS DEFINED IN 45 C.F.R. § 160.103; OR

~~(IV)~~ (VI) A CARRIER EXCHANGING INFORMATION AS REQUIRED BY 45 C.F.R. § 156.221.

4-302.2.

(a) The Maryland Health Care Commission shall adopt regulations for the privacy and security of protected health information obtained or released through a health information exchange.

(b) (1) The regulations adopted under subsection (a) of this section shall:

(i) Govern the access, use, maintenance, disclosure, and redisclosure of protected health information as required by State or federal law, including the federal Health Insurance Portability and Accountability Act, the federal Health Information Technology for Economic and Clinical Health Act, the federal 21st Century Cures Act, and Title 21, Subtitle 2A of this article;

(ii) Include protections for the secondary use of protected health information obtained or released through a health information exchange;

(iii) Require the State-designated health information exchange to develop and maintain a consent management application, subject to State and federal law, that:

1. Allows a person in interest to opt out of having electronic health information shared or disclosed by a health information exchange;

2. Informs the person in interest of the electronic health information that may be shared or disclosed notwithstanding the choice to opt out;

3. Requires that the State-designated health information exchange provide a health information exchange with the opt-out status of a person in interest, on receipt of an electronic request from the health



information exchange for the opt-out status of the person in interest;

4. Requires a health information exchange to obtain the opt-out status of a person in interest from the State-designated health information exchange before sharing or disclosing the electronic health information of the person in interest; and

5. Except as provided in paragraph (2) of this subsection, prohibits a health information exchange from sharing or disclosing the electronic health information of a person in interest if the person in interest has opted out of having electronic health information shared or disclosed by a health information exchange; and

(iv) Provide appropriate penalties for noncompliance with the regulations, including fines that do not exceed \$10,000 per day and that are determined based on:

1. The extent of actual or potential public harm caused by the violation;
2. The cost of investigating the violation; and
3. Whether the person committed previous violations.

(2) The regulations adopted under subsection (a) of this section [shall, subject to State and federal law, allow the Department, the Maryland Health Care Commission, and the Health Services Cost Review Commission to use electronic health information for planning activities and public health functions] **MAY NOT PROHIBIT:**

(I) THE DEPARTMENT, THE MARYLAND HEALTH CARE COMMISSION, OR THE HEALTH SERVICES COST REVIEW COMMISSION FROM USING ELECTRONIC HEALTH INFORMATION, SUBJECT TO FEDERAL AND STATE LAW, FOR HEALTH REGULATORY AND PUBLIC HEALTH FUNCTIONS;

(II) THE SHARING OR DISCLOSING OF INFORMATION THAT IS REQUIRED TO BE EXCHANGED UNDER FEDERAL LAW OR TITLE 21,



SUBTITLE 2A OF THIS ARTICLE; OR

~~(H)~~ (III) THE SHARING OR DISCLOSING OF INFORMATION THAT IS REQUIRED TO BE EXCHANGED UNDER FEDERAL LAW, INCLUDING FOR THE PURPOSES OF PAYMENT, AS DEFINED IN 45 C.F.R. § 164.501, ~~OR~~

~~(H) THE USE OF THE ELECTRONIC HEALTH INFORMATION, SUBJECT TO STATE AND FEDERAL LAW, FOR PURPOSES THAT ARE IMPORTANT TO PUBLIC HEALTH FUNCTIONS OR HEALTH PLANNING ACTIVITIES OF THE DEPARTMENT, THE MARYLAND HEALTH CARE COMMISSION, OR THE HEALTH SERVICES COST REVIEW COMMISSION.~~

(3) THIS SECTION DOES NOT PROHIBIT THE COMMISSION FROM ADOPTING REGULATIONS THAT ARE MORE STRINGENT THAN FEDERAL LAW IN ACCORDANCE WITH 45 C.F.R. § 160.203.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2022.

Enacted under Article II, § 17(c) of the Maryland Constitution, May 29, 2022.



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MARYLAND
Health Care
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