Chapter 798

(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.

- $\{(h)\}$ (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:

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- 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. §

160.103; or

Article.

3. An administrator, as defined in § 8–301 of the Insurance

- **{**(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 or recipient.
- **(k)** (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.
- **f**(l)**f** (M) "Patient" means a person who receives health care and on whom a medical record is maintained.

$\{(m)\}$ "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.
- $\{(n)\}$ "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.

- **f**(o)**f** (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)** "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:
- 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;
- 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:
- (1) 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) 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.

- (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

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(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;

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- 4. An outpatient clinic;
- 5. A freestanding medical facility, as defined in § 19–3A–01

of this title;

of this title; and

- 6. An ambulatory surgical facility, as defined in § 19–3B–01
- 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 $\stackrel{2}{=}$ 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.