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:

(1) 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


(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.

4. (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

   (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
(III) 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.