By: **Delegate Kelly** Introduced and read first time: March 1, 2021

Assigned to: Rules and Executive Nominations

A BILL ENTITLED

1 AN ACT concerning

Health Information Exchanges – Electronic Health Information – Sharing and Disclosure

- 4 FOR the purpose of requiring that certain regulations adopted by the Maryland Health $\mathbf{5}$ Care Commission require the State-designated health information exchange to 6 develop and maintain a certain consent management application and provide for 7 certain penalties; providing that certain regulations may not prohibit certain sharing 8 and disclosing of certain information or certain uses of electronic health information; 9 requiring, to the extent authorized under certain laws, certain health information exchanges and payors to transmit to the State-designated health information 10 11 exchange certain clinical information; altering the purposes for which certain 12regulations adopted by the Commission are required to limit the scope of certain 13 clinical information; defining certain terms; altering certain definitions; making 14conforming changes; and generally relating to health information exchanges.
- 15 BY repealing and reenacting, with amendments,
- 16 Article Health General
- 17 Section 4–301, 4–302.2(b), 4–302.3, 19–142, and 19–143(a)(2) and (f)(1)(ii)
- 18 Annotated Code of Maryland
- 19 (2019 Replacement Volume and 2020 Supplement)
- 20 BY repealing and reenacting, without amendments,
- 21 Article Health General
- 22 Section 4–302.2(a)
- 23 Annotated Code of Maryland
- 24 (2019 Replacement Volume and 2020 Supplement)
- 25 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
 26 That the Laws of Maryland read as follows:
- 27

Article – Health – General

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW. [Brackets] indicate matter deleted from existing law.



	2	HOUSE BILL 1375							
1	4-301.								
2	(a)	In this subtitle the following words have the meanings indicated.							
3	(b)	(b) "Common ownership" means ownership of a health care entity:							
4		(1) By two or more health care providers;							
$5\\6$	for a wage,	(2) By two or more health care providers employed by a mutual employer salary, fee, or payment to perform work for the employer;							
$7 \\ 8$	arrangemen	(3) By health care organizations operating as an organized health care at, as defined in 45 C.F.R. § 160.103;							
9 10	or equity in	(4) By a health care entity or health care entities that possess an ownership terest of 5% or more in another health care entity; or							
11		(5) By affiliated providers operating under the same trade name.							
$12 \\ 13 \\ 14$	(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.								
$15 \\ 16 \\ 17$	(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.								
$18 \\ 19 \\ 20$	(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.								
$\begin{array}{c} 21 \\ 22 \end{array}$	(f) terms of "cr	"General health condition" means the health status of a patient described in itical", "poor", "fair", "good", "excellent", or terms denoting similar conditions.							
$\begin{array}{c} 23\\ 24 \end{array}$	(g) provider:	"Health care" means any care, treatment, or procedure by a health care							
$\frac{25}{26}$	physical or	(1) To diagnose, evaluate, rehabilitate, manage, treat, or maintain the mental condition of a patient or recipient; or							
27		(2) That affects the structure or any function of the human body.							
28 29	(H) § 164.501.	"HEALTH CARE OPERATIONS" HAS THE MEANING STATED IN 45 C.F.R.							
30	[(h)]	(I) (1) "Health care provider" means:							

1 (i) A person who is licensed, certified, or otherwise authorized under 2 the Health Occupations Article or § 13–516 of the Education Article to provide health care 3 in the ordinary course of business or practice of a profession or in an approved education or 4 training program; or

5 (ii) A facility where health care is provided to patients or recipients, 6 including a facility as defined in § 10–101(g) of this article, a hospital as defined in § 7 19–301 of this article, a related institution as defined in § 19–301 of this article, a health 8 maintenance organization as defined in § 19–701(g) of this article, an outpatient clinic, a 9 medical laboratory, a comprehensive crisis response center, a crisis stabilization center, 10 and a crisis treatment center established under § 7.5–207 of this article.

11 (2) "Health care provider" includes the agents, employees, officers, and 12 directors of a facility and the agents and employees of a health care provider.

13 [(i)] (J) (1) "Health information exchange" means an entity that [provides]:

14 (I) DETERMINES, CONTROLS, OR HAS THE DISCRETION TO 15 ADMINISTER A REQUIREMENT, A POLICY, OR AN AGREEMENT THAT AUTHORIZES, 16 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]:

201. BETWEEN or among UNAFFILIATED health care21providers or entities [through an interoperable system] THAT ARE ENABLED TO22EXCHANGE ELECTRONIC HEALTH INFORMATION WITH EACH OTHER; AND

23 **2.** FOR A TREATMENT, PAYMENT, OR HEALTH CARE 24 OPERATIONS PURPOSE.

- 25
- (2) "Health information exchange" does not include:
- 26 (i) An entity composed of health care providers under common 27 ownership; or
- 28 (ii) If the organizational and technical processes it provides or 29 governs are transactions, as defined in 45 C.F.R. § 160.103:
- 301.A carrier, as defined in § 15–1301 of the Insurance Article;

31 2. A carrier's business associate, as defined in 45 C.F.R. §

32 160.103; or

	4	HOUSE BILL 1375			
$\frac{1}{2}$	Article.	8. An administrator, as defined in § 8–301 of the Insurance			
$\frac{3}{4}$	[(j)] (K) (1) "Medical record" means any oral, written, or other transmission in any form or medium of information that:				
5	(i) I	s entered in the record of a patient or recipient;			
$6 \\ 7$					
8	(iii) H	Relates to the health care of the patient or recipient.			
9	(2) "Medical record" includes any:				
10 11		Documentation of disclosures of a medical record to any person ent, or consultant of the health care provider;			
$12 \\ 13 \\ 14$	Occupations Article by a pharmacy of a prescription order for drugs, medicines, or devices				
15	(iii) I	Documentation of an examination of a patient regardless of who:			
16	1	. Requested the examination; or			
17	2	2. Is making payment for the examination; and			
18	(iv) I	File or record received from another health care provider that:			
19 20	1 from that health care provi	Relates to the health care of a patient or recipient received ider; and			
$\begin{array}{c} 21 \\ 22 \end{array}$	2 the patient or recipient.	2. Identifies or can readily be associated with the identity of			
$23 \\ 24 \\ 25$	recipient primarily in connection with the diagnosis, evaluation, treatment, case				
26 27 28	considered to be the primarily rendered service only if service is provided pursuant to Title				
29 30	[(l)] (M) "Patient" means a person who receives health care and on whom a medical record is maintained.				

"Person in interest" means: 1 [(m)] **(N)** $\mathbf{2}$ An adult on whom a health care provider maintains a medical record; (1)3 A person authorized to consent to health care for an adult consistent (2)4 with the authority granted; $\mathbf{5}$ (3)A duly appointed personal representative of a deceased person; 6 (4)(i) A minor, if the medical record concerns treatment to which the 7 minor has the right to consent and has consented under Title 20, Subtitle 1 of this article; 8 or 9 (ii) A parent, guardian, custodian, or a representative of the minor 10 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; 11 12(5)If item (4) of this subsection does not apply to a minor: 13A parent of the minor, except if the parent's authority to consent (i) to health care for the minor has been specifically limited by a court order or a valid 14separation agreement entered into by the parents of the minor; or 1516 A person authorized to consent to health care for the minor (ii) 17consistent with the authority granted; or 18 (6)An attorney appointed in writing by a person listed in item (1), (2), (3), (4), or (5) of this subsection. 19 20"Primary provider of mental health services" means the designated [(n)] (0)21mental health services provider who: 22Has primary responsibility for the development of the mental health (1)23treatment plan for the recipient; and 24Is actively involved in providing that treatment. (2)**(**(0)**] (**P**)** 25"Protected health information" means all individually identifiable 26health information held or transmitted by a covered entity or its business associate 27protected under the U.S. Department of Health and Human Services Privacy Rule. 28"Recipient" means a person who has applied for, for whom an (p)] (Q) 29application has been submitted, or who has received mental health services. "STATE-DESIGNATED HEALTH INFORMATION EXCHANGE" MEANS THE 30 (R) HEALTH INFORMATION EXCHANGE DESIGNATED BY THE MARYLAND HEALTH CARE 31

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1 COMMISSION AND THE HEALTH SERVICES COST REVIEW COMMISSION UNDER § 2 19–143 OF THIS ARTICLE.

3 4-302.2.

4 (a) The Maryland Health Care Commission shall adopt regulations for the 5 privacy and security of protected health information obtained or released through a health 6 information exchange.

7

(b)

(1)

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

8 [(1)] (I) Govern the access, use, maintenance, disclosure, and 9 redisclosure of protected health information as required by State or federal law, including 10 the federal Health Insurance Portability and Accountability Act and the federal Health 11 Information Technology for Economic and Clinical Health Act; [and]

12 [(2)] (II) Include protections for the secondary use of protected health 13 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
 THAT:

17 **1.** ALLOWS A PERSON IN INTEREST TO OPT OUT OF 18 HAVING ELECTRONIC HEALTH INFORMATION SHARED OR DISCLOSED BY A HEALTH 19 INFORMATION EXCHANGE;

20 2. REQUIRES THAT THE STATE-DESIGNATED HEALTH 21 INFORMATION EXCHANGE PROVIDE A HEALTH INFORMATION EXCHANGE WITH THE 22 OPT-OUT STATUS OF A PERSON IN INTEREST, ON RECEIPT OF AN ELECTRONIC 23 REQUEST FROM THE HEALTH INFORMATION EXCHANGE FOR THE OPT-OUT STATUS 24 OF THE PERSON IN INTEREST;

253. REQUIRES A HEALTH INFORMATION EXCHANGE TO26OBTAIN THE OPT-OUT STATUS OF A PERSON IN INTEREST FROM THE27STATE-DESIGNATED HEALTH INFORMATION EXCHANGE BEFORE SHARING OR28DISCLOSING THE ELECTRONIC HEALTH INFORMATION OF THE PERSON IN INTEREST;29AND

304. EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS31SUBSECTION, PROHIBITS A HEALTH INFORMATION EXCHANGE FROM SHARING OR32DISCLOSING THE ELECTRONIC HEALTH INFORMATION OF A PERSON IN INTEREST IF33THE PERSON IN INTEREST HAS OPTED OUT OF HAVING ELECTRONIC HEALTH34INFORMATION SHARED OR DISCLOSED BY A HEALTH INFORMATION EXCHANGE; AND

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WITH THE REGULATIONS, INCLUDING FINES THAT DO NOT EXCEED \$10,000 PER DAY

AND THAT ARE DETERMINED BASED ON:

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(IV) **PROVIDE APPROPRIATE PENALTIES FOR NONCOMPLIANCE**

THE EXTENT OF ACTUAL OR POTENTIAL PUBLIC

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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. 4 - 302.3. [(1)] In this section [the following words have the meanings indicated. (a) (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. "State designated exchange" means the health information exchange (3)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: Except for the [State designated] STATE-DESIGNATED HEALTH (1)**INFORMATION** exchange, a health information exchange operating in the State; and (2)A payor that:

 $\mathbf{7}$

1 (i) Holds a valid certificate of authority issued by the Maryland 2 Insurance Commissioner; and

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

4 (c) An entity to which this section applies shall connect to the [State designated] 5 STATE-DESIGNATED HEALTH INFORMATION exchange in a manner consistent with 6 applicable federal and State privacy laws.

7 (d) (1) When a standard request for clinical information is received through 8 the [State designated] STATE-DESIGNATED HEALTH INFORMATION exchange, an entity 9 to which this section applies shall respond to the request to the extent authorized under 10 federal and State privacy laws.

11 (2) TO THE EXTENT AUTHORIZED UNDER FEDERAL OR STATE 12 PRIVACY LAW, AN ENTITY TO WHICH THIS SECTION APPLIES SHALL TRANSMIT TO 13 THE STATE-DESIGNATED HEALTH INFORMATION EXCHANGE THE CLINICAL 14 INFORMATION SPECIFIED IN THE REGULATIONS ADOPTED IN ACCORDANCE WITH 15 SUBSECTION (G) OF THIS SECTION.

16 (e) A consent from a patient to release clinical information to a provider obtained 17 by an entity to which this section applies shall apply to information transmitted through 18 the [State designated] **STATE-DESIGNATED HEALTH INFORMATION** exchange or by 19 other means.

20 (f) The Maryland Health Care Commission:

21 (1) May adopt regulations for implementing the connectivity to the 22 [State designated] **STATE-DESIGNATED HEALTH INFORMATION** exchange required 23 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.

27 (g) (1) The Maryland Health Care Commission may adopt regulations 28 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:

31 (i) Improved **TREATMENT**, **INCLUDING IMPROVED** access to 32 clinical records by treating clinicians; [or]

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(ii) Uses of the [State designated] STATE-DESIGNATED HEALTH

1	INFORMATION	exchange important to public health [agencies]; OR
$2 \\ 3 \\ 4 \\ 5$		(III) THE PROTECTION OF THE ELECTRONIC HEALTH OF A PERSON IN INTEREST WHO HAS OPTED OUT OF HAVING HEALTH INFORMATION SHARED OR DISCLOSED BY A HEALTH EXCHANGE.
6	(h) Th	is section does not:
7 8 9 10	relating to in	Require an entity to which this section applies to collect clinical obtain any authorizations, not otherwise required by federal or State law, formation to be sent or received through the [State designated] NATED HEALTH INFORMATION exchange;
11 12 13		Prohibit an entity to which this section applies from directly receiving ormation to providers or subscribers outside of the [State designated] NATED HEALTH INFORMATION exchange; or
$\begin{array}{c} 14\\ 15\\ 16\end{array}$	1 0	Prohibit an entity to which this section applies from connecting and with the [State designated] STATE-DESIGNATED HEALTH INFORMATION nanner and scope beyond that required under this section.
17	19–142.	
$\frac{18}{19}$	(a) In indicated.	this Part IV of this subtitle the following words have the meanings
20	(b) "Ca	arrier" means:
21	(1)	An insurer;
22	(2)	A nonprofit health service plan;
23	(3)	A health maintenance organization; or
24 25	(4) regulation by th	
$\frac{26}{27}$	· · ·	lectronic health record" means an electronic record of health–related an individual that:
28	(1)	Includes patient demographic and clinical health information; and
29	(2)	Has the capacity to:
30		(i) Provide clinical decision support;

1		(ii)	Support physician order entry;			
$2 \\ 3$	and	(iii)	Capture and query information relevant to health care quality;			
4 5	information from o	(iv) other so	Exchange electronic health information with and integrate the ources.			
$6\\7$	(d) (1) "Health benefit plan" means a hospital or medical policy, contract, or certificate issued by a carrier.					
8	(2)	"Heal	th benefit plan" does not include:			
9		(i)	Coverage for accident or disability income insurance;			
10		(ii)	Coverage issued as a supplement to liability insurance;			
$\begin{array}{c} 11 \\ 12 \end{array}$	(iii) Liability insurance, including general liability insurance and automobile liability insurance;					
13		(iv)	Workers' compensation or similar insurance;			
14		(v)	Automobile or property medical payment insurance;			
15		(vi)	Credit–only insurance;			
16		(vii)	Coverage for on-site medical clinics;			
17		(viii)	Dental or vision insurance;			
18 19	home health care,	(ix) commu	Long-term care insurance or benefits for nursing home care, unity-based care, or any combination of these;			
20		(x)	Coverage only for a specified disease or illness;			
21		(xi)	Hospital indemnity or other fixed indemnity insurance; or			
22		(xii)	The following benefits if offered as a separate insurance policy:			
$\begin{array}{c} 23 \\ 24 \end{array}$	1882(g)(1) of the S	ocial S	1. Medicare supplemental health insurance, as defined in § ecurity Act;			
$\begin{array}{c} 25\\ 26 \end{array}$	Chapter 55 of Title	e 10, U	2. Coverage supplemental to the coverage provided under .S.C.; or			
27			3. Similar supplemental coverage provided to coverage under			

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1	an employer–sponsored plan.					
2	(e)	(1)	"Health care provider" means:			
$3 \\ 4 \\ 5$		-	(i) A person who is licensed, certified, or otherwise authorized under ations Article to provide health care in the ordinary course of business or ssion or in an approved education or training program; or			
$6 \\ 7$	including:		(ii)	A fac	ility where health care is provided to patients or recipients,	
8				1.	A facility, as defined in § 10–101(g) of this article;	
9				2.	A hospital, as defined in § 19–301 of this title;	
10				3.	A related institution, as defined in § 19–301 of this title;	
11				4.	An outpatient clinic;	
$\begin{array}{c} 12\\ 13 \end{array}$	of this title;	i		5.	A freestanding medical facility, as defined in § 19–3A–01	
$\begin{array}{c} 14 \\ 15 \end{array}$	of this title;	and		6.	An ambulatory surgical facility, as defined in § 19–3B–01	
16				7.	A nursing home, as defined in § 19–1401 of this title.	
17 18	(2) "Health care provider" does not include a health maintenance organization as defined in § 19–701 of this title.					
19 20 21 22 23	(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.					
$\begin{array}{c} 24 \\ 25 \\ 26 \end{array}$	(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.					
27 28 29	(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 §					

30 19–143 OF THIS SUBTITLE.

31 [(h)] (I) (1) "State-regulated payor" means a carrier issuing or delivering

1 health benefit plans in the State.

2 (2) "State-regulated payor" does not include a managed care organization 3 as defined in Title 15, Subtitle 1 of this article.

4 19–143.

5 (a) (2) The Secretary, to align funding opportunities with the purposes of this 6 section and the development and effective operation of the [State's] **STATE-DESIGNATED** 7 health information exchange, may provide grants to the **STATE-DESIGNATED** health 8 information exchange [designated under paragraph (1) of this subsection].

9 (f) On and after the later of January 1, 2015, or the date established for the 10 imposition of penalties under § 4102 of the federal American Recovery and Reinvestment 11 Act of 2009:

12 (1) Each health care provider using an electronic health record that seeks 13 payment from a State–regulated payor shall use electronic health records that are:

14 (ii) Capable of connecting to and exchanging data with the 15 **STATE-DESIGNATED** health information exchange [designated by the Commission under 16 subsection (a) of this section]; and

17 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 18 October 1, 2021.