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By: Delegates Saab, Charles, Howard, and Kelly

Introduced and read first time: February 8, 2019 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

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Health Information - Commercial Sale

3 FOR the purpose of requiring a covered entity, business associate, or subcontractor to 4 obtain authorization from an individual before engaging in the commercial sale of 5 certain health information; requiring a covered entity, business associate, or 6 subcontractor to inform an individual that the individual may elect to receive a share 7 of any payment received by the covered entity, business associate, or subcontractor 8 for the commercial sale of certain health information before the individual authorizes 9 a certain sale; requiring that a certain authorization meet certain requirements; prohibiting a covered entity, business associate, or subcontractor from 10 11 discriminating against or penalizing a certain individual for certain actions; 12 authorizing the Maryland Department of Health to adopt regulations to carry out 13 this Act; prohibiting the Department from taking certain actions on or before a 14 certain date; providing for the construction of certain provisions of this Act; defining 15 certain terms; and generally relating to the commercial sale of health information.

16 BY adding to

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- 17 Article Health General
- 18 Section 4–501 to be under the new subtitle "Subtitle 5. Commercial Sale of Health
- 19 Information"
- 20 Annotated Code of Maryland
- 21 (2015 Replacement Volume and 2018 Supplement)

22 Preamble

WHEREAS, The Health Insurance Portability and Accountability Act (HIPAA) protects the privacy and security of an individual's protected health information and affords the individual with rights to access, amend, and obtain an accounting of disclosures of the individual's protected health information; and

WHEREAS, HIPAA balances protections and individual rights with the need to

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1 avoid the creation of unnecessary barriers to quality health care; and

2 WHEREAS, The Office of Civil Rights within the U.S. Department of Health and 3 Human Services, the entity charged with enforcing HIPAA, has explained, "[r]eady access 4 to treatment and efficient payment for health care, both of which requires use and 5 disclosure of protected health information, are essential to the effective operation of the 6 health care system. In addition, certain health care operations — such as administrative, financial, legal, and quality improvement activities — conducted by or for health care providers and health plans, are essential to support treatment and payment. Many 9 individuals expect that their health information will be used and disclosed as necessary to 10 treat them, bill for treatment, and, to some extent, operate the covered entity's health care business. To avoid interfering with an individual's access to quality health care or the 11 12 efficient payment for such health care, the Privacy Rule permits a covered entity to use and 13 disclose protected health information, with certain limits and protections, for treatment, 14 payment, and health care operations activities."; and

WHEREAS, Notwithstanding an individual's expectations that protected health information will be used and disclosed as necessary to treat the individual, bill for the treatment, and, to some extent, operate the covered entity's health care business, protected health information is often used for purposes unrelated to payment, treatment, health care operations of the covered entity, or other purposes as permitted under HIPAA; and

WHEREAS, Companies that provide services on behalf of covered entities that involve access to protected health information, known as business associations under HIPAA, and their contractors, known as subcontractors under HIPAA, routinely de-identify individuals' protected health information in order to sell it to third parties in exchange for remuneration; and

WHEREAS, After protected health information has been de-identified, it is no longer protected by or subject to HIPAA; and

WHEREAS, The de-identification process itself is a use of protected health information that may be performed only under limited circumstances and for limited purposes under HIPAA; and

WHEREAS, An individual may authorize a use or disclosure of the individual's protected health information when such use or disclosure is not otherwise permitted by HIPAA, such as for the de-identification of protected health information for the purpose of commercial sale; and

WHEREAS, The individual who authorizes the de-identification of the individual's protected health information for the purpose of commercial sale should have the right to assert a property interest in the health information and have the option to receive remuneration in connection with the commercial sale of the individual's information; now, therefore,

- 1 That the Laws of Maryland read as follows:
- 2 Article Health General
- 3 SUBTITLE 5. COMMERCIAL SALE OF HEALTH INFORMATION.
- 4 **4–501**.
- 5 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
- 6 INDICATED.
- 7 (2) "BUSINESS ASSOCIATE" HAS THE MEANING STATED IN 45 C.F.R.
- 8 **§ 160.103.**
- 9 (3) (I) "COMMERCIAL SALE" MEANS THE DISCLOSURE OF HEALTH
- 10 INFORMATION THAT IS OR WAS PROTECTED HEALTH INFORMATION, INCLUDING
- 11 DE-IDENTIFIED HEALTH DATA, BY A COVERED ENTITY, BUSINESS ASSOCIATE, OR
- 12 SUBCONTRACTOR FOR WHICH THE RECIPIENT PAYS FOR THE INFORMATION.
- 13 (II) "COMMERCIAL SALE" DOES NOT INCLUDE THE DISCLOSURE
- 14 OF HEALTH INFORMATION THAT IS OR WAS PROTECTED HEALTH INFORMATION,
- 15 INCLUDING DE-IDENTIFIED HEALTH DATA, BY A COVERED ENTITY, BUSINESS
- 16 ASSOCIATE, OR SUBCONTRACTOR FOR:
- 17 1. PUBLIC HEALTH PURPOSES UNDER 45 C.F.R. §
- 18 **164.512(B)**;
- 2. RESEARCH PURPOSES UNDER 45 C.F.R. § 164.512(I)
- 20 OR 45 C.F.R. § 514(E), IN WHICH THE ONLY PAYMENT RECEIVED IS A FEE TO COVER
- 21 THE COST TO PREPARE AND TRANSMIT THE DE-IDENTIFIED DATA IN RELATION TO
- 22 THE RESEARCH;
- 23 3. Treatment, payment, or health care
- 24 OPERATIONS UNDER 45 C.F.R. § 164.506;
- 25 4. The sale, transfer, merger, or consolidation,
- 26 OF ALL OR PART OF THE COVERED ENTITY, BUSINESS ASSOCIATE, OR
- 27 SUBCONTRACTOR OR ANY RELATED DUE DILIGENCE;
- 5. SERVICES PERFORMED IN ACCORDANCE WITH AN
- 29 AGREEMENT THAT MEETS THE REQUIREMENTS OF 45 C.F.R. § 164.502(E) OR 45
- 30 C.F.R. 164.504(E) BETWEEN A COVERED ENTITY AND A BUSINESS ASSOCIATE OR A
- 31 BUSINESS ASSOCIATE AND A SUBCONTRACTOR IF THE ONLY PAYMENT MADE IS FOR
- 32 THE PERFORMANCE OF THE SERVICES;

- 6. Complying with the law, as authorized under
- 2 45 C.F.R. § 164.512(A);
- 3 Tealth oversight purposes under 45 C.F.R. §
- 4 **164.512(D)**;
- 5 8. LAW ENFORCEMENT PURPOSES UNDER 45 C.F.R. §
- 6 **164.512(F)**;
- 7 PREVENTING A SERIOUS THREAT TO HEALTH OR
- 8 SAFETY UNDER 45 C.F.R. § 164.512(J);
- 9 10. Specialized government functions purposes
- 10 UNDER 45 C.F.R. § 164.512(K);
- 11. WORKERS' COMPENSATION PURPOSES UNDER 45
- 12 C.F.R. § 164.512(L); OR
- 13 12. Addressing fraud, security, or technical
- 14 ISSUES WHEN THOSE ACTIVITIES ARE NECESSARY TO PROTECT THE COVERED
- 15 ENTITY, BUSINESS ASSOCIATE, OR SUBCONTRACTOR, OR THE INDIVIDUAL WHOSE
- 16 INFORMATION IS IN THE POSSESSION OF THE COVERED ENTITY, BUSINESS
- 17 ASSOCIATE, OR SUBCONTRACTOR.
- 18 (4) "COVERED ENTITY" HAS THE MEANING STATED IN 45 C.F.R. §
- 19 **160.103.**
- 20 (5) "HEALTH INFORMATION" HAS THE MEANING STATED IN 45 C.F.R
- 21 **§ 160.103.**
- 22 (6) "PROTECTED HEALTH INFORMATION" HAS THE MEANING STATED
- 23 IN **45 C.F.R. § 160.103.**
- 24 (7) "SUBCONTRACTOR" HAS THE MEANING STATED IN 45 C.F.R. §
- 25 **160.103.**
- 26 (B) (1) SUBJECT TO PARAGRAPHS (2) AND (3) OF THIS SUBSECTION, A
- 27 COVERED ENTITY, BUSINESS ASSOCIATE, OR SUBCONTRACTOR SHALL OBTAIN
- 28 AUTHORIZATION FROM AN INDIVIDUAL BEFORE ENGAGING IN A COMMERCIAL SALE
- 29 OF THE INDIVIDUAL'S HEALTH INFORMATION OR PROTECTED HEALTH
- 30 INFORMATION, INCLUDING DE-IDENTIFIED DATA.

- BEFORE AN INDIVIDUAL AUTHORIZES THE SALE OF THE 1 **(2)** 2 INDIVIDUAL'S HEALTH INFORMATION OR PROTECTED HEALTH INFORMATION 3 UNDER PARAGRAPH (1) OF THIS SUBSECTION, A COVERED ENTITY, BUSINESS ASSOCIATE, OR SUBCONTRACTOR SHALL INFORM THE INDIVIDUAL THAT THE 4 INDIVIDUAL MAY ELECT TO RECEIVE A SHARE OF ANY PAYMENT RECEIVED BY THE 5 6 COVERED ENTITY, BUSINESS ASSOCIATE, OR SUBCONTRACTOR IN EXCHANGE FOR THE COMMERCIAL SALE OF THE INDIVIDUAL'S HEALTH INFORMATION OR 7 8 PROTECTED HEALTH INFORMATION.
- 9 (3) THE AUTHORIZATION REQUIRED UNDER PARAGRAPH (1) OF THIS 10 SUBSECTION SHALL MEET THE REQUIREMENTS OF 45 C.F.R. § 164.508.
- 11 (C) A COVERED ENTITY, BUSINESS ASSOCIATE, OR SUBCONTRACTOR MAY 12 NOT DISCRIMINATE AGAINST OR PENALIZE AN INDIVIDUAL WHO, UNDER 13 SUBSECTION (B) OF THIS SECTION:
- 14 (1) DOES NOT SIGN AN AUTHORIZATION; OR
- 15 (2) ELECTS TO RECEIVE COMPENSATION.
- 16 (D) THIS SECTION MAY NOT BE CONSTRUED TO APPLY TO:
- 17 (1) ANY STATE AGENCY OR POLITICAL SUBDIVISION OF THE STATE;
- 18 (2) ANY FEDERAL AGENCY; OR
- 19 (3) ANY COVERED ENTITY, BUSINESS ASSOCIATE, OR 20 SUBCONTRACTOR THAT POSSESSES PROTECTED HEALTH INFORMATION THAT WAS 21 CREATED, RECEIVED, TRANSMITTED, OR MAINTAINED ON BEHALF OF A STATE 22 AGENCY OR POLITICAL SUBDIVISION OF THE STATE, OR A FEDERAL AGENCY.
- 23 (E) THE DEPARTMENT MAY ADOPT REGULATIONS TO CARRY OUT THIS 24 SECTION.
- SECTION 2. AND BE IT FURTHER ENACTED, That the Maryland Department of Health may not take any action to enforce this Act on or before December 31, 2020.
- SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2019.