EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

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David Sharp, Director
Center for Health Information Technology and Innovative Care Delivery
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. Sharp,

Thank you for collecting questions from Health Information Exchanges (HIEs) and Electronic Health Networks (EHNs) in late 2023 and for issuing the "Implementation Guidance: Health Information Exchanges" publication on January 26, 2024. On behalf of the 29 member companies of the HIMSS Electronic Health Record (EHR) Association, we appreciate the acknowledgment that many regulated actors had questions concerning the law and guidance. We agree that issuing an implementation guidance document provides clarity on these questions more quickly than regulatory amendments could.

EHR Association members convened in February to review the implementation guidance and have compiled the following follow-up questions. The table below is organized with excerpts from the guidance document on the left, and the EHR Association's related comments or requests for clarification in the column on the right.

We hope these questions or feedback on our interpretation of the implementation guidance are helpful. We welcome any clarifications or further opportunities to discuss. The Association's leadership can be reached by contacting Kasey Nicholoff at knicholoff@ehra.org.

Sincerely,

Stephanie Jamison
Chair, EHR Association
Greenway Health

William J. Hayes, M.D., M.B.A.
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Established in 2004, the Electronic Health Record (EHR) Association is comprised of 29 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Excerpt from Guidance Document	**EHR Association Clarification Request**
Does patient consent need to be shared with a State registry? The use of a State registry is not required by the regulations. A patient consent State registry does not exist at this time. The MHCC anticipates the establishment of such registry maintained by the State Designated HIE (CRISP) in Q4 2024.	We appreciate the clarification that the use of a State registry is not currently expected. We anticipate that time will be necessary to complete development to integrate with such a State registry after it becomes available. Association members are not currently focused on such work, as we have been prioritizing data segmentation enhancements for privacy. We suggest that an implementation timeframe of no less than 18-24 months would be appropriate after specifications are available for testing with the future State registry.
How should HIEs approach situations in which their clients do not or delay upgrading the necessary technology for the regulated entity to be in compliance with the regulations? The MHCC does not believe blocking records that contain legally protected health information complies with the intent of the law. COMAR 10.25.18.09G requires an HIE that has reasonably determined it is unable to independently meet any requirement included in the regulations to develop and implement policies to ensure the HIE's compliance through the execution of a written agreement with a participating organization or a business associate. HIE's should execute written agreements by June 1, 2024 to avoid blocking all records that contain legally protected health information as a result of a client's decision to delay implementing an HIEs technical solution. It is common for HIEs to include clauses in their contracts stipulating that users must comply with State and federal laws, especially those related to data privacy. These clauses serve to emphasize the importance of legal compliance and help protect HIEs and providers using their systems.	We interpret this FAQ to say that if an HIE requires client cooperation (such as upgrades) to protect the privacy of reproductive health information, then the HIE should have their clients sign a written agreement committing to the cooperative action by June 1, 2024. Our concern is that EHR clients have no reason to commit to upgrading in a contract or written agreement. There is no incentive for clients to sign a new or additional agreement that obligates the client to new responsibilities without any incentives. We suggest that instead, a notification to clients regarding the availability of an upgrade and the need to upgrade to use new features to protect the privacy of reproductive health information should be considered reasonable.

Clarify if legally protected health information can be shared within an electronic health record ("EHR") instance or between providers within a health system? The MHCC emphasizes the critical importance of safeguarding legally protected health information and the vital role of HIEs in upholding individuals' reproductive health privacy. The regulations do not permit the exchange of legally protected health information with providers who share the same EHR instance or are part of the same health system unless the exchange of information meets the requirements under COMAR 10.25.18.01C(1). Permitted exchanges include: • Between a hospital and a health care professional credentialed by that hospital to deliver care; • Among credentialed professionals of a hospital's medical staff; • Between a hospital and its affiliated ancillary clinical service provider who is affiliated with the hospital and who, if required by HIPAA, has entered into a business associate agreement with the hospital; and • Among entities under common ownership as defined at Health-General Article §4-301, Annotated Code of Maryland for health care treatment, payment, or health care operations purposes, as those terms are defined in 45 CFR §164.501.	The EHR Association assumes that electronic access to information (which is not exchanged) is outside of the scope of HB 812 as an HIE law. Exchange as an activity does not seem to be defined in 10.25.18.02. ONC defines Exchange as "Exchange means the ability for electronic health information to be transmitted between and among different technologies, systems, platforms, or networks." (https://www.federalregister.gov/d/2020-07419/p-3827) The question "Clarify if legally protected health information can be shared within an electronic health record ("EHR") instance or between providers within a health system?" is not about exchange but refers to access. We infer from the answer, which is focused on exchange, that access rights are out of the scope of this law/regulation. Healthcare providers are able to determine appropriate access to their medical records based on other applicable Maryland statutes and federal laws such as HIPAA. Clarifying that the law focuses exclusively on exchange and that regulating access to medical records is out of the scope of the law would be helpful.
Can a patient consent to having their legally protected health information disclosed to multiple providers or future providers by an HIE? Do providers who receive legally protected health information from a prior treating provider need to obtain consent from the patient before sharing with another treating provider? A patient cannot provide general consent to an HIE for the release of legally protected health	COMAR 10.25.18.02 defines a provider as: (26) "Health care provider" means: (a) A person who is licensed, certified, or otherwise authorized under Health Occupations Article, Annotated Code of Maryland, or Education Article, §13516, Annotated Code of Maryland, to provide health care in the ordinary course of business or practice of a profession or in an approved education or training program; or (b) A facility where health care is provided to

information. The use of general consent could result in the unintentional over-sharing of legally protected health information. The regulations require legally protected health information only be released by an HIE to a specific treating provider at the written request of a patient, for services for which the patient can provide consent under State law, or a parent or guardian of a patient, for services which the parent or guardian can provide consent under State law. Consent is not required for the release of information to a payer or its business associates for the adjudication of claims (COMAR 10.25.18.04C(1)).	patients or recipients, including: (i) A facility as defined in Health-General Article, §10101(e), Annotated Code of Maryland; (ii) A hospital as defined in Health-General Article, §19-301(f), Annotated Code of Maryland; (iii) A related institution as defined in Health-General Article, §19-301(o), Annotated Code of Maryland; (iv) A State-certified substance use disorder program, as defined in Health-General Article, §8-403, Annotated Code of Maryland; (v) A health maintenance organization as defined in Health-General Article, §19701(g), Annotated Code of Maryland; (vi) An outpatient clinic; or (vii) A medical laboratory; (c) An agent, employee, officer, or director of a health care facility, or an agent or employee of a health care provider. Given that a "provider" could already include a group or facility and its staff, we assume that patient consent to release information to a group or facility is sufficient as consent for a "specific treating provider." We suggest that clarifying that a specific treating provider could be a group or facility would be helpful. Current exchange standards do not facilitate specifying individual practitioners within a group or facility as being permitted different access to exchange information than other practitioners in the same group or facility.
Can information relating to the prescribing of mifepristone be shared if the prescription was provided to treat a diagnosis not related to abortion care? Should entities suppress prescription information for generic medications for drugs with NDCs on the list of legally protected health information? Should entities suppress medication information within a health	The EHR Association suggests that the Maryland Department of Health would be better served by maintaining a list of RxNorm codes rather than NDCs. NDC codes are frequently updated and will increase the maintenance necessary by the MDH and by all HIEs. Expecting individual HIEs to each map NDCs to RxNorm introduces the potential for error as well as wasteful duplicative activity.

record that is not included in HCPCS? HIEs are required to block legally protected health information identified in COMAR 10.11.08 (MDH regulations). Mifepristone has applications beyond its use in medical abortion and is used in the treatment of certain medical conditions. The MDH regulations include a list of diagnoses, procedure, and medication codes for mifepristone specific to abortion care. Brand name and generic drugs prescribed for abortion care listed in the regulations must be blocked. It is anticipated that HIEs will need to crosswalk the related medication codes in the regulations with codes included in RxNorm (www.nlm.nih.gov/research/umls/rxnorm/index.html).	The current (January 2024) MDH list includes some generic codes that might be used for purposes of abortion or other diagnoses; it is not clear if these are to be included or suppressed.
What sort of advance notice should health care organizations anticipate if the definition of legally protected health information changes? The MHCC will notify HIEs of any changes to the regulations within 30-60 days prior to their publication in the Maryland Register. The effective date shall be determined after consideration of various factors, i.e., policy or technology, and will be noted in the Maryland Register posting. The Protected Health Care Commission, established by the law, is required to submit semiannual reports to the Secretary of Health on recommendations regarding services that should be treated as legally protected health information; the Secretary of Health will consider the recommendations within 60 days of receiving the report. Questions regarding the codes released by MDH should be directed to: reproductive.health@maryland.gov.	In addition to the notice of changes to the regulation, the EHR Association suggests an implementation timeframe appropriate to the scope of change proposed. The definition of legally protected health information could have minimal need for updates (for example, updating a couple of NDC codes) or a significant need for updates (for example, adding implants to the scope of legally protected health information). Three to four months might be sufficient for a minimal code update. Eighteen months is likely necessary for significant scope changes to permit time for development, testing, and deployment.
Is consent needed for an entity to disclose legally protected health information to pharmacies via eprescribing, laboratories, or other ancillary care providers? Can legally protected health information be disclosed through provider direct	We appreciate the assurance that key operational activities for healthcare providers, such as e-prescribing or ordering labs, will be unaffected by this law.

messaging? The direct consent requirement in law is satisfied when a patient or guardian directs a provider to a specific pharmacy to send an electronic prescription. The direct consent requirement is also met when a patient or a patient's guardian consents to a specific provider for the ordering of ancillary services, such as laboratory and diagnostic services. COMAR 10.25.18.04C(1) requires HIEs to comply with Health General § 4-302.5, Annotated Code of Maryland and COMAR 10.11.08, where among other things, legally protected health information may only be disclosed to a specific treating provider at the written request of and with the consent of a patient, for services for which the patient can provide consent under State law, a parent or guardian of a patient, for services for which the parent or guardian can provide consent under State law, or for the adjudication of claims. The use of direct messaging between providers is permitted unless an HIE is involved in the transmission of the message (COMAR 10.25.18.01C(2)).	The EHR Association notes that both e-prescribing and ordering labs are typically interface activities not traditionally involving an HIE.
Can legally protected health information be disclosed for credentialing purposes? Can identifiable or de-identified legally protected health information be disclosed for research? Can patients request disclosure of legally protected health information through an HIE if the recipient is not a provider (e.g., disability benefits or life insurance coverage)? No. The disclosure of legally protected health information to business entities by an HIE is limited to directed consent beyond the exchange for adjudication of claims. The regulations permit HIEs to disclose legally protected health information for the adjudication of claims or to a specific treating provider at the written request of and with the consent of a patient, for services for which the patient can provide consent, or a	We appreciate the clarification in the final sentence that healthcare providers are not restricted from disclosing legally protected health information unless an HIE is involved in the transmission of the data. As developers of certified health IT, Maryland has defined EHR Association member companies as HIEs. However, the developer companies are not involved in provider's disclosures of health information for purposes such as provider credentialing, research, disability benefits coverage, or life insurance coverage. All of these disclosures are made by providers. The disclosures may use features of certified health IT, but the developer of the certified health IT is not involved in the decision regarding what to disclose and does not transmit the data.

parent or guardian of a patient, for services for which the parent or guardian can provide consent under State law (COMAR 10.25.18.04C(1)). While HIEs play a crucial role in enhancing interoperability within the health care system, connections to disability benefit administrators or life insurance companies are uncommon due to divergent data requirements not routinely exchanged by HIEs. The law does not restrict health care providers from disclosing legally protected health information unless an HIE is involved in the transmission of the data.	We conclude that all of these example activities (and others that are similar) are out of scope.
How should legally protected health information stored in clinical notes be managed? HIEs must block non-structured health information (COMAR 10.25.18.02B(31)) that relates to legally protected health information in clinical notes. This includes clinical notes encompassing a provider's narrative descriptions, observations, and interpretations of a patient's condition, treatment, and other relevant information. Unlike structured data, which is organized in a standardized format with defined fields and categories, clinical notes rely on free-text and may vary in format and content from one provider to another. The MHCC encourages HIEs that are not capable of blocking non-structured legally protected health information by June 1, 2024 to demonstrate measurable progress in implementing technology to block text-based data in their April 1, 2024 status report and June 1, 2024 validation that it possesses the technological capability to restrict from disclosure legally protected health information. HIEs that fail to demonstrate measurable progress may receive a monetary penalty (COMAR 10.25.18.09C(3)).	EHR Association members have been focusing on filtering the codes identified by MDH from exchange activities, and have not invested in filtering free text notes. It is not currently possible to identify programmatically whether a note contains legally protected health information, so appropriate restriction of free text notes will be dependent on clinicians accurately labeling the content within a note they have written. EHR developers do not have the capability to force clinicians to accurately label their notes. We suggest that expectations for free text notes be discussed with the Maryland clinician community and EHR developer community to determine a timeframe that both parties think is feasible to develop features to permit clinicians to label certain notes as needing to be blocked and for clinicians to begin to use such features. June 1, 2024, is not a reasonable timeframe for this activity.
Are printed or faxed materials in scope? The restrictions on the disclosure of legally protected health information apply to printed or	As developers of certified health IT, Maryland has defined EHR Association member companies as HIEs. However, the developer companies are not involved in providers' disclosures of health

faxed materials if the disclosure is made by an HIE or EHN.	information by printing or faxing outside of the EHR. All of these disclosures are made by providers. The disclosures may use features of certified health IT, but the developer of the certified health IT is not involved in the disclosure and does not transmit the data. We conclude that all of these example activities (and others that are similar) are out of scope.
Is it acceptable to completely restrict the sharing of any of the patient's clinical information in order to comply with the reproductive health statute? No. To be in full compliance with the law, the regulations require HIEs to affirm that they are "parsing restricted codes and conveying all other information in the health record that is not prohibited by law to exchange." Completely restricting the sharing of a patient's clinical information may also be prohibited by other State or federal law, such as the 21st Century Cures Act.	ONC's 21st Century Cures Act includes an exception for segmentation infeasibility. (https://www.federalregister.gov/d/2020-07419/p-3918) We assume that if an actor cannot unambiguously segment the requested electronic health information from electronic health information that cannot be made available under this law, then the use of that exception is appropriate. It may also be appropriate to restrict the sharing of a patient's entire record to honor the patient's request.