Cooperative Exchange
The National Clearinghouse Association

RE: Implementation of Chapter 790 (HB 1022)

Analysis of the relevant statute provisions

The law requires EHNs to submit electronic health care transactions to the state-designated Health Information Exchange (HIE), currently the Chesapeake Regional Information System for Our Patients (CRISP). These transactions are to be submitted for public health and clinical purposes.

Overview of Electronic Healthcare Transactions

Cooperative Exchange member organizations[1] serve as an EHN to both health care providers and payers. (Over 32 EHNs operate in MD.) Our role is to route administrative transactions (aka, electronic health care transactions) on behalf of a provider and/or payer. For example, a provider submits a claim to a payer (United Healthcare, CareFirst, etc.) and we route that claim to the destination payer. The payer then sends information back to the provider, which we also route. These transactions are not medical records. They are administrative transactions supporting financial coverage, billing, and payment between a provider and a payer (e.g., health care claim submission for payment for a furnished service or item).

Overview of Key Considerations

1. Provide clear standards to ensure that patient privacy preferences are honored and that patient's transparency and notice rights, put in place by federal and state regulations, are upheld.
2. Ensure the regulations align with HIPAA and current State regulation provisions that empower covered entities (CEs) to make determinations about how patient data is used and under what circumstances they, or their BA, may disclose patient data.
3. Align the regulations with core data use and disclosure principles in federal and state privacy rules, including Treatment, Payment, Health Care Operations (TPO) and minimum necessary.
4. Ensure transparency in identified data uses cases. i.e., how will EHN shared data content be used?
5. Provide clear standards to ensure that patient information from EHNs is only re-disclosed to appropriate users of the HIE, aligned with the purposes specified in the law.
6. Ensure the long-term success of this program by establishing a clear operational and financial sustainability plan for all stakeholders.

[1] The Cooperative Exchange (CE) is comprised of 23 of the leading clearinghouses in the US. The views expressed herein are a compilation of the views gathered from our member constituents and reflect the directional feedback of the majority of its collective members. CE has synthesized member feedback and the views, opinions, and positions should not be attributed to any single member and an individual member could disagree with all or certain views, opinions, and positions expressed by CE.

Our Considerations in Implementation of Chapter 790

The below considerations detail what we ask the Maryland Health Care Commission (MHCC), the HIE Policy Board, and EHN Workgroup (workgroups) to contemplate in drafting amendments to COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information*, (Maryland regulations). Each consideration outlines our specific recommendation, justification for the recommendation. Additionally, we outline operational and technical factors (i.e., potential challenges or barriers) that would need to be addressed for the specific policy to be implemented by the affected parties, e.g., providers, EHNs, state-designated HIE, etc.

Consideration 1: Provide clear standards to ensure that patient privacy preferences are honored, and that patient's transparency and notice rights put in place by federal and state regulations are upheld. Specifically, we recommend that the regulations clarify that EHNs only send electronic health care transactions to the state-designated HIE on behalf of "participating organizations" (as defined in COMAR 10.25.18.02B(43)); i.e., those that are currently required to provide patient notice of opt-out.

Justification:

- Federal regulation requires a covered entity (CE) (e.g., health care providers and payors) to provide notice to its patients of how their information may be used and disclosed (e.g., Notice of Privacy Practices); the notice typically specifies that patient information may be disclosed to data processors or vendors (i.e., BAs) (See 45 C.F.R. § 164.520(a)(1)).
- Business Associates (BAs), such as EHNs, don't have a direct relationship with the patient and thus no mechanism to provide notice that patient's information will be re-disclosed (under the new Maryland law) to CRISP.
- In addition to providing notice under HIPAA, providers participating with CRISP are required to provide patients with notice (in accordance with Maryland regulations, COMAR 10.25.18.03H(1)) regarding their right to opt-out of having their information shared through the HIE. Without clarification in regulation, patient information from nonparticipating providers could flow to CRISP, where patient opt-out notice has not been provided (e.g., claims data from a dermatologist who is not using CRISP, could be disclosed to CRISP).

Operational and Technical Factors:

- Multiple vendors and EHNs are often involved in the routing of transactions from the originating billing provider to the destination payer. This could result in duplicate claim submissions from multiple EHNs processed at different times resulting in added complexity. The destination payer would have the "clean" transaction as received in the last and final "hop" to the payer. Also, many claim transactions may not route through a clearinghouse. A provider may send direct to the payer and/or submit the claim on paper to the payer. Also, in some instances, multiple payers may be involved and therefore subject to coordination of benefits (payer to payer) workflows. Patient could also be uninsured and/or self-pay where the claim would never be received by the EHN or payer.

- Administrative claim transaction submissions can be rejected or denied due to transaction standard non-compliance, billing errors, or policy violations and thus may not accurately reflect the clinical care provided.
- Administrative claim transaction standards accommodate multiple claims from multiple providers batched in file submissions to a destination payer or third-party administrator. Payers will accept and process claim files regardless of the state where the provider practices, the facility is located, or the patient resides. EHNs will need to segment out transactions from only Maryland providers, routed to payers operating in Maryland, for Maryland residents (and associated patient matching challenges), which requires significant recurring operational and technical effort and expense.
- The HIPAA 837 claim standard does not support data elements to denote if the patient has opted out of having their information shared through a third-party HIE. Even if the HIE were to provide a list of patients that have opted-in, there would be significant recurring operational and technical expense and potential HIPAA breach risk to identify and extract only claims specific to patients that have opted-in. EHNs process over six billion health care claims annually and are not equipped to extract certain transactions for non-billing/payment purposes.

Consideration 2: Ensure the regulations align with HIPAA and current Maryland regulation provisions that empower CEs to make determinations about how patient data is used and under what circumstances they, or their BA, may disclose patient data. Specifically, we recommend that the regulations clarify that EHNs shall disclose electronic healthcare transactions to the State-Designated HIE on behalf of participating organizations when permitted by the BAAs or applicable data use agreements.

Justification:

- The privacy protections under HIPAA applies to CEs and their business associates (BAs). BAs are service providers or data processors (i.e., EHN's) that operate on behalf of CEs.
- EHNs are typically considered BAs, and because they process patient information on behalf of CEs, federal privacy regulations require a CE to enter a BAA (e.g., contract) with a BA. (See 45 § C.F.R. 164.502(e)(2)).
    - Federal privacy regulations specify what must be in the agreement and what the BA can and cannot do with patient information it processes on behalf of the CE. (See 45 § C.F.R. 164.504(e) and 164.502(a)(3)).
    - Federal privacy regulations prohibit a BA from re-disclosing the patient information it processes (apart from disclosures to subcontractors) and may only use patient information for very limited purposes (See 45 § C.F.R. 164.502(a)(3)).
    - Federal privacy regulations require a CE to provide an accounting of certain disclosures, including certain disclosures by its BA, to the individual upon request. The BA contract must provide that the BA will make such information available to the CE in order for the CE to fulfill its obligation to the individual. (See 45 § C.F.R. 164.528).

- Many BAAs do not permit EHNs to re-disclose patient information to CRISP; thus, this regulation could compel EHNs to breach these BAAs and violate federal law.
- Federal regulation does permit BA to disclose patient information "as required by law;" (See 45 § C.F.R. 164.502(a)(2)). However, these disclosures are typically directed at CE (providers/payers) (e.g., labs are required to submit certain lab results to public health authorities).
- COMAR 10.25.18.05 authorizes only "participating organizations" to exchange information through HIEs and defines "participating organizations" to include only HIPAA CEs.

Operational and Technical Factors:

- Current BAAs in place between EHNs and CEs don't typically include provisions allowing for the redisclosure of electronic health care transactions to an HIE, thus, BAA will need to be amended.
- There would be significant EHN and EHN client burden and expense associated with renegotiating and amending existing binding contractual terms and/or BAAs.

Consideration 3: Align the regulations with core data use and disclosure principles in federal and state privacy rules, including TPO and minimum necessary. Specifically, we recommend that the regulations clearly limit the types of data disclosed by EHNs to the HIE to align with TPO and meet the minimum necessary for purposes specified in the law. We also recommend the types of data being disclosed by EHNs be made public.

Justification

- Patients deserve and expect that their data will be shared to the extent necessary to provide, improve, and facilitate patient care and no more. This concept is a bedrock of HIPAA, which outlines permitted uses and disclosures for TPO[1] (45 § CFR 164.501, 45 § CFR 164.506) and uses the term "minimum necessary," (45 § C.F.R. 164.502(b), 164.514(d)). These mandated principles should guide Maryland regulations or policy.
- Minimum necessary requires that sharing be for clearly defined purposes which avoids overly broad or unexpected disclosures of confidential patient information.
- In developing the regulations or policy, the law requires the regulations "provide for a uniform, gradual implementation of the exchange of clinical information…".

Operational and Technical Factors:

As previously described in Consideration 1, among other factors, EHNs will need to segment out certain information from the six billion health care claim transactions processed annually, which requires significant recurring operational and technical effort and expense.

Consideration 4: Ensure transparency in identified data uses cases. Specifically, we recommend the regulation clearly identify specific data use cases prior to EHNs disclosing healthcare transactions, including how administrative healthcare transactional data content sourced by EHNs will be used.

[1] HHS.gov - Uses and Disclosures for Treatment, Payment, and Health Care Operations

Justification

- Provides full disclosure and transparency of established use cases allowing all interested stakeholders to participate in the data use case development process.
- Aligns data content requirements with established use cases.
- Ensures that EHN disclosures to fulfill use cases are compliant with federal and state privacy regulations.

Operational and Technical Factors:

Depending on the data content requirements of each use case, data exchange technical specifications may need to be developed to share required data from the EHN to the HIE to satisfy each use case while adhering to consideration 3 above.

Consideration 5: Provide clear standards to ensure that patient information from EHNs is only re-disclosed to appropriate users of the HIE, aligned with the purposes specified in the law. Specifically, we recommend the regulations clarify that electronic health care transactions:

- May only be disclosed by the state-designated HIE to:
    - A participating organization or its authorized user that is a health care provider; and may not disclose electronic health care transactions to payers.
    - A state or federal public health authority for public health purposes, in accordance with Maryland regulations.
- May not be used for purposes other than those specified in the law, including:
    - Licensing or certification.
    - Secondary uses (as defined by COMAR 10.25.18.02B(57)).
    - By the state-designated HIE or an HIE authorized by the MHCC for benefit outside of the use specified in the regulations or policies.
    - Shall not include payment or rate information that may be within the transaction.

Justification

- The law limits the purposes for which EHNs submit data to a state health improvement program, mitigation of public health emergency, and improve patient safety. See Health General § 4–302.3. (G)(1).
- Electronic health care transactions are essentially financial transactions between a provider and payer; i.e., claims paid by public and private payers for health care services. Information contained in these transactions include payer fees, rates, etc. The State of Maryland's all-payer claims database includes similar information and data about rates by payer are not typically released.
- EHNs have invested significant human and financial capital in developing, deploying, and supporting valuable and innovative private sector products and solutions in the U.S. health care

marketplace. If not clarified in regulations, the data provided by EHNs to CRISP could provide them with unfair, state-sponsored competitive advantage in the market. (E.g., benefit outside of the use specified in the regulations or policies).

Operational and Technical Factors:

- See Consideration 1.

Consideration 6: Ensure the long-term success of this program by establishing a clear operational and financial sustainability plan for all stakeholders. Specifically, we recommend, before requiring EHNs to submit electronic health care transactions to the state-designated HIE, the MHCC first report to the Governor as required by the Maryland law.

In addition, we recommend that Statewide HIE developed services and solutions be made available via API free of charge to approved and authorized EHNs to promote extended adoption and use resulting in expanded public health benefit and patient safety.

Justification:

- While the statute prohibits EHNs from charging a fee to payers or providers for providing administrative transactions to the state-designated HIE, it does not address how EHNs should be reimbursed for the recurring expense of these new obligations (including the operational and technical considerations highlighted herein), or how EHN would obtain value in disclosing the data.
- The statute charges the Maryland Department of Health (the "Department") with identifying appropriate funding to implement HB1022 as well as requiring the MHCC to prepare a report for the Governor on the availability of such funding and the sustainability of the technical infrastructure required to implement the statute.

Operational and Technical Factors:

- We recommend that the potential development of API specifications be conducted in open and mutual collaboration with the EHNs.

Conclusion

Cooperative Exchange supports the work of the State of Maryland to ensure secure statewide access to clinical information at the point of care and for essential public health surveillance and response. Maryland is a model for a robust statewide health information exchange (HIE), and we applaud the work of the Committee and State agencies, like the MHCC and the Health Services Cost Review Commission, in these efforts. We look forward to working with MHCC and HIE Policy Board on modernizing the HIE regulations.

Please note that the recommendations within this letter are non-binding and solely for the purpose of establishing a basis for continued discussions. As such, we look forward to continued discussions and are happy to speak with you or your staff on this matter.