MARYLAND Health Care Commission

Marcia Boyle, MS, Acting Chair
Douglas Jacobs, MD, MPH, Executive Director

Public Comments in Response to Reproposed Amendments: COMAR 10.25.07, *Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses*

A Notice of Proposed Action to COMAR 10.25.07 was printed in the August 8, 2025 issue of the Maryland Register. The proposed amendments support the implementation of Chapter 791 (Senate Bill 748) and Chapter 790 (House Bill 1022), *Public Health – State Designated Exchange – Clinical Information,* 2021.

The Maryland Health Care Commission received comments from one organization, Optum.

Comment Period: August 8, 2025 through September 8, 2025

Optum

August 29, 2025

Dr. Douglas Jacobs
Executive Director
Maryland Health Care Commission
4160 Patterson Ave
Baltimore, MD 21215

Subject: Comments on COMAR 10.25.07, Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses

Dear Dr. Jacobs:

Below please find Optum Insight's comments in response to the Code of Maryland Regulations (COMAR) 10.25.07 Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses as proposed by the Maryland Health Care Commission (MHCC). The proposed rules address new data sharing requirements for Electronic Health Networks (EHN) in Maryland. We appreciate the opportunity to provide comments on this important proposed regulation; however, we are concerned at the lack of attention to our previous comments and note that the majority of our comments were not addressed in the most recent proposed rule.

Optum Insight provides data, analytics, research, consulting, technology and managed services solutions to hospitals, physicians, health plans, governments, and life sciences companies. This business helps customers reduce administrative costs, meet compliance mandates, improve clinical performance, and transform operations. Optum Insight is a certified EHN in Maryland.

We offer the following comments on the proposed regulatory text.[1]

To start, as we have previously stated, we do not agree with Maryland's procurement of electronic health information from EHNs under Md. Code Ann., Health-Gen. § 4-302.3(h) or the proposed regulations.

We continue to have concerns that the law and proposed regulations may be preempted by the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations; *see* 45 C.F.R. §§ 160.201.205, 45 C.F.R. Part 164, Subpart E, as well as other federal laws. Compliance with HIPAA is critically important for patient privacy, and we take our responsibilities to ensure that privacy very seriously. Indeed, MHCC's own regulation requires EHNs like Optum Insight to "[d]emonstrate compliance with HIPAA security standards set forth in 45 CFR Parts 160, 162, and 164." COMAR 10.25.07.05(b). We continue to believe that the requirements of Md. Code Ann., Health-Gen. § 4-302.3(h) and the proposed regulations will make compliance with HIPAA difficult, if not impossible. As Change Healthcare, which was recently acquired by Optum Insight, previously commented about the then-proposed Md. Code Ann., Health-Gen. § 4-302.3(h), the requirements of the law "established a broad mandate without a cost-based mechanism, provided a competitive advantage to the State Designated Health Information Exchange, threatened data use agreements and data governance, and was incompatible with federal and state privacy law regulations." Optum Insight does not believe that the proposed regulations, including the newest revisions, mitigate these concerns; to the contrary, by requiring the broad disclosure of health information, the proposed regulations exacerbate these concerns and further highlight the conflict with federal privacy law.

We are also concerned about the economic impact of this proposed regulation. The proposed rule again states that the proposed action has an indeterminable economic impact on electronic health networks (EHNs); we reiterate that the economic effect is in fact substantial and existing infrastructure will likely not be able to be reused for this new data sharing requirement..

[1] Optum Insight incorporates by reference its previous comments on earlier drafts of the proposed rule.

Our remaining comments focus on the more technical issues raised by this important proposed regulation.

Proposed Text

.02 Definitions MHCC has proposed the following definitions:

"Improvement of patient safety" means actions, strategies, or protocols to prevent health care errors, enhance the quality of care, and ensure a safe health care environment.

"Mitigation of a public health emergency" means taking actions to lessen the impact of a public health emergency and reduce harm, including implementing preventive measures, managing resources, and coordinating responses to limit disease spread, minimize health risks, and support affected communities effectively.

"State health improvement program" means a State initiative designed to enhance public health through strategic planning, targeted interventions, and collaboration with stakeholders and the federal government, including State efforts in support of the Total Cost of Care model and successor models agreed to by the federal government and the State.

Comments

We continue to be concerned that the proposed definitions add little specificity to the use cases for which the State Designated HIE or MHCC would utilize the data. As written, the definitions are extremely broad and could conceivably cover a wide range of use cases. For example, does MHCC consider "patient safety" to include the patient safety activities contemplated by 42 CFR 3.20, which HIPAA's Privacy Rule includes in its definition of health care operations?

We again recommend that MHCC include specific use case examples that would fall under each definition, similar to how the Total Cost of Care model is specifically called out. Additionally, as we have previously stated, we request that the regulation define the three statutory purposes to make clear which, if any, electronic health care transactions fall outside of these purposes, which would then correspond to technical implementation decisions related to filtering of data. Moreover, the proposed rule does not discuss limitations on secondary use or reuse of the data by the State Designated HIE. We ask that MHCC make clear in the final regulation that the data may only be used for the three stated public health and clinical purposes in accordance with the definitions and use cases finalized, and as permitted by federal and state privacy laws.

Proposed Text

.09(B) An MHCC-certified EHN shall submit electronic health care transactions information for services delivered in Maryland to the State-designated HIE that consist of the following transactions:

(1) Health care claim or equivalent encounter information (837P and 837I);

(2) Health plan eligibility inquiry and response (270); or

(3) Benefit enrollment and maintenance (834).

Comments

We generally support MHCC's decision to modify the language from "transactions originating in Maryland" to "healthcare transactions information for services delivered in Maryland." This change helps clarify which transactions would need to be included or excluded; however, we are still concerned about including transactions for payors that do not operate in Maryland but whose members may seek care in Maryland. We again ask MHCC to clarify that the transactions should be for services delivered in Maryland that are sent to payors that operate in Maryland. Absent this clarification, EHNs will be required to modify their Business Associate Agreements for every payor they are contracted with regardless of whether the payor operates in Maryland, a feat which would be difficult to accomplish.

For Health plan eligibility inquiry and response, we again note that the proposed rule indicates the 270 transaction set only and fails to include the 271 transaction set despite indicating that the responses be sent. We ask MHCC to clarify if the response transaction content will need to be submitted. Additionally, we continue to be confused by the inclusion of "Benefit enrollment and maintenance transactions" (834s) since clearinghouses generally do not process these transactions. We recommend removal of those transaction types from the submission list.

On a practical note, it is still unclear which EHNs are responsible for submitting a transaction when multiple clearinghouses handle the same transaction. For example, a submitter may work with our EHN to submit an 837 but the payor may work with a different EHN to receive an 837. In this scenario, the submitter would submit the claim to our EHN, and under our Trading Partner Agreement, we would send the claim to a different EHN, which would then deliver the claim to the payor. In such a scenario (which is not a small portion of transactions) are both EHNs responsible for submitting the claims? How will the State-designated HIE know it is a duplicate claim if the IDs do not match up? Claim IDs may not match as each EHN assigns different claim IDs and submitter/payor IDs, thus resulting in duplicate claims recorded at the HIE. Is only the first EHN responsible for submitting the claim, and if so, should EHNs filter out claims received from other EHNs? We are concerned that MHCC may not be considering the technical intricacies of how EHNs bridge transactions between themselves, which may lead to a significant amount of work for either EHNs to add additional filters or the State-Designated HIE to build deduplication processes that do not exist today and may be difficult to construct and/or manage effectively. Relatedly, we are concerned that if EHNs submit duplicate transactions, then privacy risks will substantially increase. We again ask MHCC to clarify in the regulatory language which EHN would submit the required transactions, i.e. the initial EHN that receives it or all EHNs that touch it.

Additionally, the proposed text does not appear to leave room for or acknowledge additional transactions that may need to be filtered out. Certainly, we are required under Health-General Article, §4-302.5, Annotated Code of Maryland to filter out Legally Protected Health Information. However, Md. Health Gen. § 4-302.3(h)(3) indicates that "*Regulations adopted under paragraph (1) of this subsection shall: (i) limit redisclosure of financial information, including billed or paid amounts available in electronic claims transactions…(iii) restrict data of patients who have opted out of records sharing through the state designated exchange or a health information exchange authorized by the Maryland Health Care Commission; and (iv) restrict data from health care providers that possess sensitive health care information*." The proposed regulation does not include any clarifications on EHNs filtering out the specified restrictions. It remains unclear if we are even allowed to filter out such data, or if MHCC intends to mandate that we rely on the State-designated HIE for such filtering—which would create an issue for our customers, particularly around financial information which is considered Intellectual Property. It also creates an issue for patient privacy if EHNs are required to produce sensitive patient information to the State-designated HIE when there are no corresponding privacy requirements on the State-designated HIE in the regulation.

The breadth of this submission requirement continues to raise substantial concerns that the requirement is not consistent with federal law. As stated above, we remain concerned that the law, and these proposed implementing regulations, are preempted by HIPAA, which certified EHNs are required to abide by per COMAR 10.25.07.05. Under 45 CFR 164.502, for example, a business associate may generally only use or disclose protected health information as permitted or required by its business associate contract, and it is prohibited from using or disclosing protected data if done by the covered entity. As written, it is unclear that the proposed basis for disclosure would be permitted under the HIPAA Privacy Rule if done by a covered entity and, therefore, its business associate.

Moreover, there are federal prohibitions and restrictions on sharing healthcare data from specific entities beyond HIPAA. States may not require disclosure of data from a self-funded group plan governed by the Employee Retirement Income Security Act (ERISA) as held by the United States Supreme Court in *Gobeille v Liberty Mutual*, 577 US 312 (2016). Similarly, data from Medicare Advantage organizations and Part D plans (42 CFR § 422.402) and from carriers providing coverage under the Federal Employees Health Benefits Program (5 U.S.C. § 8902(m)(1) and 48 C.F.R. § 1652.224–70) may be protected from disclosure. For example, it is our understanding that the Office of Personnel Management has prohibited carriers from sharing Federal Employee Health Benefit Program information with state programs, and as

a Business Associate of the carrier, we would be bound to the same prohibition. MHCC recently finalized COMAR 10.25.18 that requires: "(b) The State-designated HIE shall report the electronic health care transactions information it receives pursuant to COMAR 10.25.07.09 to the Medicare Care Data Base in accordance with the reporting requirements found in COMAR 10.25.06." As such, we believe any sharing of data by an EHN to the State-designated HIE that would be for an individual covered under a self-funded group plan governed by ERISA or Mecdicare Part D plans, or the Federal Employees Health Benefits Program would be prohibited.

As we and other EHNs have repeatedly shared with MHCC, we serve as Business Associates to providers, their vendors, and payors, and we do not ourselves have blanket data sharing rights. Through discussions with payors, it is clear that EHNs will not be granted rights to share data with the State-designated HIE, since federal laws and rules prohibit payors from sharing with state entities, such as All Payor Claims Databases. Additionally, many providers will need to update their Notice of Privacy Practices to include this data sharing, and it is unlikely a Business Associate could share data with the State Designated HIE prior to providers making such updates. In the proposed rule, MHCC has failed to address any filtering that would need to occur to remove data that an EHN has not been granted the right to share in its Business Associate Agreements. Furthermore, MHCC has failed to address what an EHN should do if it has attempted to update a Business Associate Agreement with a customer to allow for the mandated data sharing, but the customer has refused to make the update. Would the EHN be out of compliance? Would it be barred from operating in the state? Would the EHN be expected to violate its Business Associate Agreement in order to comply with the state mandate? These concerns should be addressed in the regulation.

Proposed Text

.09(F) Submission Schedule
(1) No later than the last business day of each month, an MHCC-certified EHN shall submit electronic health care transactions information from the preceding month to the State-designated HIE.
(2) An MHCC-certified EHN shall submit electronic health transaction information at least once per month, but may submit data more often

Comments

To the extent Maryland lawfully requires the reporting of data, we support a quarterly reporting schedule. We reiterate that there is significant work that must occur to filter transactions appropriately, and doing so on a monthly basis is not feasible. MHCC is increasing the burden on EHNs by requiring monthly reporting (reporting on which EHNs may not recoup any fees), while the purposes for which data will be used do not require monthly reporting. The generally accepted industry schedules for patient safety analysis, public health management, and healthcare improvement programs are quarterly, since data does not need to be incredibly fresh for purposes of managing population level programs. The change to monthly reporting seems to indicate that the data will be used for Treatment purposes (generally the only use case that requires fresh data), which is contrary to the statutory language, and this proposed rule. The burden that monthly reporting creates for EHNs should not be incurred unless there is a compelling reason to incur such burden. As it is now, the stated purposes do not provide the necessary justification. We recommend that MHCC revert to the originally proposed quarterly schedule.

Proposed Text

.09(H) Exemptions
(1) An MHCC-certified EHN may request a 1-year exemption from certain reporting requirements in this regulation.
(2) An exemption request shall:
(a) Be in writing;
(b) Identify each specific requirement of this regulation from which the EHN is requesting an exemption;
(c) Identify the time period of the exemption, if any;
(d) State the reason for each exemption request; and
(e) Include information that justifies the exemption request.
(3) Within 45 days after receipt of complete information from an EHN requesting an exemption, the Commission shall take one of the following actions:

(a) Grant the exemption by providing written notification; or
(b) Deny the exemption request by providing written notification that enumerates the reasons for the denial to the EHN.
(4) The Commission may not exempt an MHCC-certified EHN from any requirement within this regulation that is otherwise required by federal or other State law.
(5) The Commission may grant an exemption on the following grounds:
(a) The absence of functionality in the infrastructure of the EHN that prevents the EHN from complying with the requirement;
(b) The requirement would hinder the ability of the EHN to comply with other requirements of this chapter or federal or other State laws; or
(c) The requirement would cause an undue burden or hardship on the EHN, such that the EHN would no longer be able to provide EHN services in the State.
(6) For good cause shown, the Commission may renew a 1-year exemption for an additional 1-year period

Comments

We continue to recommend that MHCC add outright exclusions rather than solely regulating an exemption process. At a minimum compliance with federal and other state laws should be included as an outright exclusion. We generally support MHCC's addition of an additional exemption process to the regulation for issues that would not have an outright exclusion. In the alternative, we request that MHCC clarify in the allowed exemption section whether an inability to obtain Business Associate Agreement updates would be allowed grounds for exemption. As we and other EHNs have noted to MHCC numerous times, we are Business Associates of our customers who dictate what we can and cannot do with this data via our Business Associate Agreements. To comply with the state requirements, our Business Associate Agreements will need to be updated, and it is unclear if we could be granted an exemption if this process takes longer than 12 months.

Proposed Text

.10(A) The Commission may withdraw certification from an MHCC-certified EHN if the Commission finds that:

…

(5) The MHCC-certified EHN fails to submit electronic health care transactions to the State Designated HIE in accordance with Regulation .09 of this chapter.

…

(D) A MHCC-certified EHN that fails to submit electronic health transactions to the State Designated HIE in accordance with Regulation .09 of this chapter may be subject to a financial penalty not to exceed $10,000 per day 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 MHCC-certified EHN committed previous violations.

Comments

We are concerned about the statutory basis for the proposed penalty provisions. No provision expressly authorizes the agency to adopt penalty provisions and there does not appear to be a basis to assume a delegation of such authority from the limited provisions granting regulatory authority in Md. Health Gen. § 4-302.3 or any other applicable sections. To the extent that the MHCC is authorized to promulgate a penalty provision, we are concerned that the proposed penalties are excessive and do not account for good faith errors. We recommend that the MHCC expressly adopt a safe harbor for *de minimis* failures to submit electronic health transactions and for failures that are the result of good faith errors and cured within a reasonable time after actual notice of the failure.

Optum Insight thanks MHCC for allowing comments on this proposed regulation. We welcome the opportunity to meet with you to discuss our comments and answer any follow-up questions.

Thank you,

John Foss
SVP, Medical and Pharmacy Networks