September 8, 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,

The Cooperative Exchange, the National Clearinghouse Association (CE), composed of 19 member organizations[1], representing over 90% of the clearinghouse industry that supports over 1 million provider organizations, through more than 7,000 payor connections and 1,000 Health Information Technology (HIT) Vendors, and processes over 6 billion healthcare transactions annually; represents *the U.S. healthcare electronic data interstate highway system* enabling connectivity across all lines of healthcare eCommerce in the United States. We are pleased to comment on behalf of the Cooperative Exchange members on the COMAR 10.25.07, Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses.

CE Comments on Maryland Proposed Rule

Proposed Text

.02 Definitions

(9) "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

[13] (14) "Mitigation of a public health emergency" means taking actions to lessen the impact of public health emergency and reduce harm, including implementing preventive measures,

[1] 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.

managing resources, and coordinating responses to limit disease spread, minimize health risks, and support affected communities effectively.

(17) "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

The CE remains concerned with the proposed definitions as they are broad and potentially cover a wide range of use cases. The CE recommends that MHCC add more specific use cases for how the State Designated HIE or MHCC would use this data. Additionally, as you will read further in our comments, the CE members are concerned about the legality of releasing patient data that is already restricted by HIPAA, federal, or state laws. The CE will also discuss the need for an exemption that allows the clearinghouses or EHNs to determine the data that should be carved out based on HIPAA, federal, and/or state laws.

The CE requests clarity on the definition of "improvement of patient safety". We recommend that MHCC consider "patient safety" to include the patient safety activities considered by 42 CFR 3.20, which HIPAA's Privacy Rule includes in its definition of health care operations.

The CE appreciates the state's effort to support the Total Cost of Care model; however, we do have some concerns regarding lack of specific use cases for "state health improvement program" definition. The data requested by the state is non-adjudicated claims data, including rejected or duplicate claim data which have errors or invalid data reported. This potentially compromises the integrity of the data received by the state.

Additionally, we request that the MHCC clarify whether, if any, electronic health care transactions fall outside of the state initiative in order for us to make appropriate implementation decisions related to filtering the data. For instance, federal law and contractual agreements prevent clearinghouses from sharing Employee Retirement Income Security Act (ERISA) and Federal Employees Health Benefits Program (FEHBP) data with state entities, therefore this claim data must be excluded.

The CE strongly recommends that MHCC make it 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).
(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
The CE generally supports modifying the language from "transactions originating in Maryland" to "healthcare transactions information for services delivered in Maryland". The change clarifies which transactions need to be included or excluded; however, the CE members are still concerned about including transactions for payors that do not operate in Maryland but whose members may seek care in Maryland, particularly members who are not Maryland residents. The clearinghouses need clear guidelines on how to determine if a service is delivered in Maryland from the claims received when claims originate from large healthcare systems with care sites in surrounding states or the District of Columbia. The CE made note that there also isn't a consideration for coordination of benefit claims (secondary, tertiary, etc.) and what claim data Maryland expects to receive. If MHCC decides not to include this clarification, the clearinghouses will be required to amend their Business Associate Agreements (BAA) for every payor with a contracted connection to that clearinghouse, regardless of whether the payor operates in Maryland. Amending all BAAs presents significant logistical and financial challenges, even in situations where the covered entity client is willing to modify their contract. With that said, we must emphasize again that by the definition of "as required under law" under HIPAA, BAAs do not permit EHNs to re-disclose patient information to the state HIE. This regulation would compel EHNs to breach these BAAs and violate federal law. The EHNs are uncertain about what to do if covered entity clients refuse to amend a BAA that allows EHNs to re-disclose patient information to the state HIE or demand to renegotiate the entire BAA.

The CE commented, via our previous letter, that it is unclear which transactions are to be submitted to MHCC. We understand that the claim or equivalent encounter information (837P/837I), health plan eligibility inquiry and *response* (270), and benefit enrollment and maintenance (834) are the transactions named in the regulation. Unfortunately, the concerns from the CE were not addressed in the amended regulation and there are still questions that should be addressed:

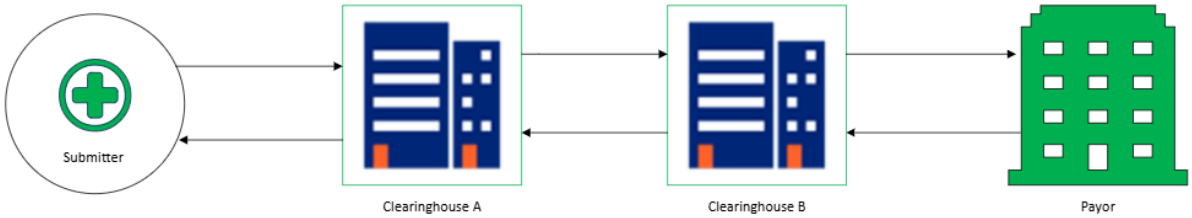
- The dental health care claim or equivalent encounter information (837D) was left off. Is dental claim/encounter information not needed?
- The rule calls for the inquiry and response but only lists the 270, which is only the inquiry. The CE strongly recommends adding the eligibility response, 271, to help prevent confusion if MHCC desires the response to be provided.
- The Benefit Enrollment and Maintenance transaction (834) isn't generally transmitted by our members. The CE recommends removing the 834 transaction, providing a specific use case, or guidance on the entities that should provide the 834 data to the state.

The CE requested, in our previous comment, that MHCC clarify if it requires every transaction for all services delivered in Maryland, or only for services that meet the specific purpose that the State or the HIE may determine (i.e. state health improvement program, mitigation of public health

emergency, or improving patient safety). EHNs will need to know how to determine the specific transactions and dates of service they would need to provide for these use cases. Such filtering will need specific directions and will require EHNs to examine each transaction in detail. This will be a time-consuming and costly process that needs to be considered when determining the implementation time frame and frequency of submissions. EHNs are concerned that simply asking for every transaction has privacy and administrative issues under HIPAA which generally requires minimum necessary, even when sharing for public health related purposes. The "minimum necessary" data is not explained in the regulation and requesting all transactions without the ability to filter could violate HIPAA, federal, and state laws.

The CE members want to remind MHCC about the complexity of the workflow that EDI transactions follow in the healthcare ecosystem. A transaction can flow through multiple clearinghouses before finally reaching the destination payor. In this regulation, it is still unclear which EHNs are responsible for submitting a transaction when multiple clearinghouses handle the same transaction. The simplest example is one submitter, to one clearinghouse, to one payor, and the responses follow the path back from the payor, to the clearinghouse, to the submitter:

However, this is not the true nature of EDI transactions today as the transaction will touch more than one intermediary before reaching the destination payor. In the next simplest and most common example, a submitter may work with one of our CE member clearinghouses (A) to submit an 837 but the payor may work with a different CE member clearinghouse (B) to receive the 837. In this scenario, the submitter would submit the claim to clearinghouse A, and under that clearinghouse's Trading Partner Agreement, clearinghouse A would send the claim to clearinghouse B, which would then deliver the claim to the payor. In a happy path scenario with no rejections, the responses to this transaction would seamlessly make the same path back to the submitter:



In this scenario, which clearinghouse is responsible for submitting the claims to the State-HIE, clearinghouse A, clearinghouse B, or both. The CE would be remiss if did not bring it to the attention of MHCC the possible issues if the regulation guidelines do not specify which clearinghouse is

responsible for providing the State-HIE with this transaction data. The CE sees some potential adverse downstream issues from receiving the transaction data from all clearinghouses involved in a transaction:

- Duplicate claim data: 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.
    - 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?
- Privacy implications of duplicated data: We are concerned that if EHNs submit duplicate transactions, then privacy risks will substantially increase.

The regulation does not take into consideration more than one clearinghouse/EHN "jump" or when multiple payors are involved in the adjudication of the claim. In reality, there is the possibility for more than two clearinghouses being involved and this must be considered. A recommendation is to have the clearinghouse/EHN that first/middle/last receives the transaction data provides it to the State-HIE. We urge MHCC to clarify the regulatory language around which EHN would submit the required transactions, i.e. the initial EHN that receives it or all EHNs that touch it which could avoid many duplicates.

Additionally, the proposed text does not acknowledge or provide guidance on filtering additional categories of data beyond "Legally Protected Health Information". Specifically, MD. Health Gen. §4-302.3(h)(3) mandates restrictions on:

- (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
- (iv) Restrict data from health care providers that possess sensitive health care information.

The proposed regulation lacks clarity on whether EHNs are permitted or required to filter such data independently, or if reliance on the MHCC State-designated HIE is mandated. This ambiguity creates operational and compliance challenges. Mandating that EHNs submit financial data to the State-designated HIE without corresponding privacy safeguards raises concerns about the protection of intellectual property. Additionally, requiring EHNs to transmit sensitive private data without clear privacy obligations on the HIE could compromise patient confidentiality.

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 whether the proposed basis for disclosure would be permitted under the HIPAA Privacy Rule if done by a covered entity and, therefore, its business associate.

Also, 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 instance, 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, clearinghouses 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.

The CE has stated before that we serve as Business Associates to providers, their vendors, and payors, and we do not have unfettered data sharing rights. The CE membership knows that payers may not grant rights to clearinghouses to share particular data with the State-designated HIE. 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 in the proposed rule. MHCC has also 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. Does this mean that the EHN is out of compliance and excluded from doing business in the state? Otherwise, it appears that the state expects the EHN to violate BAAs in order to comply. The CE membership respectfully requests that these concerns be addressed in the proposed regulation.

Proposed Text:

.09(E) Electronic Health Care Transactions Technical Submission Guidance.
(1) In consultation with stakeholders, including Commission staff, [The] the State-designated HIE shall develop an Electronic Health Care Transactions Technical Submission Guidance that: [in consultation with stakeholders that details the technical requirements for submitting electronic health care transactions information to the State-designated HIE in accordance with this regulation]

(a) Contains detailed technical requirements for submitting electronic health care transaction information to the State-designated HIE;

(b) Provides an option for MHCC-certified EHNs to submit electronic health care transactions in a flat file; and (c) To the extent possible, utilizes industry recognized standards.

(2) The State-designated HIE shall:

(a) Invite all MHCC-certified EHNs and Commission staff to at least one meeting to discuss the initial development of the Electronic Health Care Transactions Technical Submission Guidance;

(b) Invite all MHCC-certified EHNs and Commission staff to at least one meeting prior to making any material updates to the Electronic Health Care Transactions Technical Submission Guidance;

(c) Solicit public comments on a draft copy of the initial Electronic Health Care Transactions Technical Submission Guidance, and any material updates to the guidance, by:

(i) Publishing the draft guidance on its website; and

(ii) Sending the draft guidance to MHCC-certified EHNs and the Commission by e-mail;

(d) Accept comments on the draft Electronic Health Care Transactions Technical Submission Guidance for at least 30 days

(e) Publish a written response to any significant, substantive issues raised in comments; and

(f) Consider all stakeholder feedback prior to finalizing the Electronic Health Care Transactions Technical Submission Guidance.

[(2)] (3) The State-designated HIE shall annually submit to Commission staff a final draft of [update] the Electronic Health Care Transactions Technical Submission Guidance for approval, which shall not be unreasonably denied [on an annual basis].

(4) The State-designated HIE and the Commission shall publish the final, approved Electronic Health Care Transactions Technical Submission Guidance on their websites.

[(3)] (5) An MHCC-certified EHN shall submit electronic health care transactions information to the State designated HIE in a manner detailed in the most recent version of the Electronic Health Care Transactions Technical Submission Guidance.

Comments:

The CE is pleased that MHCC heard and responded to the recommendations about expanding submission guidance by adding a detailed process. The MHCC-certified CE members are looking forward to working with the State-designated HIE to develop the submission guidance.

The CE also notes that the flat file format is back in the proposed regulation and we appreciate the return of that detail.

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:

The CE still believes that monthly reporting is not sustainable, and we recommend quarterly reporting as it aligns with other healthcare entity's data reporting requirements. If MHCC takes our recommendation, the proposed regulation needs to provide a timeframe for when the State needs to receive the data. For example, would the expectation be that the data is received on the last day of the quarter or a within a number of days/weeks after the end of the quarter?

We must reiterate that the work required to filter the transactions appropriately is significant and costly, especially since EHNs are not allowed to recoup any costs associated with providing this data to the State. There is also concern about the method of data transmission due to the size of the data set being requested, even in a flat file format. A safe, secure, and efficient process needs to be established for the sharing of the data.

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:

The CE strongly recommends that MHCC incorporates outright exclusions into the regulation, rather than relying solely on an exemption process. At a minimum, compliance with federal and other state laws should be recognized as grounds for automatic exclusion. This would provide clarity and reduce the administrative burden for EHNs and other stakeholders.

We generally support MHCC's inclusion of an additional exemption process for circumstances not covered by outright exclusions. However, we request clarification on whether inability to obtain timely updates to BAAs would qualify as a valid exemption. The CE membership previously communicated, we are a Business Associates of our customers and are contractually bound by the terms of our BAAs. These agreements dictate how we may use and disclose data. To comply with the proposed state requirements, many EHNs will need to renegotiate and update these agreements. Given the complexity of this process, it is unclear whether delays exceeding 12 months would be grounds for exemption under the current proposed regulation.

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:

The CE is concerned about the statutory basis for the proposed penalty provisions. There is no clear statutory provision that explicitly authorizes MHCC to impose penalties under Md. Health Gen. §4-302.3 or related sections. The proposed penalty provisions may exceed the scope of MHCC's delegated regulatory authority. The proposed penalties are considered disproportionate, especially

in cases which involved good faith errors. There is concern that the regulation does not distinguish between intentional violations and minor, unintentional errors. The CE recommends that MHCC adopt a safe harbor provision for de minimis failures to submit electronic health transactions and good faith errors that are corrected within a reasonable timeframe after receiving notice. This would help ensure fairness and encourage compliance without penalizing entities acting in good faith.

The CE appreciates the opportunity to comment on this proposed rule and we thank MHCC for considering our comments and concerns. Please feel free to contact the Cooperative Exchange Board Chair if you have any questions.

Respectfully submitted,

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