MARYLAND
Health Care
Commission

Randolph S. Sergent, Esq., Chairman
Ben Steffen, Executive Director

Public Comments in Response to Proposed 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 December 2, 2024 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.

Comment Period: December 2nd 2024 through January 2nd 2025

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January 2, 2025

Nikki Majewski
Maryland Health Care Commission
Submitted via email to mhcc_regs.comment@maryland.gov

RE: *MHCC Seeks Public Comments on Draft Amendments to COMAR 10.25.07 and COMAR 10.25.18*

Dear Ms. Majewski:

The Chesapeake Regional Information System for our Patients ("CRISP"), the state designated health information exchange ("HIE") and health data utility ("HDU") for Maryland, appreciates the opportunity to comment on the draft amendments to COMAR 10.25.07 and COMAR 10.25.18 (the "Draft Regulations"). CRISP connects to over 75 percent of clinicians in Maryland and is a "best-in-class" HIE and HDU. As such, we have significant experience working with and across interested parties to normalize data and present information based on the need of that party while upholding the privacy of patients. We are grateful for these groundbreaking regulations, which will continue to push forward not only the state of Maryland, but also the entire country.

COMAR 10.25.18.03(D) – Consent Management Application

The proposals in COMAR 10.25.18.03(D) seek to implement the country's first "one-stop shop" to allow a patient to opt-out of data sharing across HIEs, which include electronic health records in Maryland. Without these regulations, patients may opt-out at one location, thinking they have opted-out of all data exchange within the state. CRISP has experienced many conversations with patients who are devastated to learn that their sensitive data is still being shared and that they must opt-out at every HIE, a daunting task for a patient, if it is even possible. We are grateful for these proposals and believe they will greatly reduce patient burden, while also increasing their choices and honoring their preferences in data sharing. Below, we share our detailed comments on specific proposals in this section.

Proposal: (1)(b) The State-designated HIE shall implement a consent management application that . . . allows a person in interest to view the interested patient's opt-out status.

Comment: CRISP does not currently possess the technical ability to verify identity through a portal or other electronic system. Although we have explored options for doing so, the identity management required for the security we uphold would likely be cost prohibitive without additional funding. Therefore, CRISP relies on point-of-care verification and persons in interest providing copies of required documentation to CRISP; for each, the process is manual. We are interpreting these proposed regulations to continue to allow such manual identity verification, with the viewable opt-out status to be provided via email or other method selected by the person in interest. If this is not MHCC's intention, we would request additional lead time and funding to create such a patient portal with the appropriate identity verification.

Proposal: (1)(c) The State-designated HIE shall implement a consent management application that . . . informs the person in interest of the types of electronic health information that may be shared or disclosed in accordance with §A(2)(a) of this regulation notwithstanding the choice to opt out.

Comment: Although CRISP can inform persons in interest of the types of electronic health information that may be shared by CRISP, we cannot represent the type of information that may be shared by other HIEs within the state of Maryland. Therefore, we suggest that this section be changed to state " . . . types of electronic health information that may be shared or disclosed *by the designated HIE* in accordance with §A(2)(a) of this regulation notwithstanding the choice to opt out." If this language is not included, CRISP could share with persons in interest the potential or likely types of data shared, but it would not be conclusive and could be misleading. Therefore, we believe this change will more accurately reflect and explain to patients the exchange of their data and consequences of their opt-out.

Proposal: (2) Within 6 months of the effective date of this regulation, the State-designated HIE shall make the consent management application it develops available to registered HIEs.

Comment: Within the suite of regulations proposed by MHCC, much is required of CRISP in the next 18 months. To meet all deadlines appropriately and prioritize each concurrently, we request that MHCC finalize this proposal to allow twelve (12) months from the date of publication. We believe this timeline will allow more fulsome pilots with other HIEs and time for us to learn from and implement changes based on those pilots. This additional lead time will lead to a smoother, overall roll-out after those 12 months.

Proposal: (3) The State-designated HIE shall implement the consent management application with a secure electronic interface that supports standardized interoperability between various recipient HIE systems.

Comment: CRISP is interpreting this proposal such that "standardized" does not necessarily mean "standards" as the health IT community would interpret standards, such as Data Segmentation for Privacy (DS4P). Rather, CRISP is interpreting any number of solutions, such as application program interfaces and secure file transfers that could convey the necessary information in a standardized way. We believe this interpretation brings the necessary flexibility to Maryland's cutting-edge requirements, which will likely require agile approaches based on differing needs of Maryland's interested parties. CRISP, as always, strives to use and implement health IT standards, and will do so within this effort, and continues to believe flexibility in data exchange is critical to Maryland's success.

Proposal: (4)(b)(i) An HIE shall . . . Establish bi-directional connectivity with the consent management application within 18 months of receiving notification from the State-designated HIE that the application is operational.

Comment: CRISP assumes the other HIEs in the state will participate in pilots that we will be running as we stand-up the consent management application functionality. If that is the case, we believe that a twelve (12) month timeline will suffice for bi-directional connectivity. Based our conversations with patients and with our Consumer Advisory Council, we believe that patients

assume when opting-out with CRISP, they opt-out with all other HIEs. Thus, we request MHCC finalize a 12-month timeline for bi-directional connectivity to make that assumption a reality for patients.

Proposal: (8) The State-designated HIE shall promptly notify the Commission and all HIEs any time the consumer management application is not operational and when services are resumed.

Comment: CRISP considers "not operational" to be a downtime of fifteen (15) minutes or more. If a functionality within our system becomes not operational, we follow our standard processes by sending out communication and making a banner available in our portal and website. We would interpret this proposal to allow for our standard procedures, as stated above.

Proposal: (9)(b) An HIE is not required to comply with §D(4)(b) of this regulation when . . . The consent management application is not operational.

Comment: Note that, if the consent management application is not operational, depending on the mode of bi-directional exchange, the data may need to be re-exchanged with CRISP. CRISP would work with any affected HIEs during a time the consent management application is not operational to ensure opt-out statuses conveyed during that time are received. MHCC may wish to require HIEs to ensure that opt-out statutes are re-conveyed if necessary if the consent management application becomes non-operational.

COMAR 10.25.18.13 Non-Controlled Prescription Drug Dispenser Reporting

CRISP has appreciated the collaborative process in creating the Noncontrolled Prescription Drugs Dispenser Data Submission Manual. Thus, our comments in this section are limited. We are grateful for all the interested parties that were willing to engage beforehand, and we hope to have similar engagement with the consent management application and Electronic Health Network Transactions. Even so, we believe there are a limited number of places these regulations could be improved, which we discuss below.

Proposal: (E)(1)(d) The State-designated HIE shall . . . Retain noncontrolled prescription drug information collected pursuant to this section for at least 5 years from the date of receipt.

Comment: Under COMAR 10.25.18.03, a "health care consumer has the . . . right to opt out of an HIE." In the past, CRISP has interpreted this section to require us to delete or make un-useable all data for an opted-out consumer except for the areas discussed in subsection (2)(a) of the same section. We request that MHCC clarify whether this proposal is an exception to COMAR 10.25.18.03 or HIEs should not retain noncontrolled prescription drug information collected if a patient has opted-out. We believe this clarification is necessary to ensure both HIEs and consumers understand the implications of opting out.

Proposal: (E)(1)(4) The State-designated HIE shall make patient-specific prescription information submitted by dispensers under this section available for purposes allowed under applicable law.

Comment: In subsection (F)(1) of this section, dispensers are required to report on and after September 1, 2025. CRISP anticipates that there may be a period of time after collection that will require data normalization and testing in our system before it is fully available for display for those allowed to view it under applicable law. Therefore, we request that we receive an additional three (3) months after September 1, 2025 for this testing before we are required to display such data. Specifically, we request MHCC change this text to read "Beginning January 1, 2026, the state-designated HIE shall make patient-specific prescription information submitted by dispensers under this section available for purposes allowed under applicable law."

Proposal: (E)(5) Upon written request for public health purposes, the State-designated HIE shall provide data collected under this regulation within 5 days to the Maryland Department of Health, local health departments, the Commission, or the Health Services Cost Review Commission.

Comment: Along with COMAR, CRISP is subject to other Maryland and federal law and regulations with which it must comply. CRISP can only provide data if allowed by such laws. To ensure that those reading the regulations are aware of such limitations, we recommend modifying this section to read, "Upon written request for public health purposes *and as allowed by applicable law* . . ." As MHCC knows, this change is not necessary; CRISP will abide by all laws. However, in our experience, we have found that ensuring all interested parties are aware of such limitations not only sets expectations, but also provides comfort to consumers engaged with such regulations.

COMAR 10.25.18.14 Operation of the State-designated HIE as a Health Data Utility

CRISP has been honored to serve as not only the state-designated HIE, but also the state-designated HDU for Maryland for the last several years. We are leading the nation in what is possible in reuseable data exchange with robust governance. We believe the proposals in this section are intended to codify the work and processes CRISP already has in place, memorializing core functions of an HDU. Our comments reflect this understanding and also make minor suggestions for clarification.

Proposal: (C)(2) The State-designated HIE may not redisclose financial information in electronic health care transactions it receives in accordance with COMAR 10.25.07.09 to any person other than the Commission.

Comment: Based on our experience, what is considered "financial information" varies greatly based on an individual's or company's concerns. We are interpreting "financial information" to be the "billed amount" and "allowed amount." If we are correct in this interpretation, we request that MHCC clarify "financial information" accordingly by either adding a definition of the term or explicitly stating what it is intended to mean in this section. We believe such clarification will ensure all interested parties are on the same page when designing solutions and collaborating on COMAR 10.25.07.09.

Proposal: (C)(4)(a) The State-designated HIE shall (a) Develop a process in which requests for data are submitted and data are shared, and post this information on its website; and (b) Provide a written explanation for a denial of a request which shall include an appeal process.

Comment: Currently, CRISP accepts all requests for data and documents all outcomes for these requests when an individual contacts us through phone, email, or other means as stated on our

website. After first-line requests and answers are generated, requestors can speak with the CRISP Privacy Officer, who then further documents the results of these requests. We are interpreting this proposal to continue to allow our current process.

Proposal: (E) (1) The State-designated HIE shall establish a Consumer Advisory Council in accordance with Health-General, § 19-145, Annotated Code of Maryland. (2) The State-designated HIE shall: (a) Appoint two consumer representatives identified by the Commission who have significant experience in public health and patient privacy as council members; (b) Post advance notice of council meetings on its website, including an expected agenda; and (c) Require the Consumer Advisory Council to comply with the requirements of the Maryland Open Meetings Act as if it were a public body.

Comment: For two (2) years, CRISP has engaged our Consumer Advisory Council. This body has repeatedly requested that CRISP facilitate closed, confidential meetings to discuss concerns the members consider sensitive. Section 3–305 of the Maryland Open Meetings Act allows closed meetings if certain exceptions apply, including to "protect the privacy or reputation of an individual with respect to a matter that is not related to public business." Therefore, we believe that most of these meetings can still be conducted privately, as requested by the Consumer Advisory Council. If our understanding is not correct, we request an exception in this section for confidential matters as determined by the Consumer Advisory Council. Specifically, we request that (c) be modified to read, "*except when the Consumer Advisory Council requests confidential meetings, as documented in writing,* require the Consumer Advisory Council to comply with the requirements of the Maryland Open Meetings Act as if it were a public body."

COMAR 10.25.07.09 Electronic Health Network Transaction Submission

Electronic Health Networks provide a wealth of data that fills information gaps and are yet untapped in the state of Maryland. We are excited by these proposals and what they can bring to users of CRISP as they benefit the larger state. Below, we provide suggestions to ensure that this data can truly fill such gaps and meet the promise of the original legislation.

Proposal: (A) An MHCC-certified EHN shall submit electronic health care transactions information in accordance with this regulation to the State-designated HIE for public health and clinical purposes to facilitate: (1) A State health improvement program; (2) Mitigation of a public health emergency; or (3) Improvement of patient safety.

Comment: We are grateful for these regulations and believe that sharing of this data will greatly fill information gaps in health and healthcare, helping both consumers and providers alike. However, based on this proposal, CRISP believes MHCC is overly limiting the uses of this information. For example, "treatment" is not a blanket permitted purpose in these proposed regulations although it is under federal law; thus, the uses for providers may be limited if this proposal is finalized as is. Furthermore, the impending AHEAD model may not be able to use the information to inform its goals, including quality care and reduced costs. Perhaps most troubling, while this regulation states the data could be used to "mitigate" a public health emergency, it is not clear that it could be used to proactively prevent a public health emergency; that is, as written, the data likely could only be used once a public health emergency has been declared, when one of the goals of public health is to keep such emergencies from occurring at all.

Therefore, we request that MHCC modify this section to state, "An MHCC-certified EHN shall submit electronic health care transactions information in accordance with this regulation to the State-designated HIE for *any purpose allowed by applicable law*."

Proposal: (I) The State-designated HIE shall publish the Electronic Health Care Transactions Technical Submission Guidance within six months of the final effective date of this regulation.

Comment: As MHCC knows, CRISP has actively and persistently attempted to engage Electronic Health Networks in pilot projects to help both us and them understand how to comply with potential regulations. Despite these attempts, we have not been able to launch a pilot. In addition, this type of data exchange is first in the nation, without a "playbook." Therefore, to both create and publish the Electronic Health Care Transactions Technical Submission Guidance, we believe we would need *at minimum* twelve (12) months. This timeline is especially necessary given the competing priorities of the consent management application and the collection of non-controlled prescription drugs. With this additional time, we believe we can adequately complete these concurrent regulatory requirements, continuing our best-in-class leadership throughout the country.

CRISP highly values its relationship with the Commission and is honored to serve as the state designated HIE and HDU for Maryland. As we engage throughout the country, there is no doubt that Maryland is best-in-class and is leading the way with other states. We look forward to continuing to leadership role, as we work together to implement these ground-breaking regulations.

Best,

Craig R. Behm
CEO and President, CRISP

January 2, 2025

Ben Steffen
Commissioner
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 Commissioner Steffen,

The Cooperative Exchange, the National Clearinghouse Association, 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 payer 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:

.09 Electronic Health Network Transaction Submission.

A. An MHCC-certified EHN shall submit electronic health care transactions information in accordance with this

regulation to the State-designated HIE for public health and clinical purposes to facilitate:

(1) A State health improvement program;

(2) Mitigation of a public health emergency; or

(3) Improvement of patient safety

.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] 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.

(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 modifying the language from transactions originating in Maryland to "healthcare transactions information for services delivered in Maryland". There is still a concern about including transactions for payers that do not operate in Maryland but whose members may seek care in Maryland, particularly when members are not Maryland residents. Our members are also unclear on how they would determine if a service is delivered in Maryland from the claims data received when claims originate from large healthcare systems with care sites in surrounding states or the District of Columbia. (how to determine a service delivered in Maryland?)

The regulation is not clear on what transactions are to be submitted to MHCC. The X12 transactions provided in the rule are:

- Health care claim or equivalent encounter information (837P and 837I)
- Health plan eligibility inquiry and response (270)
- Benefit enrollment and maintenance (834)

Our members have noted some concerns and questions on the transactions named in the rule:

- The dental health care claim or equivalent encounter information (837D) was left off. Is dental claim/encounter information not needed?
- The rule fails to include the eligibility response (271) along with the request (270). The CE recommends adding the eligibility response to help prevent confusion if MHCC desires the response to be provided.
- The Benefit Enrollment and Maintenance transactions (834) isn't EHNgenerally transmitted by our members. The CE recommends removing the 834 transaction.

Cooperative Exchange is also unclear on whether or not MHCC is requiring 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 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 look into each transaction. This will be a time-consuming process and 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.

Currently, BAAs do not permit EHNs to re-disclose patient information to the state HIE. This regulation would therefore compel EHNs to breach these BAAs and violate federal law. The definition of 'as required by law' under HIPAA does not allow an EHN to re-disclose patient information in this situation. Additionally, what are EHNs to do when their Covered Entity clients

refuse to execute a BAA with an amendment that allows EHNs to re-disclose patient information to the state HIE or demand to renegotiate the entire BAA? With thousands of clients and BAAs, it would be a logistical and financial nightmare for EHNs.

The CE wants to ensure that MHCC is aware that there is a high probability that the transactions received would contain potentially rejected or denied claims, since the claims are pre-adjudicated. The submission of claims that ultimately are rejected or denied will invalidate some of the transactions received by the state of Maryland, but the state will not have a method for determining which transactions are invalid.

The CE requests clarification for instances where a transaction is routed through multiple EHNEHNs. EHNs have different connections. For example, a submitter sends a claim to EHN A, EHN A forwards the claim to EHN B, and EHN B submits it to the payer. Which EHN is responsible for submitting the transaction to MHCC? The rule doesn't include a mechanism to identify duplicate transactions if each EHN that touches the transaction sends it to MHCC. Please keep in mind that identifiers within the transaction change when the transaction is received by a different EHN (i.e. submitter id, payer id, etc.). The CE members are concerned that MHCC is not aware of the technical intricacies of how EHNs bridge transactions between them, and this will lead to a significant amount of work for EHNs to either add filters in or the State-Designated HIE to build deduplication processes that does not have today and potentially will not have an easy key for deduplication.

Proposed Text:

.09(E) Electronic Health Care Transactions Technical Submission Guidance.

(1) The State-designated HIE shall develop an Electronic Health Care Transactions Technical Submission Guidance 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.

(3) 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:

MHCC removed the language from the proposed rule about the method of submission being a flat file and instead has delegated all technical decisions to the State-Designated HIE with guidance and consultation with stakeholders. The rule does not set any expectations of what the consultation looks like and how the consultation will take place. The CE is concerned that an HIE that does not have historical experience with X12 transactions will be solely responsible for developing the technical requirements. Additionally, sending the X12 transaction to the state-designated HIE isn't feasible with the amount of filtering that is required, and CE is concerned that the HIE may simply require the X12 transactions rather than the more reasonable flat file originally proposed. The CE recommends that MHCC add language to include guidelines for stakeholder

consultation, provide information on the number of listening sessions with the stakeholders, a proposed technical guidance document, and review of comments timeline before finalization.

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 supports a quarterly reporting schedule. Our members are concerned and confused on why Maryland modified the proposal from quarterly to a monthly reporting schedule. The work required in order to filter the transactions appropriately is significant and doing this on a monthly basis is not feasible. This increases the burden on EHNs by requiring monthly reporting while the three purposes for which the data will be used do not require monthly reporting. Please note, this is also work that the EHN may not recoup any of the fees related to this reporting.

I. Effective Date.
(1) The State-designated HIE shall publish the Electronic Health Care Transactions Technical Submission Guidance within six months of the final effective date of this regulation.
(2) An MHCC-certified EHN shall begin submitting electronic health care transactions information based on the most recent version of the Electronic Health Care Transactions Technical Submission Guidance within 12 months following the initial publication of the Electronic Health Care Transactions Technical Submission Guidance.

The CE is concerned about the timeframes noted in the proposed rule, especially the implementation timing. Without knowing the specifications for submittal, it is impossible to determine the cost and time necessary to develop, test, and operate the process for submission. Instead of a specific timeframe in the regulation, the CE suggests that MHCC work with the industry to determine a reasonable timeframe once the specifications are finalized. We cannot know if one year, two years, or more is necessary.

G. An EHN may not charge a fee to a health care provider, health care payor, or the State-designated HIE for providing the information required under this regulation

Notwithstanding the provisions of the law, the CE is opposed to this provision as written. There will be costs to EHNs to develop and operate this process, and as noted in the proposed rule publication these costs are “Indeterminable” at this time. EHNs will need to recover the costs associated with this requirement. The MHCC must make clear that while a specific fee just for this requirement is not allowed, EHNs will be able to include these costs when determining overall fees

to providers and health plans for the general services provided to them. The MHCC must make clear that there is no limit or restriction on EHNs raising overall fees to cover these costs.

The CE is also concerned that this requirement duplicates information that entities already provide to Maryland State agencies and wonders why the MHCC is not simply obtaining the existing information. For example, the Maryland HSCRC collects various data sets from all acute care hospitals and licensed specialty hospitals. By legislative mandate (COMAR 10.37.04, 10.37.01.08 and 10.37.06), these hospitals in Maryland are required to submit to the Commission both financial and confidential patient-level administrative data (referred to as "case mix data") on all inpatient and outpatient hospital visits. Additionally, the Maryland Medical Care Data Base (MCDB) is the Maryland's All Payer Claims Database (APCDD includes enrollment, provider, and claims data for Maryland residents enrolled in private insurance including Medicare Advantage, Medicare fee-for-service, and Medicaid Managed Care Organizations.

We believe that these data submissions are far superior to the information that the MHCC is asking for and have been in place for a considerable amount of time. Adding another data flow on EHNs is a needless exercise and creates data comparison and other issues, especially since the data requested from EHNs is pre-payment data, with its associated issues we have discussed earlier.

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,

Pam Grosze
Board Chair, Cooperative Exchange
Pamela.grosze@pnc.com

THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

DILLON CLAIR
Director, State Advocacy

January 2, 2024

Nikki Majewski
Chair, Health Information Technology
Maryland Health Care Commission
4160 Patterson Avenue,
Baltimore, MD 21215

Submitted Electronically

RE: ERIC Public Comments on COMAR 10.25.07, Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses – ERISA Preemption and Employer Plan Concerns

Dear Chair Majewski:

The ERISA Industry Committee ("ERIC") appreciates the opportunity to comment on the proposed regulations contained in "COMAR 10.25.07, Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses" ("Proposed Rules") issued by the Maryland Health Care Commission ("Commission") to implement changes to All Payer Claims Database ("APCD") reporting requirements made by House Bill 1022 and Senate Bill 748 in 2021. ERIC has deep concerns with the Proposed Rules and underlying law, which would overstep state authority to collect claims data from self-insured employer health care plans governed by the federal Employee Retirement Income Security Act of 1974 ("ERISA"). Instead of collecting this data directly from self-insured employer health benefit plans, which is prohibited by federal law and legal precedent, the Proposed Rules seek to collect otherwise protected claims data from the Electronic Health Networks ("EHNs") that are contracted to provide technical support to these plans.

If finalized in their current form, the Proposed Rules would: 1) create an immediate conflict with federal law, and 2) ignore the legal precedent established in this space by the U.S. Supreme Court in *Gobeille v. Liberty Mut. Ins. Co*., 577 U.S. 312 (2016) and restated in *Rutledge v. PCMA*, 141 S.Ct. 474 (2020). Because state attempts to collect this data from ERISA self-insured plans have been held to be preempted by ERISA, ERIC would consider pursuing or supporting litigation challenging the Proposed Rules on behalf of our large employer member companies if advanced. **ERIC therefore strongly urges the Department to amend the Proposed Rule to explicitly exclude claims data reporting requirements related to ERISA self-insured health benefit plans.**

ERIC is a national advocacy organization exclusively representing the largest employers in the United States in their capacity as sponsors of employee benefit plans for their nationwide workforces. With member companies that are leaders in every economic sector, ERIC is the voice of large employer plan sponsors on federal, state, and local public policies impacting their

ability to sponsor benefit plans. ERIC member companies offer benefits to tens of millions of employees and their families, located in every state and city.

Large employers have long been at the forefront of innovating health care benefit design and administration. By combining nationwide workforces into uniform benefit plans, employers are able to negotiate from a position of strength and secure valuable health care coverage at reduced rates, all to the benefit of plan participants. Use of these cost-saving advantages was the precise intention behind ERISA's creation by Congress, which provides a single set of standards for multistate employers to design and administer uniform health care and retirement benefits to their nationwide workforces, regardless of where they live or work. Since ERISA's enactment, multistate employers have done just that, securing truly effective and efficient health care coverage enjoyed today by millions of Americans.

Unfortunately, a series of state laws proposed and enacted in recent years threaten to erode ERISA preemption, aiming to place a growing number of compliance burdens on self-insured plans and endangering the valuable benefits that these plans have long provided. The Proposed Rules, as well as the underlying legislation that they seek to implement, fit squarely within this trend by attempting to directly require EHNs servicing ERISA self-insured health benefits plans to compile and submit claims data reports on a regular basis to the Commission.

Critically, the legal issue of whether states have the authority to apply this policy to ERISA self-insured health benefits plans has already been decided by the U.S. Supreme Court in the case of *Gobeille v. Liberty Mut. Ins. Co*., 577 U.S. 312 (2016). That case involved a similarly constructed Vermont law that required ERISA self-insured health benefits plans operating within the state to compile and provide regular claims data reports to the state's APCD system. The Court not only reinforced the core principle that ERISA expressly preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" but held that the Vermont APCD reporting law had an impermissible "connection with" ERISA plans by attempting to govern and interfere with the uniformity of plan administration.

At its core, the *Gobeille* ruling states in no uncertain terms that under ERISA's uniform design:

> "*The Secretary of Labor, not the States, is authorized to administer the reporting requirements of plans governed by ERISA. He may exempt plans from ERISA reporting requirements altogether … And, he may be authorized to require ERISA plans to report data similar to that which Vermont seeks, though that question is not presented here. Either way, the uniform rule design of ERISA makes it clear that these decisions are for federal authorities, not for the separate States.*"

While the Proposed Rules do not seek to collect claims data directly from ERISA self-insured plans, as did the Vermont law at issue in *Gobeille*, they nevertheless attempt to extract that protected data from the EHNs servicing these plans. Importantly, EHNs do not own the

claims data of the health care plans that they provide services to, but merely hold and share that information according to the contractual terms of the business associate agreement formed with those client plans. As such, a state requirement that EHNs share confidential client claims data with the Commission would force EHNs to either break the terms of their contract with a group health plan or be out of compliance with state law.

The Proposed Rules stand to create direct conflict with ERISA preemption and the *Gobeille* decision, and will erode the ability of multistate employer health benefit plans to effectively operate uniform benefits at scale. **To avoid these conflicts and prevent litigation challenging the Proposed Rules and the underlying Maryland law on ERISA preemption grounds, ERIC respectfully urges the Department to amend the Proposed Rules to explicitly exclude claims data reporting requirements related to ERISA self-insured health benefit plans.**

If you have any questions concerning our comments or would like to discuss the impact the Proposed Rules' would have on health care benefits administration within the state and across the country, please contact us at (202) 789-1400 or dclair@eric.org.

Sincerely,

Dillon Clair

Dillon Clair
Director, State Advocacy

Optum

January 2, 2025

Ben Steffen
Commissioner
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 Commissioner Steffen:

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.

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.

At the outset, and applicable to the proposed regulations, generally, we do not agree with Maryland's procurement of electronic health information from EHNs.

Among other issues, 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. Change Healthcare, which was recently acquired by Optum Insight, previously commented in opposition to the law that the proposed regulations would implement, Md. Code Ann., Health-Gen. § 4-302.3(h). It commented that, among other things, the then-proposed 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 resolve or lessen 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. Although the proposed rule states that the proposed action has an indeterminable economic impact on electronic health networks (EHNs), the economic effect is in fact substantial.

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 appreciate that MHCC has responded to stakeholder feedback requesting further definitions for the three purposes stated in Md. Health Gen. § 4-302.3(h)(1); however, we are 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?

Given this lack of clarity, we 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 include or exclude; however, we are still concerned about including transactions for payers that do not operate in Maryland but whose members may seek care in Maryland. For Health plan eligibility inquiry and response, we note that the proposed rule indicates the 270transaction set only and fails to include the 271 transaction set. We ask MHCC to clarify if the response transaction content will need to be submitted. Additionally, we are 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 payer 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 payer. 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/payer 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.

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; (ii) 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 (iii) 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 is 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 HIE in the regulation.

The breadth of this submission requirement, moreover, raises 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. 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.

As we and other EHNs have shared with MHCC previously, 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, which federal laws and rules prohibit payors from sharing with state entities, such as All Payer 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(E) Electronic Health Care Transactions Technical Submission Guidance.

(1) The State-designated HIE shall develop an Electronic Health Care Transactions Technical Submission Guidance 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.

(3) 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

We are concerned that MHCC has removed language indicating a flat file format as the method of submission and instead has delegated all technical decisions to the State-designated HIE. While the proposed language indicates that the State-designated HIE should "develop the guidance in consultation with stakeholders", the rule fails to set any expectations of what such consultation should look like—e.g., is it sufficient to be considered "consultation with stakeholders" if the State-designated HIE sends a survey to stakeholders or holds one meeting with a stakeholder? We are deeply concerned that an organization that has little to no experience with X12 transactions would be solely responsible for developing the technical requirements for submissions. As we have noted to MHCC, simply sending X12 transactions to the State-designated HIE is not feasible with the amount of filtering that must be done (filtering cannot be done to an X12 transaction itself). But what is to prevent the State-designated HIE from requiring that X12 transactions be sent? The State-designated HIE may specify a format that is incredibly costly to develop versus more economical methods, and as noted earlier while MHCC has indicated that they believe the cost to be minimal that is entirely dependent on the technical specifications finalized by the State-designated HIE. Said another way, without the flat file requirement, EHNs may be required to do work that is technically infeasible and incredibly expensive. We recommend that MHCC put language back into the regulation that makes it clear that (a) flat files of some type will be submitted, and (b) there will be stakeholder consultation. We also recommend including guidelines for that consultation; for example, MHCC should indicate that in "consultation with stakeholders" means a minimum of three listening sessions, a proposed technical guidance document, and a review of comments with updates to the guidance prior to finalization.

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 are concerned and confused that Maryland modified its proposal from a quarterly reporting schedule to a monthly reporting schedule. 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 three 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 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

.09(I) Effective Date.
(1) The State-designated HIE shall publish the Electronic Health Care Transactions Technical Submission Guidance within six months of the final effective date of this regulation.
(2) An MHCC-certified EHN shall begin submitting electronic health care transactions information based on the most recent version of the Electronic Health Care Transactions Technical Submission Guidance within 12 months following the initial publication of the Electronic Health Care Transactions Technical Submission Guidance.

Comments

We appreciate that MHCC has proposed a 12-month implementation; however, MHCC's previous proposal included only claims within the initial period. The new proposal seems to indicate that all transactions would need to be sent within one year of the State-designated entity finalizing the Submission Guidance. Since we have no indications of what the State-designated Entity may propose for the three sets of transactions, we do not believe that one year will be adequate time to begin submission. We recommend that MHCC modify item 2 to allow for 18 months following the initial publication of the guidance.

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

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

January 2, 2025

Dear Sir or Madam,

Oracle Health, a leading supplier of electronic health record, clinical and revenue cycle information systems appreciates the opportunity to submit comments on provisions of COMAR 10.25.07, Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses and COMAR 10.25.18, Health Information Exchanges: Privacy and Security of Protected Health Information. We offer comments on the following provisions outlined below.

Oracle Health hopes these comments will be of value to the Maryland Health Care Commission (MHCC) in considering possible updates to COMAR 10.25.07 and COMAR 10.25.18. We are happy to help clarify any of the comments should MHCC wish to pursue any such conversations with us during the period of comment review.

Sincerely.

Mike Hourigan
Sr. Director, Product Regulatory Strategy
Oracle Health Corporation

As a general consideration Oracle continues to raise concerns with the conflation of health IT being considered Electronic Health Networks (EHN) and Health Information Exchanges (HIE). In this context, there are widely different purposes, functions, and use of Electronic Health Records and Revenue Cycle Management systems supporting providers. HIE's enable data sharing across providers and other entities at a geographic (local, state, national) level, and Electronic Claims Clearinghouses as a specific intermediary network. Such conflation creates ambiguities in which health IT which is only responsible for certain capabilities, must be capable of everything. We suggest role-based definitions of functional and technical capabilities that are incorporated into ASTP/ONCs certification program provide a more practical and scalable approach to address the complexities of the health IT eco system at a state and national level.

10.25.07 Certification of Electronic Health Networks (EHN) and Medical Care Electronic Claims Clearinghouses. Reporting of Electronic Healthcare Transactions for Certified EHN or Clearinghouse

Electronic Health Network/Clearinghouse will submit electronic health care transactions originating in Maryland to the State Designated HIE

- Some of these transactions are single, "real-time" transactions and some are batch files. Does the EHN/Clearinghouse submit a data feed of real-time 270s/271s, or is it a batch up submitted on some sort of schedule? Clarification is needed as development will be necessary for this.
- Some trading partner contracts with payers restrict sharing of the data. See Medicare transaction system (HETS) trading partner agreement (TPA) as an example. Each payer including Medicare or private payer, may restrict the storing and sharing of the 271 responses as they consider that data proprietary. This may impact the allowance of transaction data sharing.
- All clearinghouses that transact with payers likely use intermediaries or other clearinghouses to route transactions to payers. Requirements should be clear and acknowledge who is required to submit electronic health care transactions. Is it the primary/contracted clearinghouse that is a registered EHN in Maryland only? We suggest that more specific role-based attribution of these capabilities and responsibilities would enable the relevant health IT to provide such capabilities.

EHN shall begin submitting electronic health care transactions information based on the most recent version of the Electronic Health Care Transactions Technical Submission Guidance within 12 months following the initial publication of the Technical Submission Guidance.

- Considering the development and deployment requirements to enable the proposed capabilities, we suggest that an EHN/Clearinghouse would need more than 12 months post publication of the technical submission guidance to develop and be able to submit electronic health care transactions to the state designated HIE, not considering the roll-out and deployment to all clients impacted. We recommend that 18 months is more feasible to develop and deploy the required solution.

Submit electronic health care transactions originating in Maryland to the State Designated HIE for public health and other clinical purposes.

- Clarification is needed on what transactions fall under this requirement. Specifically, does this mean all 270/271 transactions from any Maryland providers to any payer must be submitted by the appropriate EHN/Clearinghouse to the state designated HIE? Or do only 270/271 transactions from any Maryland provider to just Maryland payers (MD Medicaid, Blue, etc) need to be submitted by the appropriate EHN/Clearinghouse to the state designated HIE? We note that transactions originating in Maryland, may be subject to trading partner agreements as identified above.

10.25.18 Health Information Exchanges (HIE): Privacy and Security of Protected Health Information, Consent Management Application

Requirements for an HIE

"Update the consent management application with any opt-out or opt-in requests it has received from an HIE or directly from a person in interest within 5 business days."

We request further clarification in the following areas:

- Does this require an HIE to use a CRISP app locally to manage opt in/out, or that the providers' health IT can use CRISP provided APIs to maintain the relevant data?
- Oracle recommends, all communications with the central CRISP consent repository should be API based (with a clear migration path to FHIR-based APIs).

"Withhold sharing or disclosure of the electronic health information of a patient to the extent the consent management application indicates that the patient has opted out of having electronic health information shared or disclosed by an HIE"

- We note that the scope of an opt-out by the patient is effectively retroactive, i.e., when the patient opts out, no information (past, current, future) can be shared from that point forward by any health IT holding that patient's information. Does that opt-out apply only to exchange within Maryland, or to any provider whether communicating directly or via a local, state or national network to the health IT holding the data? Conversely, when a patient is opted in with CRISP, can they opt out from national network exchange in particular, which could result in not sharing their data with other Maryland providers when data flows through the national network? Would a patient be required to manage opt in status with CRISP for national network sharing? And lastly, as other consent management tools emerge for the patient to manage all their consents across their providers and other data holders, what is the precedence relationship between the CRISP consent manager and the patient's consent manager?

  Considering the need for patient centric consent management tools that are on the cusp of emerging that enable a more robust approach than a state focused consent management approach, we urge Maryland to carefully advance its requirements that will not preclude if not prohibit such patient centric approaches.

- Considering the ambiguity of the reference to HIE and EHNs, would a Clearinghouse have to exclude submitting transactions where the patient has opted out? We suggest clarification of conditions and transactions where the opt out applies.

"*An HIE shall place a link on its website directing a person in interest to the State-designated HIE's website to globally opt out or opt in to having a patient's electronic health information shared or disclosed by an HIE.*"

- Centralized state consent managers are not patient centric (e.g., one might end up with four to five state-based repositories considering the proximity of Maryland to health care providers in neighboring states where patients can seek their care, e.g, PA, NJ, MD, DE, NY, VA). The focus should be advancing a patient centric approach towards capturing and managing a patient's consent directives, one that is not artificially bound by jurisdictions. This makes it more agnostic and focuses on the essence that an opt-in/out directive is used to share or not share, rather than introducing an additional location where consent directives would be maintained.

"HIE shall Electronically notify authorized users when a patient has restricted data sharing."

- We note that this statement is very ambiguous. What is considered an authorized user and of which health IT can know that the patient has restricted data sharing, particularly as such notification may in fact already divulge to the user what data may be. What action is the authorized user supposed to take having that knowledge? We suggest that within a provider's health IT, it manages which users can or cannot see certain patient data and when data is not shared externally. There should not be an indication that data is not shared as that would impact the patient's intent to not share data. Thus, raising the question of what, if any, exceptions there are to still share some information. Such exceptions need to be very well defined.

"An HIE shall implement the consent management application in a manner that is consistent with this chapter, its existing policies and procedures regarding use and disclosure of PHI and other personal identifiable information, and its technological capabilities."

- We note that per the [48](57) ["Opt-Out"] definition the patient may utilize a consent directive management app of their own choice. We appreciate and support that flexibility in light of our prior comments. Given that, we suggest that this statement should be clear that data holders (whether EHRs or state HIEs) shall implement "consent management", not "the consent management application" and focus on API based interaction with the CRISP consent management tooling, thus maintaining flexibility on how this is implemented and how it should evolve over time as we go more granular, advance a true patient centric approach to consent management, and the need to manage the interaction with jurisdictional privacy rules.

"An HIE shall continue to manage local opt-outs locally."

- In context to our prior comments, this requirement would drive a patient to have to maintain their consent directives with all the data holders that manage some or all of their data. Rather we suggest that the approach is not that prescriptive at this time and allows for

patient centric consent management tools to emerge where the patient maintains their consents in one place of their choice, allowing others to access that designated repository for the full and most up-to-date directives. We recognize this is not a reality today, however, with the advances being made, it is a viable approach that should not be precluded through regulatory requirements to the contrary. At the same time, the statement does recognize that consent management has a clear need for provider side health IT, particularly an EHR, to have certain capabilities that a network would, could, or should not provide.

- Maryland is carving out a role for CRISP and firmly believes that a centralized, state-based consent management capability is essential. Given the above-described need for patient centric approach and the variant requirements for the different health IT, including networks, to manage data sharing in accordance with the patient's consent directives, the capabilities are more relevant and critical on the provider or more generally, the data holder side. Effectively, the data holder needs to assess on every transaction (query response or push) in whatever form (not just HL7/IHE doc exchange, but HL7 v2, HL7 FHIR AND anything else including proprietary) whether it can share, even if the information does not go through an HIE. And from a patient perspective, as we get to more granular consent controls, only having centralized state based consent repositories are not the answer. We therefore urge a flexible, federated approach that allows for, but does not require a state-based capability in the middle as it will still not provide the patient centric capabilities that are essential to manage the complex data sharing requirements across a national health IT eco system.

***Data the Consent Management Application/ Health Data Utility will contain*:**

- **Personal identifiers consisting of the full name, date of birth, mailing address, telephone number and other unique identifiers of the patient and person in interest, if not the patient**
- **Communication contact preferences and the relationship to the patient.**
- **The date the patient's consent preferences were last updated.**
- **The Health Data Utility will Transmit clinical information or electronic health care transactions to the Maryland Department of Health, the Commission, or the Health Services Cost Review Commission for public health purposes upon written request.**

We note that full name, date of birth, mailing address, and telephone number to be used to match patients, but also "other unique identifiers". Further definition is needed considering that full name, date of birth mailing address, and telephone number are not identifiers, rather demographic data used in in patient matching. A state-designated HIE should reasonably use the Medical Record Number (MRN) across its participants in a Master Patient Index (MPI)to link it all together in the absence of a unique identifier that is statewide or national and acceptable to identify a large number of patients. Enabling a real patient centric consent repository to access it for all of a patient's consent directives, there should be a unique "address" to the patient specific consent repository that can be shared, and in combination with an authorization component can enable data holders to access that repository and allows them to assert the most current, applicable directives. A clearinghouse may not have all the EHR identifiers as part of these transactions, i.e. MRN, etc., but should include at least one of the identifiers that can improve on patient matching.

What is the scope of "Transmit clinical information or electronic health care transactions to the Maryland Department of Health, the Commission, or the Health Services Cost Review Commission for public health purposes upon written request." Why is that stated here as this should not yield a larger scope of data sharing than already authorized by Public Health and patient under these proposals. This seems to require more data to be shared.

Since the Change Healthcare breach, providers send inquiries to the clearinghouse around security. We request for specifics around CRISP security practices.

January 2, 2025

Ben Steffen
Commissioner
Maryland Health Care Commission
4160 Patterson Ave
Baltimore, MD 21215

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

Dear Commissioner Steffen:

Veradigm is a health information technology (HIT) company that offers a variety of solutions to clients. Our Veradigm Payerpath solution is an integrated clearinghouse service with a suite of revenue cycle management tools that enable health care providers and payers—including those in Maryland—to manage their transactions efficiently. Veradigm Payerpath is a certified Electronic Health Network (EHN) in Maryland and will be directly impacted by 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). We appreciate the opportunity to provide our feedback on this significant proposed regulation.

HIT providers like Veradigm face mounting challenges due to the increasing complexity of regulatory requirements. Compliance with federal laws such as HIPAA, the 21st Century Cures Act, and new interoperability mandates imposes strict limitations on the sharing of protected health information (PHI) while demanding seamless interoperability to enhance care coordination. Consequently, HIT providers must balance compliance obligations with operational sustainability. Imposing additional obligations on EHNs in this already demanding regulatory environment risks limiting HIT investments in innovation and client service.

The proposed regulation risks exacerbating these challenges for HIT providers operating certified EHNs in Maryland. The potential for conflicts between the proposed regulation and other state and federal laws, including HIPAA, combined with the lack of specificity in technical details, makes it challenging to estimate and plan for compliance costs. Notably, larger EHNs with substantial market share may be better positioned to absorb these costs, but smaller EHNs could face disproportionate financial strain, jeopardizing their ability to remain competitive. This in turn may effectively reduce the number of EHNs in Maryland, particularly clearinghouses, undermining market competition.

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Reduced competition in the clearinghouse market could have significant negative consequences: higher costs for health care providers, greater privacy and security risks from the centralization of PHI, decreased innovation, and diminished quality of service. These outcomes would not only burden health care providers but also potentially harm patients, contradicting the proposed regulation's objectives. Additionally, transitioning providers to a different clearinghouse would, in most cases, entail logistical and financial expenditures, such as payer re-enrollment, further burdening health care providers.

While Veradigm supports MHCC's goals of improving patient safety, protecting public health, and supporting health management programs, we believe EHNs are not the optimal source for building accurate data sets. EHN data is transactional in nature and often incomplete, as multiple EHNs may hold fragmented information about the same claim. Moreover, EHNs are not record holders, increasing the risk of an EHN violating patient opt-out preferences or State-imposed restrictions. Legislators should consider sourcing such data directly from providers or payers, who typically maintain the most accurate and comprehensive records.

Outside of this general comment on the burden and complexity posed by the proposed regulation, our comments on specific provisions are set forth below.

Proposed Text

.02 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 appreciate that MHCC has considered stakeholder feedback and included definitions for the purposes under which EHNs must provide data to the State-designated health information exchange (HIE). However, the current definitions are too broad to adequately address concerns that the disclosure of PHI to the State-designated HIE could violate HIPAA. Under HIPAA, covered entities (and their business associates) may only disclose PHI without patient consent or authorization for specific purposes, such as treatment, payment, and health care operations (as those terms are defined under

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HIPAA), public health activities, or when necessary to prevent or lessen a serious and imminent threat to health or safety. *See* 42 CFR § 164.512.

To address these concerns, we recommend clarifying that activities undertaken for the "[i]mprovement of patient safety" must either fall within the scope of a covered entity's health care operations or meet the standard of necessity to prevent an imminent threat to public health, in compliance with HIPAA. Additionally, MHCC might consider incorporating into the definition the specific "patient safety activities" outlined in the Patient Safety and Quality Improvement Act of 2005 (PSQIA), 42 CFR § 299b-21(5).

Similarly, the definition of "[m]itigation of a public health emergency" requires greater precision. We suggest clarifying that a "public health emergency" refers to an emergency declared by the Governor of Maryland under the authority granted in Maryland Code, Public Safety § 14-3A-01 et seq.

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 appreciate MHCC's clarifying addition of the phrase "for services delivered in Maryland" to the proposed text. However, Maryland borders five other states, and thousands of patients likely cross state lines to receive care from health care providers in Maryland. The three purposes identified in Md. Health Gen. § 4-302.3(h)(1)—a State health improvement program, mitigation of a public health emergency, and improvement of patient safety—focus on public health, presumably that of Maryland residents. While non-residents treated in Maryland are subject to Maryland law during their visit, it is unlikely they expect their data to be disclosed to the State-designated HIE for purposes that may not directly protect or benefit them. Additionally, maintaining such data for an indefinite period raises concerns. The inclusion of non-resident data appears misaligned with the goals of the proposed regulation and potentially conflicts with HIPAA's minimum necessary standard and state data privacy laws applicable to the non-resident. To address this, we recommend narrowing the scope to "for services delivered in Maryland ***to residents of Maryland***" (emphasis added).

Additionally, the proposed list of transactions for which EHNs must submit data to the State-designated HIE does not align with types of transactions processed by EHNs. For instance, clearinghouses do not process Benefit enrollment and maintenance transactions (834). Consequently, we recommend the removal of this transaction type. Similarly, it is unclear how data included in Health plan eligibility inquiry and response (270) transactions aligns with the purposes set forth in Md. Health

Gen. § 4-302.3(h)(1). Much of the information in 270 transactions is already included in 837P/837 transactions. Requiring the submission of 270 transaction data may result in unnecessary PHI disclosures, which could conflict with HIPAA's minimum necessary standard. Accordingly, we recommend that 270 transactions also be excluded from the regulation.

The scope of the submission requirement in the proposed regulation is also unclear. Specifically, the regulation requires EHNs to submit "electronic health care transactions information for services delivered in Maryland." It is ambiguous whether this applies to all services delivered in Maryland or only those directly related to the three statutory purposes. If the latter, EHNs would face significant challenges determining whether a service pertains to, for example, "[i]mprovement of patient safety." If the former, requiring the submission of such a broad volume of data raises concerns about compliance with HIPAA's minimum necessary standard and the terms of business associate agreements (BAAs) with payers and health care providers. Under these agreements, we are limited to the uses and disclosures of PHI identified in the BAA, prohibited from using or disclosing PHI in ways that violate HIPAA and required to pass along similar restrictions to downstream recipients of PHI. The proposed regulation does not address these obligations or specify requirements for the State-designated HIE, leaving the compliance burden—both technical and financial—solely on EHNs. This is particularly problematic because EHNs typically do not interact directly with state HIEs or have mechanisms to determine whether a patient has opted out of data sharing. As a result, EHNs could unknowingly violate the HIPAA Privacy Rule by sharing this data.

Further, the proposed regulation may conflict with other federal and state laws. For example, in *Gobeille v. Liberty Mutual* (577 U.S. 312, 2016), the United States Supreme Court ruled that states cannot require data disclosure from self-funded group plans governed by ERISA. Similarly, data from Medicare Advantage organizations and Part D plans (42 CFR § 422.402) and carriers under the Federal Employee Health Benefits Program (5 U.S.C. § 8902(m)(1) and 48 C.F.R. § 1652.224–70) may also be protected from disclosure. We understand that the Office of Personnel Management prohibits carriers from sharing Federal Employee Health Benefit Program data with state programs, and where we act as a business associate for such carriers, we are bound by the same restrictions.

The proposed regulation places EHNs in a challenging position, requiring them to balance compliance with its broad requirements, adherence to the terms of their BAAs with clients, and conformity with existing federal and state laws. The ambiguity surrounding the scope of data submissions, combined with the potential for conflicts with HIPAA and other regulatory and legal obligations, creates significant compliance risks. Moreover, the lack of clear guidance regarding the responsibilities of the State-designated HIE and the exclusion of key considerations, such as patient opt-outs, further complicates this balancing act. We urge MHCC to refine the proposed regulation to align more closely with its stated purposes and existing legal frameworks, ensuring that it supports the effective functioning of EHNs while protecting patient privacy and minimizing undue burdens.

Proposed Text

.09(E) Electronic Health Care Transactions Technical Submission Guidance.

(1) The State-designated HIE shall develop an Electronic Health Care Transactions Technical Submission Guidance 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.

(3) 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

We note that MHCC has removed language specifying a flat file format as the method of submission and instead delegated all technical decisions to the State-designated HIE. While the proposed language indicates that the State-designated HIE should develop guidance in consultation with stakeholders, the rule does not establish clear expectations for what such consultation entails and the weight that will be given to stakeholder input. The removal of the only language that provided any technical details from the proposed text and the lack of clarity regarding the development of guidance raises significant concerns.

Furthermore, assigning responsibility for developing technical requirements to an organization with little or no experience handling X12 transactions is problematic. As has previously been raised to MHCC, sending raw X12 transactions to the State-designated HIE may not be feasible due to the extensive filtering that may be required, which cannot be performed on the X12 format itself. The absence of a flat file requirement creates uncertainty, leaving EHNs vulnerable to being mandated to submit X12 transactions—a format that could be technically infeasible or prohibitively expensive to implement. The State-designated HIE could specify submission formats that are unnecessarily costly to develop, negating MHCC's expressed belief that compliance costs would be minimal. As we and other EHNs have emphasized, the cost impact depends entirely on the technical specifications finalized by the State-designated HIE.

Without a flat file requirement, EHNs risk being burdened with technically impractical and excessively expensive obligations. We recommend that MHCC reintroduce language into the regulation to clearly establish that a flat file format will be required for submissions. Additionally, we suggest including specific guidelines for the consultation process that require a minimum number of meetings between the State-designated HIE and stakeholders, as well as reasonable time periods for public review and commentary on the guidance prior to finalization.

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

We are unclear why MHCC moved from its originally proposed quarterly submissions schedule to a monthly submission schedule. We assume this change was based on feedback about the potential file size of quarterly data set transmission. While we appreciate MHCC's consideration of these concerns, a monthly submissions requirement addresses only file size issues—which may still be significant depending on the scope of the data set—while imposing an unnecessary and excessive burden on EHNs. As previously noted, the filtering process required for compliance is both time-consuming and costly.

Moreover, a monthly reporting cadence does not align with the three stated purposes of data sharing: patient safety analysis, public health management, and healthcare improvement programs. These activities typically do not require "fresh" data, making quarterly reporting the accepted standard. Shifting to a monthly schedule imposes unnecessary operational strain on EHNs without clear justification or benefit. We strongly recommend that MHCC return to the originally proposed quarterly submission schedule while retaining the flexibility in the proposed text for more frequent submissions.

Proposed Text

.09(I) Effective Date.

(1) The State-designated HIE shall publish the Electronic Health Care Transactions Technical Submission Guidance within six months of the final effective date of this regulation.

(2) An MHCC-certified EHN shall begin submitting electronic health care transactions information based on the most recent version of the Electronic Health Care Transactions Technical Submission Guidance within 12 months following the initial publication of the Electronic Health Care Transactions Technical Submission Guidance.

Comments

We appreciate MHCC's proposal of a 12-month implementation period. However, without clarity on the scope of the transaction data to be submitted, we cannot assess whether this timeline is feasible. Given this uncertainty, we anticipate needing at least 18 months from the publication of the Electronic Health Care Transactions Technical Submission Guidance to commence submissions.

Proposed Text

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

…

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(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.

As an initial matter, we are unaware of the statutory basis for the proposed penalty provisions. Based on our review, there is no explicit authorization for the agency to adopt such provisions, nor does it appear reasonable to infer a delegation of this authority from the limited regulatory powers granted under Md. Health Gen. § 4-302.3 or any other applicable sections. Without clear statutory authority, the inclusion of penalty provisions raises questions about their legal validity and enforceability.

Even if MHCC is authorized to implement penalty provisions, we are concerned that the proposed penalties are excessive and fail to account for instances of good faith errors. Such errors, particularly when promptly corrected, do not warrant punitive measures. To address this issue, we recommend that MHCC incorporate an explicit safe harbor provision for inconsequential failures to submit electronic health transactions. This safe harbor should also apply to failures resulting from good faith errors, provided they are remedied within a reasonable timeframe after receiving actual notice of the failure.

Incorporating a safe harbor provision is both practical and equitable. It would recognize the operational challenges faced by EHNs while maintaining the integrity of the reporting framework. For example, minor lapses in compliance—such as inadvertent submission delays caused by technical glitches or human oversight—should not be met with severe penalties when the responsible party acts swiftly and in good faith to resolve the issue. By including language that balances accountability with fairness, MHCC can encourage compliance without discouraging participation or placing undue burdens on entities acting in good faith.

Thank you for allowing Veradigm to comment on this very important proposed regulation. We welcome the opportunity to answer any questions you might have regarding our comments.

Kind regards,

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