PROPOSED AMENDMENTS

COMAR 10.25.07, *Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses*

COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information*

OCTOBER 17, 2024

DRAFT

Background – Legislation

- The General Assembly passed legislation in 2021 and 2022 with the aim of advancing use of health information technology statewide
  - Chapter 798 (House Bill 1375), *Health Information Exchanges - Electronic Health Information - Sharing and Disclosure* (2021)
    - Requires the State-Designated Health Information Exchange (HIE) to develop and maintain a centralized consent management application allowing persons to opt-out from having their personal health information shared or disclosed by HIEs operating in the State
  - Chapter 790 (House Bill 1022)/Chapter 791 (Senate Bill 748), *Public Health – State Designated Exchange – Clinical Information* (2021)
    - Aims to facilitate a State health improvement program, mitigate a public health emergency, and improve patient safety by requiring nursing homes, on request by the Maryland Department of Health, to electronically submit clinical information to the State-Designated HIE; requires electronic health networks (EHNs) to provide electronic health care transactions to CRISP for clinical and public health purposes

Background – Legislation *(continued…)*

- Chapter 296 (House Bill 1127), *Public Health – State Designated Exchange – Health Data Utility* (2022)
  - Establishes a Health Data Utility (or HDU) operated by the State-Designated HIE and requires dispensers to submit information to CRISP on noncontrolled prescription drugs; the HDU will make select information available to providers involved in the treatment and care coordination of patients and health officials to support public health interventions and promote health equity; the State-Designated HIE must establish a Consumer Advisory Council to bring consumer perspectives into the delivery of its services

Regulations

- Existing regulatory frameworks support implementation of the statutory requirements
  - COMAR 10.25.07, *Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses*
    - Electronic health care transactions reporting
  - COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information*
    - Consent management application
    - Noncontrolled prescription drugs reporting
    - Health data utility
- Draft amendments to the regulations were released for informal public comment in May
- Three virtual working sessions were convened with stakeholders in July

A Snapshot of Informal Public Comments

- Eight organizations submitted a total of about 77 comments (including EHNs, HIEs, providers, a trade association, and a payor)
  - **Consent management application** – 37 comments; themes centered on CRISP and other HIEs role in managing consent; minimum demographic data required for patient matching, and clarifying the CMA integration approach
  - **Noncontrolled prescription drugs reporting** – 17 comments; themes centered on applicable uses of noncontrolled prescription drugs dispense data; clarifying reporting requirements and timelines; and storage requirements on dispensers
  - **Health Data Utility** – 3 comments; themes centered on permitted disclosures and processes for convening meetings of the Consumer Advisory Council
  - **Electronic health care transactions reporting** – 17 comments; themes centered on potential uses of electronic health care transactions data, clarification of reporting protocols, and compliance timeframes
  - **Miscellaneous** – received 3 other comments

Proposed Amendments – COMAR 10.25.18

Consent Management Application

Proposed Amendments

- Adds a "consent management application" definition and clarifies the meaning of "opt out" to be inclusive of consumer requests via the CMA – regulation .02 B (12) & (57)
- Lists the required CMA components that CRISP must develop and the implementation timeline – regulation .03 D (1), (2), & (3)
- Requires HIEs to connect to the CMA and describes how connectivity must be established and maintained – regulation .03 D (4) & (5)
- Adds a requirement for HIEs to link to CRISP's website with information on using the CMA to opt out and back into data sharing and to continue managing local opt outs – regulation .03 D (6) & (7)
- Requires CRISP to notify MHCC if the CMA is not operational and when services resume – regulation .03 D (8)
- Adds exceptions to complying with §D(3) and clarifies that requirements are in addition to restrictions of certain information (e.g., Part 2) – regulation .03 D (9) & (10)

Dispenser Reporting of Noncontrolled Prescription Drugs

Proposed Amendments

- Includes dispensers as part of the scope of Chapter 18 – regulation .01 B (4)
- Adds definitions for "dispense," "dispenser," and "noncontrolled prescription drugs" – regulation .02 B (23), (24), & (54)
- Adds a regulation requiring dispenses to report each noncontrolled prescription drugs dispenses to CRISP – regulation .13 A
- Requires MHCC to develop a *Noncontrolled Prescription Drugs Dispenser Data Submission Manual* (manual) annually and describes specific information to be included in the manual, timing and frequency of reporting, certain technical specifications, processes for requesting public comments and Commission approval, and processes for making the manual available to the public and notice of any updates – regulation .13 B & C
- Reporting deadlines and procedures for CRISP to accept and disclose dispense information – regulation .13 D & E
- Procedures for dispenser to request a waiver from reporting – regulation .13 F

Operation of the Health Data Utility

Proposed Amendments

- Adds definitions for "Health Data Utility," "improvement of patient safety," "state health improvement program"– regulation .02 B (37), (46), & (78)
- Adds a regulation requiring CRISP to operate as an HDU and implement the CMA in accordance with regulation .03 D – regulation .14 A & B
- Explains protocols for disclosures of clinical information or electronic health care transactions by CRISP and requires CRISP to be designated as a reporting entity to the Maryland Medical Care Data Base – regulation .14 C
- Requires collaboration between CRISP and certain State agencies on data uses pertaining to a State health improvement program, mitigation of a public health emergency, improvement of patient safety; and any other public health priorities identified by the Secretary – regulation .14 D
- Requires CRISP to establish a Consumer Advisory Council that includes certain representation and adheres to the Maryland Open Meetings Act – regulation .14 E

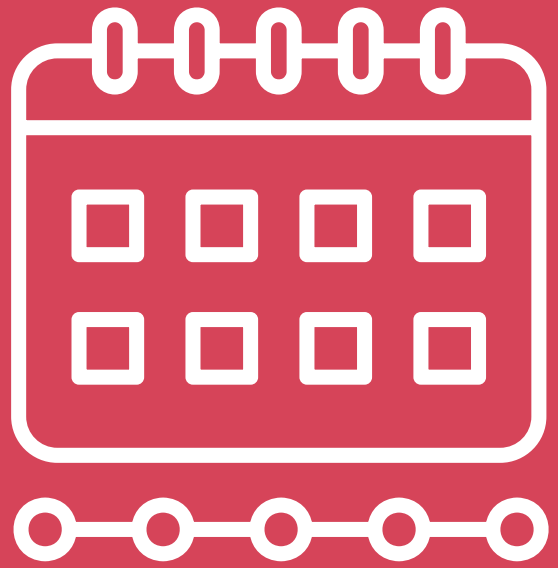
Proposed Amendments – COMAR 10.25.07

EHN Reporting of Electronic Health Care Transactions

Proposed Amendments

- Adds definitions "improvement of patient safety," "mitigation of a public health emergency," "State-designated HIE," and "state health improvement program – regulation .02 B (9), (14), (16), and (17)
- Adds a regulation requiring MHCC-certified EHNs to submit certain electronic health care transactions to CRISP for public health and clinical purposes – regulation .09 A-D
- Requires CRISP to develop electronic health care transactions technical submission guidance – regulation .09 E
- Details the submission schedule and prohibits CRISP from charging fees – regulation .09 F & G
- Allows EHNs to request a one-year exemption from certain reporting requirements – regulation .09 H
- Requires CRISP to publish the technical guidance within six months of regulations effective date – regulation .09 I

Next Steps – Timeline *(Anticipated)*



- Submit proposed amendments for publication in a December issue of the Maryland Register with a 30-day public comment period
- Present proposed permanent regulations to the Commission for consideration in February, and submit for publication in a March issue of the Maryland Register
- Final effective date of the regulations – March 17th

Commission Action Items

- Staff requests the Commission adopt COMAR 10.25.07 as proposed regulations
- Staff requests the Commission adopt COMAR 10.25.18 as proposed regulations

Appendix

Summary of Informal Comments

Count	Org - Comment #	Regulations	Comment	Bill
1	CRISP - 1	10.25.18.03D(1)(b)	The draft regulations require that the Designated HIE "informs the person in interest of the electronic health information that may be shared or disclosed notwithstanding the choice to opt-out." We are concerned that there is not a practical way to inform patients (assuming that the patient is the "person in interest") of what other HIEs do with their data. We can inform them what CRISP does with their data, of course, but not other HIEs. We suggest that this requirement be made of all HIEs rather than just the Designated HIE.	Chapter 798 CMA
2	CRISP - 2	10.25.18.03D(2)(b)	We cannot stress enough that these draft regulations do not require other HIEs to connect to the consent management application or provide information thereto. The regulations require other HIEs to "implement" the phases, without any definition of what this means. We implore the Commission to make requirements of the other HIEs by defining explicitly what "implement" means; otherwise, we believe we will be in the same position as we have been with a lack of engagement from outside of CRISP. In addition, we encourage the Commission to make the technology agnostic. An API is not necessarily the best option for all providers/their HIEs. In our opinion, other HIEs should be required to receive and exchange data at regular intervals but could do so using many different types of technology.	Chapter 798 CMA
3	CRISP - 3	10.25.18.03D(3)(c)	We suggest the Commission clarify whether the opt-out applies to the system or the HIE itself. For example, does an Epic system have to withhold that information within Care Everywhere? What about within the JHU system? For every JHU provider? What are the bounds?	Chapter 798 CMA
4	CRISP - 4	10.25.18.13E(1)(c)	We are concerned that this is overly broad, and the dispensers may use it as a shield to keep from sending data. We suggest deleting or making the language much narrower.	Chapter 296 Non-CDS
5	CRISP - 5	10.25.18.13E(1)(d)	Does this requirement apply to patients that have opted-out? We suggest clarifying.	Chapter 296 Non-CDS
6	CRISP - 6	10.25.18.13E(3)	We suggest making the purposes for which the data can be used broader to include anything allowed under applicable law. Otherwise, you could be restricting data uses like care coordination and quality improvement, to name a few.	Chapter 296 Non-CDS
7	CRISP - 7	10.25.18.13E(4)(a)	This provision is extremely broad, meaning that we would be potentially providing data for HUGE amounts of the population of Maryland. Imagine a potential change in administration that asked for all the people taking birth control or testosterone. There are large privacy issues with this approach. Therefore, we suggest limiting it to ". . . if such disclosure is required under applicable law."	Chapter 296 Non-CDS
8	CRISP - 8	10.25.18.13E(4)(b)	If you take our suggestion to broaden 10.25.18.13(E)(3), this section is no longer necessary.	Chapter 296 Non-CDS
9	CRISP - 9	10.25.07(A)	We suggest broadening the purposes for which the data can be used for any purpose allowed under applicable law; otherwise, the data could not be used, for example, for care coordination.	Other
10	CRISP - 10	10.25.18.14C(3)	We are concerned that the language "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" may eviscerate the requirement that EHNs provide data. We are concerned that they will interpret "financial information" as any information in a claim. Therefore, we suggest the following language: "The State Designated HIE may not redisclose *cost and price information* ~~financial information~~ in electronic health care transactions it receives in accordance with COMAR 10.25.07.09 to any person other than the Commission."	Chapter 790/791 EHN
11	CRISP - 11	10.25.18.14C(3)	We are concerned about the expansiveness of this provision. It could be interpreted to mean that any data within the HIE can / should be reported to an agency. However, we have found that we are successful because of the third-party trust that is bound by the Participation Agreement. Therefore, we suggest adding ". . . except as otherwise prohibited . . . by agreements with covered entities."	Chapter 790/791 EHN
12	CRISP - 12	10.25.18.14D(2)(c)	The CAC has repeatedly stated that they need closed meetings to feel comfortable sharing and giving feedback. We are concerned that forcing their hand to have public meetings will undermine trust. We recommend that this provision be removed or softened to "at least one public meeting per year."	Chapter 296 CAC

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13	EHRA - 1	10.25.18.03D	The integration of a consent management application and Health Information Exchanges (HIEs) contemplated in these informal draft amendments will clearly have a significant impact on EHR developers – which Maryland considers HIEs – and correspondingly on the providers and health systems that license, configure, and use those EHRs...There are no widely-adopted and tested industry standards for this type of integration today, which will mean significantly increased costs to Maryland healthcare providers for this integration, as well as lengthened timelines for implementation.	Chapter 798 CMA
14	EHRA - 2	10.25.18.03D	In many cases, we anticipate needing to provide technical input on the proposal beyond what is possible in two weeks, and we request ongoing discussions with MHCC to determine the best way to revise and implement these proposals to ensure minimal impact on Maryland providers, including usability burden or the cost of health IT to Maryland health systems. 10.25.18.03.D proposes integrations between the to-be-developed consent management application and all HIEs. We suggest further discussion and significant revision to this proposal. It is unclear what method of integration is envisioned for this work.	Chapter 798 CMA
15	EHRA - 3	10.25.18.03D(2)(e)(ii)	...sets an expectation that HIEs will implement the new integration with the consent management application in 60-90 days, which is definitively not possible. HIEs will need 18-24 months after final specifications for the integration are made available to implement a new integration of this type. Maryland healthcare providers will also need time to upgrade their health IT to take advantage of new features like consent integrations. We would also appreciate the opportunity to discuss the timing of the requirement with your team; it is important that our teams not be distracted from ongoing efforts to implement Maryland's reproductive privacy requirements with this new initiative. The MHCC should stagger major initiatives of this type to avoid overburdening Maryland healthcare providers. This overburdening, which we have previously mentioned, is already causing some organizations to delay adopting the new functionality we are making available to them.	Chapter 798 CMA

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16	Epic - 1	10.25.18.02.B(3)	Clarify this definition to: “Application Programming Interface” or “API” has the meaning of “Certified API Technology” at 45 CFR 170.404(c). Clarifying to reference in this way will have the same meaning in 2024 and will mean that Maryland’s regulation does not need to be updated every time ONC’s certification standards are updated. It will also avoid confusing discrepancies between API standards expected in Maryland versus in ONC’s program as ONC updates their requirements over time.	Chapter 798 CMA
17	Epic - 2	10.25.18.02.B(16)	Systems may use different data elements to identify patients in different situations, so this definition needs to be understood to be situational and not static.	Other
18	Epic - 3	10.25.18.03D	The structure envisioned for connecting HIEs to the to-be-developed consent management application seems to presume that HIEs have central repositories of protected health information and consent information, and that HIEs make disclosures of protected health information. However, because Maryland defines developers of certified health information technology as HIEs, many HIEs are not central repositories of PHI nor do they make disclosures of PHI. Rather, developers of certified health information technology develop software that is then licensed to healthcare organizations who deploy, configure, and use the software to maintain their medical records and disclose information as they deem appropriate. Developers of certified health information technology have no control, discretion, or decision-making power over the disclosure of PHI.	Chapter 798 CMA
19	Epic - 4	10.25.18.03D(1)(c)	It will be important to revise this draft and reframe the expectations of 10.25.18.03.D for the common situation of healthcare providers remaining responsible for disclosures. For example, when the healthcare provider is responsible for consent and disclosure decisions, in 10.25.18.03.D(1)(c), there is no centralized HIE to query whether a person has opted in or out of sharing. Rather, MHCC’s policy and the state-designated HIE will need to enable healthcare providers using certified health information technology to query whether a person has opted-in or out.	Chapter 798 CMA
20	Epic - 5	10.25.18.03.D(2)(b)(iii)	(2)(b)(iii) references application programming interfaces, but as defined above, there are no current application programming interfaces relevant to this use case. (The definition above points to ONC certification for the definition of application programming interfaces, but ONC’s certification does not include consent management APIs as of May 2024.) To resolve, you likely want to be less specific here about the mechanism the consent management application uses for interoperability with HIEs (and avoid specifying that the mechanism be an API). For example: (iii) Phase Three. By [DATE], the State Designated HIE shall implement a consent management application that enables a standardized way to facilitate interoperability between different recipient HIE systems.	Chapter 798 CMA
21	Epic - 6	10.25.18.03.D(2)(d)	(2)(d) needs to be clarified. It is unclear what an HIE would do to support Phase One, given that the consent management application would not yet be ready for integration.	Chapter 798 CMA
22	Epic - 7	10.25.18.03.D(2)(e)	HIEs will not be able to implement a new integration with the consent management application in 60-90 days. Further information about the technical details of the integration are necessary to estimate a timeline, which will likely require multiple years for development and rollout at healthcare organizations. For example, in the Netherlands, MITZ has been attempting something similar since 2019 but has still not yet gone live due to some of the challenges we highlight here. MITZ work is proceeding using Dutch-specific integration specifications that are unfortunately not likely to be applicable to Maryland’s use case and are not generally incorporated in software in use in Maryland	Chapter 798 CMA
23	Epic - 8	10.25.18.03.D(3)	(3)(a) indicates HIEs should update consent statuses every 5 business days, but we suggest instead that HIEs should update consent statuses prior to exchange activity for the patient in question. This will alleviate unnecessary consent updating when no transactions are taking place and ensure that up-to-date information is available when a transaction is taking place. In scenarios where HIEs do not have centralized repositories nor make disclosures of PHI, this obligations (like others mentioned above) would have to be placed on healthcare providers. We would still suggest it would be most efficient for providers to update consent statuses prior to exchange activity for the patient in question for the same reasons.	Chapter 798 CMA
24	Epic - 9	10.25.18.03D(3)(c)	10.25.18.03.D(3)(c) directs HIEs to “withhold sharing or disclosure” of the electronic health information of patients who have opted out; HIEs who do not disclose information will need to be exempted from these requirements. Instead, obligations would need to be placed on healthcare providers regarding when to withhold sharing or refrain from disclosure of information of opted-out patients.	Chapter 798 CMA
25	Epic - 10	10.25.18.04.B(1)	(1) needs to be rewritten. It is not clear what it means for an HIE to be in compliance with Part 2, which is a set of requirements for providers of Part 2 services, not for developers of HIT or HIEs	Other
26	Epic - 11	10.25.18.13.B(3)(c)	Experts in our pharmacy software reviewed the provisions in 10.25.18.13 Noncontrolled Prescription Drugs Dispenser Reporting. We appreciate the alignment with existing ASAP standards already used for PDMP reporting. Further specificity on the version of the ASAP standard to be used will be necessary, and dispensers will need a reasonable timeframe to adopt new versions of the ASAP standard over time.	Chapter 296 Non-CDS
27	Epic - 12	10.25.18.13D	Regarding the interrelationship between the consent management application and the reporting of noncontrolled prescription drugs, we assume there is no presumption that pharmacists would be consulting the consent management application for patient consent prior to submitting a patient’s prescription. If it is expected that pharmacists would consult the consent management application, further clarification would be appreciated.	Chapter 296 Non-CDS
28	Epic - 13	10.25.18.13D(1)	We anticipate that some pharmacies will be submitting a very large quantity of prescriptions. In cases where manual review of the submission files is necessary, the volume of data to be submitted every 24 hours may be burdensome to pharmacies.	Chapter 296 Non-CDS
29	Epic - 14	10.25.18.13.E(2)(a)	Typographical error: missing “submitted *by* dispensers"	Chapter 296 Non-CDS
30	Epic - 15	10.25.18.13.F(2)(c)	Is the fewer than 100 noncontrolled prescription drugs exclusion counting prescriptions or fills?	Chapter 296 Non-CDS

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31	Hopkins - 1	10.25.18.03D(1)(c)	"Enables HIEs to *readily ingest or incorporate into their system, information as to* ~~query~~ whether a person in interest has opted out of or back in to sharing a patient's electronic health information;" In order to ensure that the consent management application does not cause performance issues with HIEs, the information must be pushed to the HIEs by the consent management application. Any requirement for an HIE to query the consent management application will create significant technical challenges.	Chapter 798 CMA
32	Hopkins - 2	10.25.18.03D(1)(d) 10.25.18.03D(3)(b)	Remove 10.25.18.03D(1)(d) and 10.25.18.03D(3)(b) There should be one consent management application maintained and managed by the State Designated HIE. Individual HIEs should not be responsible for pushing specific opt-outs to the centralized consent management application. It is very common for patients to purposefully opt out of some HIEs while choosing to participate in others. It should not be assumed that just because a consumer chooses to opt-out of one HIE, that they are choosing to opt out of all HIEs in Maryland. To avoid unintentionally misunderstanding a consumer's intention and inappropriately pushing the wrong opt-out selection to the consent management application, the universal opt-out for all HIEs should be managed exclusively through the State Designated HIE consent management application. The State Designated HIE is also in the best position to educate the patient on what information might still flow through other HIEs even after effectuating the universal opt-out. Each separate HIE can continue to manage their specific opt-outs consistent with the request of the patient.	Chapter 798 CMA
33	Hopkins - 3	10.25.18.03D(1)(e)(1)	"Personal identifiers consisting of the full name, date of birth, mailing address, telephone number and other unique identifiers, *including MRN, if applicable,* of the patient. ~~and person in interest, if not the patient"~~ In order to effectuate an opt-out or opt a patient back into participating in an HIE, the HIE needs detailed information on the patient, not the person in interest. Since the opt-out for many HIEs in the State are operationalized by providers, and not the actual HIE, the providers will need the MRNs of the patients and/or confirmation of the relationship between the HIE and the patient in order to efficiently identify those individuals who have changed their preferences. This requirement is especially important to ensure accuracy given the volume of patients maintained in many of the providers' EMRs	Chapter 798 CMA
34	Hopkins - 4	10.25.18.03D(2)(b)(i) 10.25.18.03D(2)(d)	"Phase One. By [DATE] the State Designated HIE shall implement a register, database, or repository to serve as the consent management application that will store personal identifiers and minimally supports downloading by other HIE systems *and shall establish a secure mechanism by which to send such register, database, or repository to HIEs at least weekly."* Requiring HIEs to seek out and download a register of opt-outs on a regular basis is operationally infeasible. Without an automated way to ensure this information is pushed to the HIEs through an interface, the likelihood of mistakes is significant. Patient trust is paramount in the success of HIEs, and relying on a manual process will more than likely result in inappropriately sharing information through an HIE after a consumer believes they have chosen to opt-out of participating. Ultimately, this recommendation may eliminate the need for Phase 1. Johns Hopkins would support moving straight to Phase 2 unless there is some other concern that would require a Phase 1	Chapter 798 CMA
35	Hopkins - 5	10.25.18.03D(2)(b)(iii)	"Phase Three. By [DATE], the State Designated HIE shall implement a consent management application with an application programming interface *or other secure electronic interface* that enables a standardized way to facilitate interoperability between different recipient HIE systems." It is the preference of both the State Designated HIE and Johns Hopkins that Phase Three allow for greater flexibility in the technology used to accomplish interoperability. Relying on an API can make the consent management application unreliable, since it is introducing technology outside of the control of the State Designated HIE that is in the critical path to successful interoperability. The added benefit to allowing for greater flexibility with the technology used in the regulation is that the regulations will not need to be revised when new and better technologies are developed.	Chapter 798 CMA
36	Hopkins - 6	10.25.18.03D(5)	*"If an HIE maintains a website, the* ~~An~~ HIE shall place a link on its website directing a person in interest to the State Designated HIE's website to opt out or back into having a patient's electronic health information shared or disclosed by an HIE." In many contexts, the HIE is not a separate entity, and it is not the HIE that is operationalizing the opt-outs. As a result, Johns Hopkins believes that this requirement should be applicable only to the extent the HIE maintains a website.	Chapter 798 CMA
37	Hopkins - 7	10.25.18.03D(3)(c)	"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, except to the extent permitted by §~~D~~*A*(2) of this regulation;" The cross-reference in this section appears to be to the wrong section. Johns Hopkins believes MHCC meant to cross-reference §A(2), since that is the section of the regulation that addresses permitted disclosures despite a patient's opt-out.	Chapter 798 CMA

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38	KP - 1	10.25.07.09B(3)	"(3) An MHCC-certified EHN shall submit the electronic health care transactions to the State Designated HIE in: (a) A flat file; [or] (b) *The communication standard used by the Maryland Medical Care Database; or (c)*..." KP recommends that an EHN submit health care transactions to the State Designated HIE in the same standard that's used by the Maryland Medical Care Database.	Chapter 790/791 EHN
39	KP - 2	10.25.07.09B(3)	We would also like confirmation that the submission should not include any information from a self-insured health plan.	Chapter 790/791 EHN
40	KP - 3	10.25.18.03A(2)	We are concerned that these regulations are confusing as to when a consumer has the right to opt out from having their data be exchanged or accessed via an HIE and when the consumer cannot opt out. We suggest that regulation .03 be made more explicit about what data is subject to the opt-out and how granular the opt out should be (e.g., certain data is not accessible to certain providers under certain conditions and for a specified time period).	Chapter 798 CMA
41	KP - 4	10.25.18.03D(2)(a)	In Phases 1 and 2 in .03D(2)(a), it is unclear how other HIEs and their affected healthcare organizations would identify any of their own affected patients who have opted out in the state repository. We recommend clarity in the regulations that patient opt out requests are to be implemented by the HIEs and not overly burden healthcare providers to determine applicability and implement the request	Chapter 798 CMA
42	KP - 5	10.25.18.03D(2)(b)	We recommend eliminating Phase 2. We don't see a need to have the State Designated HIE first develop a system using industry standards, and then, under a third phase, have the system implement an API. We recommend that the HIEs skip the second phase and move directly to the third phase. If not, we are at risk of having parallel systems (one based on non-API standards, and the other using an API) for a long time.	Chapter 798 CMA
43	KP - 6	10.25.18.03D(2)(b)	We also recommend that only HIEs that are obligated to opt patients out under applicable law are required to implement the opt out within their systems.	Chapter 798 CMA
44	KP - 7	10.25.18.03D(7)	There should not be an expectation that an HIE query the CRISP consent management API before releasing data for each and every transaction. This would slow down exchange and provide an unnecessary bottleneck. Rather, the consent management application should push the opt outs to applicable HIE participants in routine batches based on patient rosters provided by the HIE participants.	Chapter 798 CMA
45	KP - 8	10.25.18.03D	It is important to clarify whether an HIE participating organization would have access to the consent management application. The language seems to point to the consent management application being accessible by other HIEs but is silent about HIE participating organizations, like Kaiser Permanente. It would be beneficial for KP to have access to the patient opt-out/opt-in requests to allow his/her data to be exchanged via an HIE that is being held by the HIE.	Chapter 798 CMA
46	KP - 9	10.25.18.03D(3)(b)	The regulations should address a scenario where an HIE participant — and not the HIE — obtains an opt-out or opt-in request from the consumer. We propose the following amendment to .03D(3)(b): (3) An HIE shall: (b) Update the State Designated HIE's consent management application with any opt-out or opt-in requests it has received *from an HIE participating organization or* directly from a person in interest within five business days of the request;	Chapter 798 CMA
47	KP - 10	10.25.18.03D(3)(c)	Regulation .03D(3)(c) states an HIE shall: "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." Information that is pushed by healthcare organizations to CRISP through HL7 interfaces should not be considered an HIE transaction and should be out of scope for this requirement. Mechanisms are not readily available in HL7 to opt out specific patients and since CRISP will already be opting this data out from exchange, there should not be a need to remove the data from the HL7 feed to CRISP as well.	Chapter 798 CMA
48	KP - 11	10.25.18.03D	We support the requirement for HIEs to electronically inform the querying organization/HIE that the transaction failed due to an opt out.	Chapter 798 CMA
49	KP - 12	10.25.18.03D	The regulation should also specify that it applies to generic patient opt-outs only, rather than specialized circumstances that require more specific authorization from a patient, such as 42 CFR Part 2 and reproductive health disclosure authorizations	Chapter 798 CMA
50	KP - 13	10.25.18.03D	MHCC and the HIE vendors should also thoroughly consider how this approach aligns with the TEFCA framework and available technical standards.	Chapter 798 CMA
51	KP - 14	10.25.18.04	The regulations should add corresponding regulations that align with the new OCR final rule and MD law on reproductive health data privacy (as is done with 42 CFR Part 2 data).	Other
52	KP - 15	10.25.18.13E(3)	When our members obtain their prescriptions from sources outside KP, dispensing pharmacists and prescribing clinicians may lack visibility into these medications and face challenges in accurately assessing medication adherence. KP wants to clarify that the State Designated HIE will make patient-specific prescription information available in a manner that can be reconciled with a patient's chart. We propose the following amendment to .13E(3) (p. 55): (3) The State Designated HIE shall make patient-specific prescription information submitted by dispensers under this section available to health care providers for treatment, care coordination, or population health purposes, *including via an electronic mechanism in which the prescription information can be reconciled into the patient's chart.*	Chapter 296 Non-CDS
53	KP - 16	10.25.18.13D	In light of the size of the reports KP will need to run, we request that reports be submitted every 48 hours, rather than every 24 hours. Along these lines, KP thinks five business days – rather than three – may be needed to correct improperly-submitted data.	Chapter 296 Non-CDS
54	KP - 17	10.25.18.13	The proposed regulation should clarify the applicability and impact of the Maryland law on reproductive health data privacy on dispenser submission of mifepristone prescriptions to the state designated HIE, and its subsequent disclosure to treating providers. Dispensers may not have the current technology to segment mifepristone prescription data from other dispensing data.	Chapter 296 Non-CDS

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55	Optum - 1	10.25.07.09A	The statutory text makes clear that only those electronic health care transactions that serve one or more of three, broadly stated purposes are within the scope of the submission requirement. Md. Health Gen. § 4-302.3(h)(1). The statutory text then instructs MHCC through regulations to more clearly define these three purposes and thus the scope of the requirement to submit electronic health transactions. Id. at 4- 302.3(h)(3). The proposed regulatory text, however, mirrors the statutory text without providing any clarity as to the boundaries and limits of any of these statutory purposes. Were the proposed text to be finalized, we would be compelled to submit all or virtually all electronic health care transactions, except as limited by other regulations, to avoid penalties for non-compliance. We accordingly request that any regulation define the three statutory purposes to make clear which, if any, electronic health care transactions fall outside of these purposes. Additionally, the proposed text does not discuss limitations on secondary use or reuse of the data by the State Designated HIE.	Chapter 790/791 EHN
56	Optum - 2	10.25.07.9B(1)	We ask MHCC to clarify that the phrase "health care transactions originating in Maryland" refers to all transactions originating from provider organizations that operate in Maryland for care provided in Maryland. Many provider organizations have office locations in bordering states or the District of Columbia, and EHNs need clarity on whether those providers would be included. We also ask MHCC to clarify if transactions originating in another state or the District of Columbia that are sent to a payer located in Maryland should be excluded from being shared.	Chapter 790/791 EHN
57	Optum - 3	10.25.07.09B(1)	We would also note that 271 transactions originate from payers, so we ask MHCC to clarify that 271 transactions originating from payers located in Maryland sent in relation to care provided outside of Maryland do not need to be submitted.	Chapter 790/791 EHN
58	Optum - 4	10.25.07.09B(1)	Generally, we agree with the exclusion of pharmacy transactions, which would ordinarily be processed by our Pharmacy Network as opposed to our Medical Network. However, because some pharmaceuticals are covered under medical benefits instead of pharmacy benefits, we see some pharmacy transactions pass through our Medical Network. It is extremely difficult to filter/exclude those transactions from the data Maryland is requiring us to submit. We therefore ask MHCC to clarify that although pharmacy transactions are excluded, EHNs may include transactions relating to pharmaceuticals covered by medical benefits if excluding that data would be unduly burdensome.	Chapter 790/791 EHN
59	Optum - 5	10.25.07.09B(2)-(3)	We want to emphasize the importance of submitting electronic health care transaction in the form of flat file submissions under the regulation and are concerned that Subsections (2) and (3)(a) in the proposed text have conflicting requirements. If MHCC finalizes these subsections as proposed, EHNs will likely be unable to meet the requirements. We support flat files because we are able to pull transaction data from the clearinghouse into a flat file format and then filter out data that should not be included in a submission (such as data originating outside of Maryland). By contrast, it is impossible to perform this filtering with X12 transactions, which are compressed ASCII formatted text files or clm files. These file formats are strings of data separated into loops and segments. As such, automating the filtering process is nearly impossible and would require significant human intervention. Subsections (2) and (3) also appear to impose conflicting requirements that would make it impossible to comply with both simultaneously. Subsection (2) appears to require that the data submitted adhere to the X12N implementation guides, but that would not be considered a flat file format and therefore conflicts with Subsection 3(a). As written, Subsection (2) would force us to attempt to filter batch files of transactions (for 837s) or real-time single transactions (for 270s/271s) which is infeasible and may be impossible. Batch transactions are in the .txt or .clm format and as noted above are strings of text, making filtering impossible without human intervention. Real-time transactions come through an API but are ultimately still strings of text but in the JSON format and have the same issues with filtering which are compounded since they are single transactions. We have provided samples of an X12N 837 file (with dummy data) and a flat file (with dummy data) as attachments to this letter so that MHCC can better understand the difference between the two. We accordingly recommend that MHCC either remove requirement (2) altogether or indicate that requirement (2) is applicable only to (3)(b) and would be considered a communication standard approved by an SDO. Recommended text: 10.25.07.09B(3)(b): A communication standard approved by the State Designated HIE ~~and a standards development organization for receiving electronic health care transactions~~ *that adheres to the data content and format requirements published in the most recent corresponding ASC X12N implementation guides.*	Chapter 790/791 EHN
60	Optum - 6	10.25.07.09B(4)	To the extent Maryland lawfully requires the reporting of data, we support a quarterly reporting schedule. That said, the time period for transactions that would be reported each quarter is not specified in the current proposed text. For clarity, and because it will take time to package and filter the data submissions for Maryland, we request that MHCC allow quarterly reports to contain data from prior quarters and not data that was generated in the quarter in which the reporting is taking place. We also ask MHCC to clarify that an EHN does not have to report if they do not have any transactions that meet the relevant requirements.	Chapter 790/791 EHN
61	Optum - 7	10.25.07.09E(1)	We recommend that MHCC move the compliance date to at least one year following the regulation effective date. Complying with this regulation will require not only significant and costly technical build work but also modifications to contracts and legal agreements. It is not feasible to complete these changes within 180 days.	Chapter 790/791 EHN
62	Optum - 8	10.25.07.10A(5) 10.25.07.10D	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.	Chapter 790/791 EHN
63	Optum - 9	10.25.18.13B(2)	The 60-day timeframe (November 1 to December 31) allowed to make the necessary modifications in reporting may not be sufficient. We request a minimum of 90 days for annual modifications, thus moving the approval of the MHCC Noncontrolled Prescription Drugs Dispenser Data Submission Manual to October 1st of each year to be used for reporting in the subsequent calendar year.	Chapter 296 Non-CDS
64	Optum - 10	10.25.18.13D(1)	Zero reports are often vague in structure. We request the layout/format of the zero report to be included in the MHCC Noncontrolled Prescription Drugs Dispenser Data Submission Manual.	Chapter 296 Non-CDS
65	Optum - 11	10.25.18.13E(1)(d)	Please clarify whether the sender of such information is also required to maintain documentation of the sending of this information for five years.	Chapter 296 Non-CDS
66	Optum - 12	10.25.18.13E(2)(b)	We recommend that the list of edits that will be used to parse this data be included in the MHCC Noncontrolled Prescription Drugs Dispenser Data Submission Manual. This will allow software vendors to insert pre-edits on reporting to lessen the number of errors on these reports, thereby creating less error notifications from the State Designated HIE.	Chapter 296 Non-CDS

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67	Patient First - 1	10.25.07.02B(5)	We are concerned that the definitions of "Electronic Health Network" and "Medical Care Electronic Claims Clearinghouses" are sufficiently broad to include Patient First Maryland's management services in the scope of those activities covered by the EHN draft regulation...We therefore request the adoption of an exception to clarify the terms...do not include entities that submit electronic health care transactions to an entity that is itself a MHCC-certified EHN. Proposed definition: "Electronic Health Network (EHN)" mean an entity involved in the exchange of electronic health care transactions between electronic health networks, payers, providers, vendors, and other entities; *provided, that the submissions or exchange of electronic health care transactions exclusively with an entity that is a MHCC-Certified EHN shall not cause an entity to be an EHN.*	Other
68	Patient First - 2	10.25.18.13D(1)	Patient First Maryland is concerned regarding the administrative burden that will be placed on dispensers to report noncontrolled prescription drug information to the State Designated HIE at least once every 24 hours, including "zero reports." While PF Maryland understands that the provisions in the HDU Draft Regulations align with COMAR 10.47.07, *et esq,* the reporting of noncontrolled prescription drug information is a much greater undertaking for dispensers than controlled prescription drug information and should [be] recognized as such. A key provision in chapter 296 was the requirement that the prescription information be submitted without unduly increasing the workload and expense on a dispenser. Chapter 296 also did not specifically require reporting within 24 hours or zero reports. PF Maryland believes that additional discussion may be warranted for non-pharmacy dispensers.	Chapter 296 Non-CDS
69	Patient First - 3	10.25.18.13	At the very least, PF Maryland would request that the reporting system be designed to allow for the submission of a single aggregated report by an organization, such as PF Maryland, rather than by individual dispensers, which would greatly alleviate the workload. PF Maryland believes that this will satisfy both the purpose of the legislation while at the same time minimizing the burden on dispensers and the provider community.	Chapter 296 Non-CDS
70	Patient First - 4	10.25.18.13B(2)	PF Maryland notes that the HDU Draft Regulations would permit the Commission to update the Data Submission Manual on an annual basis. Consistent with the foregoing comments regarding the workload and expenses imposed upon dispensers by the HDU Draft Regulations, PF Maryland requests the addition of language expressing the expectation that the Data Submission Manual will be adopted without amendment for three year periods, absent emergency circumstances. Again PF Maryland believes that such a limitation would alleviate the potential workload imposed on dispensers.	Chapter 296 Non-CDS

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71	Veradigm - 1	10.25.18.03D	As a general matter, electronic health record (EHR) systems like those provided by Veradigm are business-to-business solutions used by providers to document their interactions with patients; they were not designed with a consent management application in mind because the circumstances under which a provider may share data are limited to those permissible under HIPAA (unless the patient has specifically authorized otherwise). Providers have the ability to flag and prevent the disclosure of electronic health information for self-pay patients in our EHR systems, but there is no functionality that currently exists to offer more granular consent options. EHR systems are simply not designed as business-to-consumer solutions. They will always rely on provider interaction to effect patient preferences and disseminate information. As a result, the implementation of a consent management system like the one described in the amendment would not be possible. Revisions that would allow the provider to perform the actions on the patient's behalf and to provide required information directly are needed.	Chapter 798 CMA
72	Veradigm - 2	10.25.18.03D	Veradigm notes that no technical standards were provided with the amendments. Technical standards are integral to timely implementation. Accordingly, Veradigm respectfully requests that, in addition to revisions, the Maryland Health Care Commission (MHCC) provide technical standards consistent with nationally recognized Interoperability Standards to facilitate implementation.	Chapter 798 CMA
73	Veradigm - 3	10.25.18.04B	An EHR system alone cannot comply with Part 2; it's software that must be acted upon by a provider. Veradigm does not have control over the nature of the information input into its EHR systems and does not necessarily know if the provider or practice licensing its EHR system is a federally funded substance use disorder program. Veradigm respectfully requests that the proposed amendments be deleted.	Other
74	Veradigm - 4	10.25.07.09	The purpose of the proposed amendment is unclear, and therefore the breadth of the information that Veradigm would be required to report to the State Designated HIE under the proposed amendment is very concerning because it may not align with the minimum necessary standard under the HIPAA Privacy Rule. From a security perspective, best practices would not recommend the collection of such a large volume of electronic health information for no specific reason. Veradigm respectfully requests that MHCC clarify the purpose of the amendment, the reason(s) for requiring that EHNs provide so much data, and the information security safeguards that the State Designated HIE has in place to protect the data.	Chapter 790/791 EHN
75	Veradigm - 5	10.25.07.09	1. Would it be possible for MHCC to outline specific use cases where this data is required? 2. Are we required to report instances where a patient has no coverage or expired coverage? 3. Will the information be required for state programs only, or will it also be required for federal programs like Medicare? 4. Will the scope of the required reports be limited to what an EHN is permitted to report under its Business Associate Agreements?	Chapter 790/791 EHN
76	Veradigm - 6	10.25.07.09E	Veradigm is confident that the timelines in the proposed amendments are neither realistic nor, in some instances, technically feasible. Rather than have all HIEs that provide EHR systems apply for the one-year extension, we believe it would be more prudent to revise the amendments and propose new timelines to align with comments received by MHCC. Veradigm has concerns with: the 180-calendar day timeline to begin submitting health care claims or equivalent encounter information following this regulation's effective date and the 180-calendar day timeline for submitting health plan eligibility inquiries and response information following notice by the Commission.	Chapter 790/791 EHN
77	Veradigm - 7	10.25.18.03D	Veradigm is confident that the timelines in the proposed amendments are neither realistic nor, in some instances, technically feasible. Rather than have all HIEs that provide EHR systems apply for the one-year extension, we believe it would be more prudent to revise the amendments and propose new timelines to align with comments received by MHCC. Veradigm has concerns with: the 60-day timeframe to implement the first phase of the State Designated HIE consent management application and the 90-day timeframe to implement phases two and three.	Chapter 798 CMA