

Date: March 11, 2021

From: David Horrocks,
CEO CRISP Health

To: CRISP Participants, especially legal counsel and privacy and security officers

Re: Material Amendments to the CRISP Participation Agreement

Updating the Participation Agreement

The CRISP Participation Agreement (PA) is a contract that sets the rules for when and how care providers can use the records available through CRISP. All healthcare providers sign the same agreement. It also defines what CRISP is allowed to do with the records you send to us, including how those records can be stored, shared with others, and when a governance committee must approve something in advance.

The agreement was first drafted in 2010 and has gone through several modest changes. The circumstances, laws, and policy which pertain to health information exchange have evolved over time, and our Participation Agreement needs to evolve as well so that it remains relevant and supportive of the essential purpose for which CRISP was created. CRISP is proposing to materially revise several areas of the Participation Agreement and to update several other provisions. The general plan is described below – and a redlined version of the Participation Agreement has been posted on the CRISP website and sent to Participant points of contact. Participant legal counsel and privacy and security officers should review the redlined agreement and provide comments to CRISP by emailing Adrienne Ellis, Advisor to CRISP at adrienne.ellis@crisphealth.org.

How an amendment to the Terms and Conditions works

The process for Material Amendments to the Terms and Conditions includes collection of both written and oral feedback from Participants during a comment period and the consent of a majority of the Participants.

The written comment period is from March 11, 2021 to April 13, 2021- 30 days from the posting of the amendments. We will also host a virtual meeting to answer questions and provide an opportunity for oral comments. More details about that meeting and how to attend are available on the CRISP website. After the comment period, CRISP will review any comments that are submitted determine if any revisions to the agreement are necessary and advise participants of the final version. Once the final version has been posted and shared with participants, the updated and amended agreement will take effect after 30 days and upon written consent of majority of participants.

CRISP exists to advance health and wellness with health IT solutions adopted through cooperation and collaboration. We are very eager to maintain the spirit of cooperation and collaboration in everything we do. Therefore, we look forward to your comments on the proposed amendments.

Areas addressed in the updated version:

1. Repositories for rapid responses at the point-of-care.

When drafted, the PA included references to the technical architecture which would be used to store data. We would like to update this section, so CRISP can exchange and store data in modern ways that allow us to deliver it very quickly and efficiently back to clinicians.

A core concept in the PA is that clinical records submitted to CRISP, which are generally sent as documents, remain under the control of the provider organizations that submit them. CRISP is just a steward, placing documents into repositories where they are logically kept linked to the submitting organization. The PA dictates how the documents must be stored, using the concept of an “edge device”, a provision largely designed to keep the link to submitting organizations clear and to ensure that if any organization called us and required all the documents they submitted to be removed, we could easily do that.

When the PA was drafted, the primary use of data was for a clinician to open a web portal and search for a complete document, such as a discharge summary, and to open and view the document. Today, information is often exchanged as discreet data fields through a more modern interoperability method called an API. The information is often “contextual facts” about a patient used for care coordination, such as:

- **Patient has been enrolled in the xyz care management program since 05/15/2017.** (We pull that fact from patient panels submitted by care managers.)
- **Patient was discharged from a hospital less than 30 days ago.** (ADT feeds from hospitals let us calculate the number of days since a prior discharge.)
- **An opioid was dispensed to this patient less than 60 days ago.** (We use the dispense dates on the PDMP records, which MDH has asked us to manage, to flag recent receipt of opioids.)
- **Healthcare proxy on file.** (The proxy document may be saved elsewhere, and we flag that fact so that providers know it is there if they need it.)

- **Patient’s PCP wrote the following Care Alert ...** (The Care Alert may be submitted as part of a CCDA document, but we need to extract the key information to present without the clinician needing to search for or through the document.)

These small bits of information are increasingly being delivered to a clinician at the point of care as a simple flag, field, or alert within their EHR. Clinicians see these without searching for or opening an original document. Of course, this automatic workflow is far easier than opening and navigating through the CRISP portal, and the alert may help a clinician decide when it is worth the time to search further for clinical documents. This contextual information may also be helpful in other settings, such as:

- When population health managers look at a report for a cohort of patients (such as in the PaTH dashboard), we can use the information to flag whom among recent patients is already enrolled elsewhere in care management.
- When creating a Patient Care Overview (or “Snapshot”) for ambulatory clinicians, contextual information and Care Alerts can be placed directly into a single summary view.

To provide information efficiently, CRISP needs to extract or derive bits of data from the documents we receive. Sometimes that can be done on-demand, but often the technical process for doing so is too complicated and slow for a real-time query. In those cases, the bits of data need to be extracted in advance and stored in a structured repository which can respond to API requests quickly – generally in less than 500 milliseconds. The repository needs to function as a lightweight “registry”, only holding the information necessary to create the flag or the alert in an EHR.

The capability to push pieces of information into an EHR is a natural progression of HIE services, and CRISP is not alone in pursuing these new capabilities. However, our PA did not contemplate these technical approaches when drafted in 2010. Under the proposal, the CRISP Technology Committee, which is comprised largely of CIOs and technologists from CRISP participants, would be able to authorize a different technical approach for storing and delivering specific types of information. When they agree it is appropriate, data that has been extracted from clinical records could be stored in a structured Repository for speedy delivery back to EHRs, while still retaining data provenance to know to which organization it belongs.

Language referring to “Edge Devices” to store copies of each participant's data will also be revised in the PA. The CRISP data repositories continue to provide the same level of security and participant control, but the repositories generally use a “logical” separation of records (using metadata) and do not physically compartmentalize

each participant's data in separate devices as was once contemplated. Again, this approach is consistent with industry best practices for regional HIEs such as CRISP.

2. Participation in National HIE Exchanges

CRISP has monitored the development of national HIE Exchanges closely. At present, there are four significant National HIE Exchanges: EPIC's Care Everywhere, CommonWell, Carequality, and the e-Health Exchange. We believe that a significant volume of HIE transactions will be carried over national HIE Exchanges and that certain services provided by national HIE Exchanges will duplicate services that CRISP provides. (There are other CRISP services which national networks cannot or will not duplicate.)

The role of National HIE Exchanges and of CRISP will continue to evolve over time. Most importantly, the Office of National Coordinator for Health IT (ONC) is proposing a national approach for interoperability between HIEs, managed by a Recognized Coordinating Entity (RCE). ONC's aim seems to be to encourage all exchanges into this framework. It is likely that CRISP will need to participate in this new model, and we propose updating the PA to reflect participation in national HIE Exchanges.

3. Federally mandated data sharing as a permitted purpose

As stated, CRISP is only a steward of data. The participants, speaking through a governance committee such as the CRISP Clinical Committee, instruct us as to what is an allowable use of the records. (Of course, we operate under the restrictions of HIPAA and state regulations, too.) The 21st Century Cures act prohibited activities that result in "information blocking" and directed the HHS Secretary to promulgate regulations that implement Congress intent. The HHS Office of the National Coordinator for Health Information Technology (ONC) has promulgated regulations that require health care providers, such as the CRISP Participants, and Health Information Networks, such as CRISP, to not engage in practices that are likely to interfere with access, exchange or use of Electronic Health Information. These regulations are extremely complex and beyond the scope of this memo, but they require CRISP to fulfill requests of EHI without delay or other interference.

The "permitted purposes" section of the PA will need to be revised so that all CRISP Participants can enjoy the benefits of a broad range of exchange while also complying with the requirements under the ONC Information Blocking Rule

4. Patient Access as a permitted purpose

When the PA was originally drafted, patient access to data was contemplated as a permitted purpose but was deferred. The Maryland Health Care Commissions has since promulgated enabling regulations to encourage HIEs in Maryland to provide patients' access to data. It is worth noting the ONC Information Blocking Rule does

require health care providers and Health Information Networks to fulfill a patient's request to access their information unless an exception applies. Finally, the ONC TEFCA will encourage Individual Access Services to make information more easily accessible to the patient. Recently the CRISP Board approved a patient access policy which would be enabled upon update to the Participation Agreement. The proposed amendment would add patient access as a permitted purpose and enable CRISP to work with its participants and stakeholders to develop policies and procedures to enable this new use of participant data.

5. Other categories of participant

While hospitals and ambulatory providers have and will continue to sign the same form of Participation Agreement, the CRISP PA has from its inception recognized a category of "Other Participants" that may sign a different form of Participation Agreement. CRISP proposes to add language to the definition of Participant to specify that Other Participants may include state or federal agencies, and organizations formed for purposes of population health, care management, or quality improvement.

Of note, the change will especially help us better engage with organizations which are formed to support ambulatory practices in managed care efforts. Without this, our engagement with such a managed services organization is complicated. They may be a business associate for dozens of practices, and it is difficult for us to track on whose behalf we are providing the service they use. Categories of Other Participants that are not state or federal agencies will be approved by the relevant CRISP governance committee.

6. Responding to legal process

If CRISP receives legal process, such as a subpoena for medical records, the PA provides that CRISP will notify the relevant participants and cooperate with the participant in responding. Despite our efforts to keep the process as originally envisioned, in an era of increased information availability, it is not legally viable to continue making the argument that such requests must be pushed to our participants. The proposed amendment would specifically provide CRISP with options to respond to legal process, in addition to working with participants in such responses.

7. Emailing notices

The number of CRISP participants has grown enormously in the ten years since the Participation Agreement was drafted. Since the beginning, the signature line has required that each participant provide a "Designated Contact" and that individual's email address. Given the burden of delivering a paper copy of notices to each participant, we propose to eliminate the need for notice by mail, so notices may be given via email.

8. Simplification of Material Amendment Process

As noted, the participation agreement has only been materially amended since 2010 in few instances partially due to the very onerous process established in the agreement and the expansive growth of CRISP participation. The sheer number of CRISP participants makes it prohibitive to collect written consent from participants in order to update the agreement. CRISP proposes to maintain the robust notice and comment period for material amendments while simplifying the final process, removing the need for written consent and the requirement to hold a meeting of participants. In addition, CRISP proposes to add additional advisory support for this process by adding a requirement in the agreement that the Executive Committee shall be consulted for all material amendments. In the fast-changing world of HIE, it is imperative CRISP have the flexibility to keep its contract with participants current and in compliance with all new regulatory guidance.

9. Removal of references to specific, licensed services

Since 2010, CRISP has continually added tools and services for participants. Some of these services are licensed by CRISP and provided directly to all participants; others are developed and hosted by CRISP. Some services such as Direct, secure email service, were specifically mentioned in the agreement while others such as, Image Exchange, were not. For clarity and simplicity, CRISP proposes to remove all references to specific licensed services and to add new definitions of “Licensed Services” and “CRISP Services” to cover all services provided by CRISP to participants.