



October 6, 2022

Mr. Howard Shelanski  
Administrator, Office of Information and Regulatory Affairs (OIRA)  
Executive Office of the President  
Office of Management and Budget  
Washington, DC 20503

*RE: Written Remarks for EO 12866 Meeting*

Dear Administrator Shelanski,

The following is a statement of written remarks delivered for the College of Healthcare Information Management Executives Executive Order (EO) 12866 meeting on October 6, 2022.

Thank you for the opportunity to provide comments on OIRA's review of the proposed rule, "ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing" by the Office of the National Coordinator for Health Information Technology (ONC) in the Department of Health and Human Services (HHS)."

### **Background**

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders. With over 5,000 members, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate; exchange best practices; address professional development needs; and advocate for the effective use of information management to improve the health and healthcare in the communities they serve.

### **Written Remarks**

Pursuant to provisions contained in the 21st Century Cures Act (Cures Act) healthcare providers, health IT developers, health information exchanges (HIEs), and health information networks (HINs) are prohibited from engaging in "information blocking" practices. Beginning October 6<sup>th</sup>, today, these actors must be able to share all electronic protected health information (ePHI) in a designated record set, as defined under the Health Insurance Portability & Accountability Act (HIPAA). Prior to this, data sharing mandates are limited to what is contained in the United States Core Data for Interoperability (USCDI).

CHIME understands and strongly supports patients' need to access their information in a digital format. Despite our best efforts to educate our members, significant knowledge gaps and confusion still exist within the provider and vendors communities with respect to implementation and enforcement of information blocking regulations. With clinician burnout rates at an all-time high, CHIME believes that moving forward with unclear and inconsistent information sharing about data requirements could further

strain healthcare providers, their support staff, and may inadvertently undermine HHS' goals to reduce provider burden, improve interoperability, and empower patients with their information.

A chief factor limiting compliance readiness is the widespread inability to support access, exchange, and use of EHI. There is no clear definition of EHI and there is a lack of a technical infrastructure to support its secure exchange. There are widely divergent approaches to how each healthcare stakeholder is interpreting what data is ePHI, DRS, and EHI. Many stakeholders are still confused by the Office of the National Coordinator's (ONC) EHI infographic.<sup>1</sup>

Last week, CHIME sent a [letter](#) along with nine other healthcare provider organizations to HHS Secretary Xavier Becerra requesting that the Department offer providers an additional year to comply with the October 6<sup>th</sup> information sharing deadline. Despite requesting HHS allow more time so that they and the agencies under their umbrella – including the Office of the National Coordinator for Health Information Technology (ONC), Centers for Medicare & Medicaid Services (CMS), and HHS-Office of the Inspector General (HHS-OIG) – can release additional education for providers, HHS has declined to move the deadline.

CHIME has used every opportunity and avenue available to us to share our concerns, member feedback, and questions with HHS, CMS, ONC, and OIG. We have joined and led multi-stakeholder letters, provided feedback via the annual payment regulations issued by CMS (which are also included/attached), hosted webinars, and met with leadership at these agencies. We continue to urge HHS ensure that providers and clinicians have the guidance, education, and technology to support these new policies before full implementation and enforcement of information sharing regulations. We believe strongly in information sharing and want to see these policies succeed. A successful implementation of information sharing necessitates that all stakeholders have the critical tools, knowledge, guidance, and systems in place to meet the requirements of the deadline. This is simply not the case for the majority of the providers represented by CHIME.

CHIME continues to encounter basic questions about the information sharing policies across our membership. CHIME conducted a recent survey to gauge provider's readiness for the information sharing deadline. In surveying our members, we found that 14% are not aware of the upcoming deadline to comply with information sharing requirements. Furthermore, when asked what their main concerns around compliance were, 17% of members chose "education" as one of their top three concerns, with education being defined as "overall uncertainty and confusion related to new mandates and the need for more education related to compliance." Providers need best practices and implementation guides offered and published that they can reference as they strive to comply with the regulations. Without real-world guidance, providers will continue to struggle with implementing internal policies in order to avoid allegations of information blocking.

Additionally, lesser resourced providers are even more confused – if they are even aware of the policies at all. In fact, small providers/clinicians' awareness remains very low, and they are relying heavily on their vendors. Vendor readiness is lagging and their deadline for delivering needed upgrades is December 31, 2022, three months after providers are required to comply. Some vendors are not even on track to meet their own deadline, and some providers are already reporting that their vendors are delaying EHI upgrades. Further, certified vendors' deadline for delivering an EHI export isn't until December 31, 2023, a year and three months after providers are required to comply. Certified API

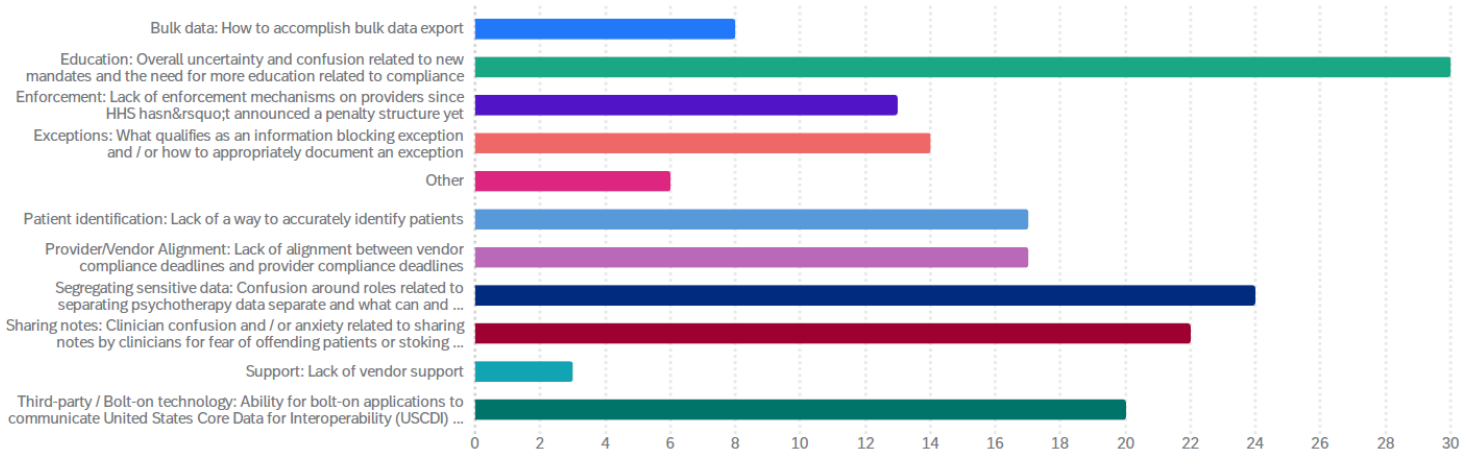
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<sup>1</sup> *Understanding the Scope of Electronic Health Information (EHI) for the Purposes of the Information Blocking Definition.* (2021, December). [https://www.healthit.gov/sites/default/files/page2/2021-12/Understanding\\_EHI-Scope-Diagram.pdf](https://www.healthit.gov/sites/default/files/page2/2021-12/Understanding_EHI-Scope-Diagram.pdf). Retrieved October 4, 2022, from [https://www.healthit.gov/sites/default/files/page2/2021-12/Understanding\\_EHI-Scope-Diagram.pdf](https://www.healthit.gov/sites/default/files/page2/2021-12/Understanding_EHI-Scope-Diagram.pdf)

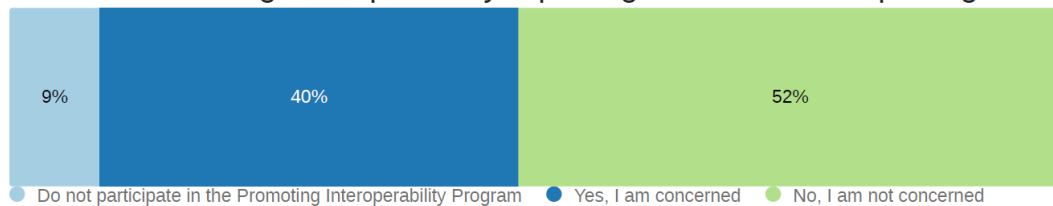
developers are required to upgrade to FHIR based APIs by December 2022, but the requirement is limited to the USCDI v1 and not all EHI. Certified vendors are tracking to their required timelines that don't necessarily align with the provider requirements which is causing confusion and limitations on sharing of EHI data. ONC's own data shows that only 26% of health IT products are certified<sup>2</sup>.

**Given the aforementioned challenges, we respectfully urge OIRA in its review of the “ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing” proposed regulation to consider offering providers an additional year to comply with the October 6th, 2022 deadline (today).** Finally, below, we share with OIRA some of the findings and results from CHIME's recent information sharing survey of our members. These results show that our members are also concerned and have questions about patient identification, segregating sensitive data, and third-party/bolt-on technologies – to name a few of the issues.

What is your biggest concern or question around Info Blocking compliance? (Pick up to three concerns) ⓘ

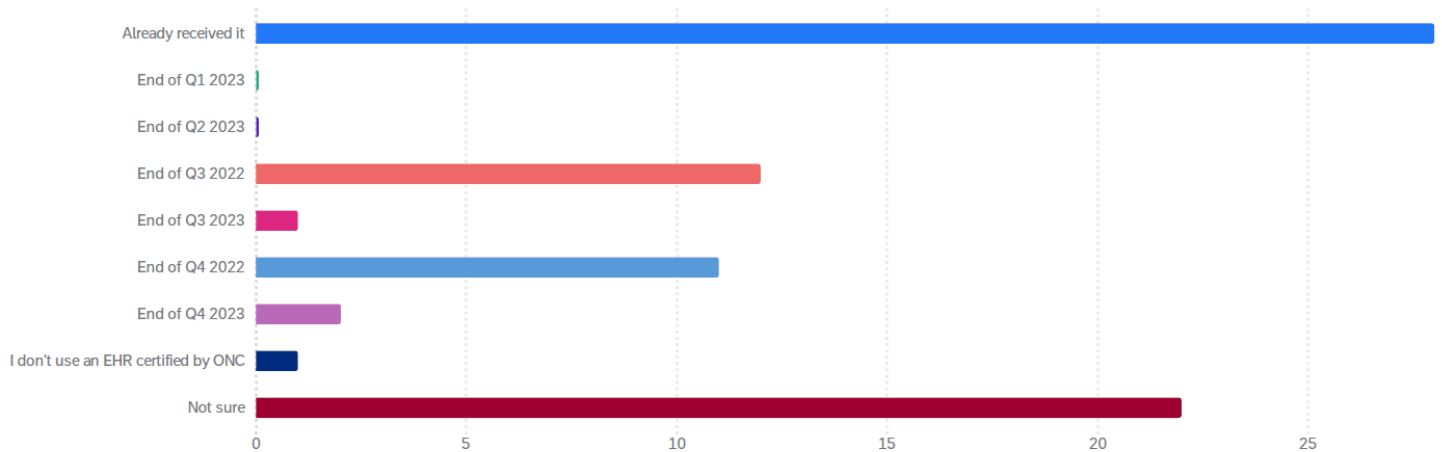


- Are you concerned about receiving your updated certified EHR in time for Promoting Interoperability reporting for 2022 data reporting?

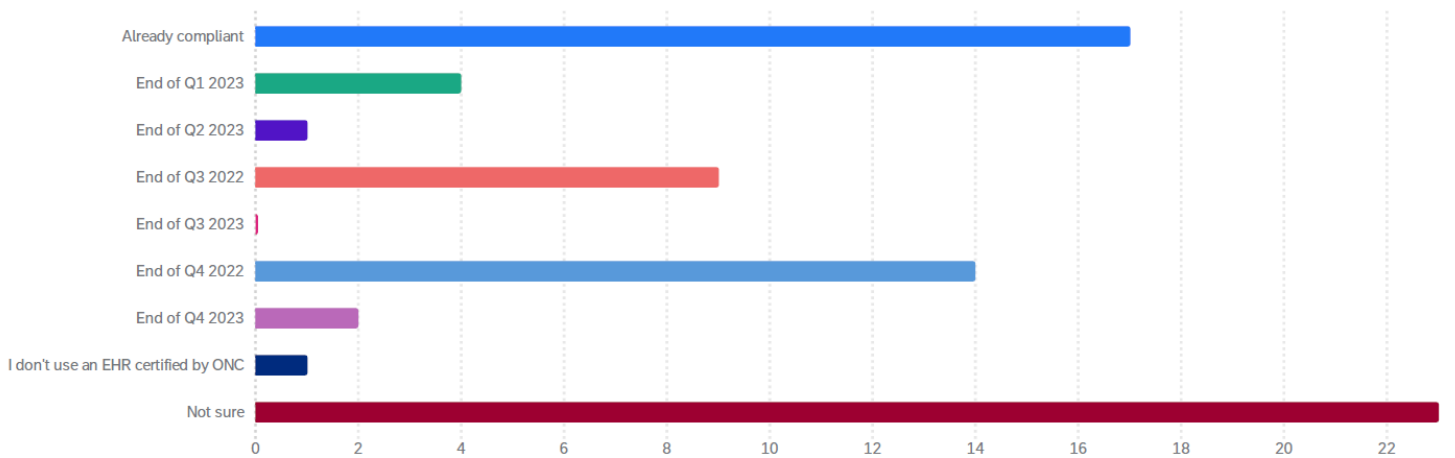


<sup>2</sup> Certified Health IT Product List (CHPL). (n.d.). Retrieved October 4, 2022, from <https://chpl.healthit.gov/#/search>

When do you expect your vendor to deliver your certified EHR update to accommodate Information Blocking mandates including FHIR V4 technology? ⓘ



When do you expect to be compliant after receiving the updated EHR? ⓘ



In closing, we would like to thank you for providing the opportunity to provide written remarks, and CHIME appreciates the chance to help inform the important work being done by the Executive Office of the President and OIRA. We look forward to continuing to be a trusted stakeholder and resource to this administration. Working together through the rulemaking process is just one way we can accomplish our shared goals and make meaningful changes in healthcare. Should you have any questions or if we can be of assistance, please contact Chelsea Arnone, Director, Federal Affairs at [carnone@chimecentral.org](mailto:carnone@chimecentral.org).

Sincerely,

Mari Savickis  
 Vice President, Public Policy  
 The College of Healthcare Information Management Executives (CHIME)