

February 16, 2024

Micky Tripathi, Ph.D., M.P.P.
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard,
Baltimore, MD 21244

RE: Timelines for Certification and Use of Certified HIT/CEHRT

Dear Dr. Tripathi and Administrator Brooks-LaSure,

On behalf of the 29 member companies of the HIMSS Electronic Health Record (EHR) Association, we appreciate this opportunity to discuss the recently finalized and published Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) rule. Our members are diligently reviewing these final requirements and compiling detailed feedback and requests for clarification, which we will present to the Office of the National Coordinator for Health Information Technology (ONC) soon.

The Association offers our appreciation for ONC's and the Centers for Medicare & Medicaid Services' (CMS) efforts in developing the regulations for the health IT certification program and requirements for the use of Certified EHR Technology (CEHRT). We understand the complexities involved in this process and the ongoing need for adjustments as the programs progress. We do, however, have concerns regarding the most recent approach to CEHRT use deadlines.

In the past, ONC has introduced certification editions (e.g., 2011, 2014, 2015, and 2015 Cures Update) with associated compliance dates for health IT developers. The HTI-1 rule transitions to an edition-less certification program, allowing ONC greater flexibility in updating or creating certification criteria. This change, along with the Standards Version Advancement Process (SVAP), enables targeted regulatory updates allowing ONC to regulate functionality in an area that may be ripe for advancement while

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Altera Digital Health	Elekta	Greenway Health	Netsmart	Sevocity
Athenahealth	EndoSoft	Harris Healthcare	Nextech	STI Computer Services
BestNotes	Epic	MatrixCare	NextGen Healthcare	Varian – A Siemens
CPSI	Experity	MEDHOST	Office Practicum	Healthineers Company

allowing the industry, standards development organizations (SDOs), or other stakeholders to make necessary advancements in other areas. This change also introduces uncertainties about when updates to certified health IT need to be implemented by healthcare providers to meet their obligations for the use of CEHRT under CMS regulations.

CMS has historically aligned its implementation timelines for new CEHRT editions for hospitals, Critical Access Hospitals (CAHs), and Eligible Professionals and Clinicians (EPs and ECs) with ONC's certification edition compliance dates as a component of compliance with the Medicare Promoting Interoperability (PI) and Merit-based Incentive Payment System (MIPS) PI category requirements. Additionally, CMS has established CEHRT use requirements with other programs, such as the Inpatient Quality Reporting (IQR) program, and Advanced Alternative Payment Models (A-APMs), among others.

In the 2024 Physician Fee Schedule (PFS) final rule, however, CMS indicated that if ONC moves to an edition-less certification program structure, healthcare providers subject to requirements for implementation and use of CEHRT under CMS and CMMI programs would be held to the same deadlines as those imposed by ONC on health IT developers for providing updated CEHRT to their customers. (See [Revisions to Certified Electronic Health Record Technology Definitions in Regulatory Text](#).) This change overturns the conventional process for setting compliance dates, requiring both health IT developers and their provider customers who are required to use CEHRT to re-evaluate their understanding of the dates established by ONC in the HTI-1 final rule and their associated impact on all parties.

For example, the HTI-1 final rule establishes a date of December 31, 2025, for health IT Developers to develop, test, certify, and make the majority of the regulation available to CEHRT users. The extension from the initially proposed December 31, 2024, deadline is appreciated. However, significant scheduling challenges remain, as providers must implement this CEHRT by 2026. Specifically, to meet Medicare PI and MIPS PI reporting requirements, providers must have the updated CEHRT operational by July 4, 2026, at the latest, with some needing it by January 1, 2026, due to full calendar year performance periods for certain A-APMs that do not specify a separate CEHRT usage date. Health IT developers and their provider clients must utilize the additional year for planning upgrade timelines, organizing training, possibly revising workflows, and preparing for the adoption of new CEHRT features. The operational implications of such health IT system upgrades on healthcare organizations are a significant concern, given the complexities involved in adopting new CEHRT and its functionalities.

Upgrading systems to a newly certified code level presents considerable challenges for health IT developers and their clients, particularly when introducing new functionalities or changes to user workflows, such as the addition of new data collection fields in line with USCDI v3 data elements. Despite developers' efforts to streamline these upgrades for healthcare providers, the process is arduous as both developers and healthcare providers work to ensure system quality, provide adequate user training, and minimize disruptions to care delivery.

Generally, most healthcare providers seek to undertake one major upgrade annually, depending on customer needs, developer schedules, and the nature of the upgrade. To ensure all customers needing the CEHRT functionality have ample time to plan and execute those upgrades, health IT developers often must make new functionality available at least a year, and sometimes more, ahead of the mandated provider compliance dates. This lead time is necessary for providers to plan the upgrade, assess its impact on training and workflow, and deploy the new capabilities effectively. Historically, CMS

has facilitated this process by offering a 'flex' year during which providers could choose between the older certification edition or the new one for compliance. However, this flexibility no longer exists.

While most, if not all, developers may be able to meet any single certification timeline, health IT developers and their CEHRT-using clients must concurrently navigate a broad and growing spectrum of regulatory requirements beyond those specified in HTI-1.

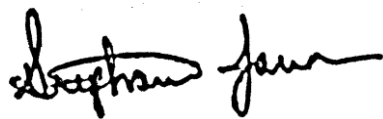
- The HTI-2 proposed rule is anticipated to be released in the next couple of months, with a final rule and additional certification requirements expected later this year.
- The recent CMS electronic Prior Authorization (ePA) final rule, while not directly imposing requirements on health IT developers and providers, sets an expectation for collaboration with affected payers to utilize these capabilities.
- Continual Trusted Exchange Framework and Common Agreement (TEFCA) updates and new requirements are being introduced through Standard Operating Procedures (SOPs) and updates to the CA and QHIN Technical Framework (QTF).
- Amid the release of other federal regulations, state-level regulations are beginning to ramp up regulations concerning health IT usage, including restrictions on the sharing or release of 'sensitive' health information, mandates for state-based exchange sharing, and data hosting restrictions.

This underscores the criticality of giving healthcare providers ample time between the availability of system updates from their developers and regulatory deadlines for the implementation and use of such updates. Therefore, the EHR Association requests CMS reintroduce the use of a 'flex' year concept, as used previously, and align CEHRT usage requirements with those for electronic Clinical Quality Measures (eCQMs).

As an example, ONC has set a date of December 31, 2025, for USCDI v3 requirements. Following the flex year/eCQM recommendation, CMS would extend the deadline for hospitals, CAHs, and ECs to have all of the HTI-1/USCDI v3 functionality in place for use until December 31, 2026. This approach would allow sufficient time for health IT developers and their provider clients to deploy these capabilities effectively while ensuring providers continue to make meaningful progress toward the implementation and use of new CEHRT during the target calendar year.

We welcome the opportunity for ongoing discussion. The Association's leadership can be reached by contacting Kasey Nicholoff at knicholoff@ehra.org.

Sincerely,



Stephanie Jamison
Chair, EHR Association
Greenway Health

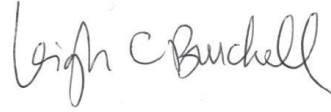


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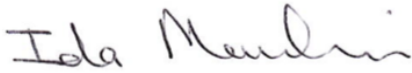
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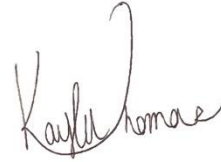
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Kayla Thomas
Oracle Health

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 29 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.