Micky Tripathi, Ph.D., M.P.P.
Assistant Secretary for Technology Policy/Office of the National Coordinator
U.S. Department of Health and Human Services
Washington, DC 20201

Dear Assistant Secretary Tripathi:
On behalf of the Healthcare Information and Management Systems Society (HIMSS), we are pleased to provide written comments to the Notice of Proposed Rule Making (NPRM) regarding Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HT1-2 RIN 0955-AA06.) HIMSS appreciates the opportunity to leverage our members' expertise to share feedback on the sweeping changes to the certification program, and we look forward to continued dialogue with ASTP/ONC to continue the discussion on these topics.

HIMSS is a global advisor and thought leader and member-based society committed to reforming the global health ecosystem through the power of information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research, and analytics to advise global leaders, healthcare leaders, and influencers on best practices in health information and technology driven by health equity. Through our innovation engine, HIMSS delivers key insights, education, and engaging events to healthcare providers, governments, and market suppliers, ensuring they have the right information at the point of decision. HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East, and Asia Pacific. Our members include more than 125,000 individuals, 480 provider organizations, 470 non-profit partners, and 650 health services organizations. Our global headquarters are in Rotterdam, Netherlands, and Americas headquarters are in Chicago, Illinois.

Decision Support Intervention (DSI) Criterion Deadline

While changes in the Decision Support Intervention criteria were not part of the proposed rule, HIMSS strongly recommends ASTP/ONC delay the implementation deadline for DSI criteria for one calendar year, to December 31, 2025. This recommendation allows for robust field testing, the safe implementation of both the criterion and new workflows required to accommodate the new requirements.

Striking the right balance between healthcare consumer expectations and market supplier and healthcare system capabilities is important to successful advancements in digital health transformation. After extensive feedback from industry representatives and end-users, we believe that many eligible hospitals and eligible clinicians will not receive the required updates associated with decision support intervention (DSI) criterion. The time allotted for DSI criterion to be implemented (December 31, 2024) in all eligible hospital and eligible clinician sites did not consider the time and extensive work required to successfully test and implement the Decision Support Intervention requirements across the entire impacted healthcare ecosystem. Accuracy of clinical decision support tools is negatively impacted by rushed implementation timelines. As HIMSS noted in comments

responding to the HTI-1 proposed rule, typically market suppliers need approximately 18 months following the finalization of new standards and specifications and publication of the final rulemaking to implement the changes at all care delivery sites within their footprint. In the case of DSI, added complexity with the industry familiarity with the requirements and challenges with real world testing made the timeline finalized by ASTP/ONC of less than 13 months for full deployment of the new DSI criterion unreasonable.

HIMSS has also recommended that the Centers for Medicare and Medicaid Services (CMS) use their regulatory discretion to allow a grace period of one additional year for the Promoting Interoperability Program eligible hospitals (EHs), Merit Based Incentives Payment System (MIPS) eligible clinicians (ECs), and Medicare Shared Savings Program (MSSP) participants requiring the use of the latest versioning of certification to meet programmatic requirements if their market supplier cannot roll out the new DSI criterion under the current ASTP/ONC deadline by the start of the January 1, 2025 program reporting year.

HIMSS recommends changing the deadline of December 31, 2024, for incorporating the complete set of new and revised certification criteria. ASTP/ONC's deadline does not allow for enough time to successfully complete the extensive work required to implement and test the certification changes across the healthcare ecosystem, while ensuring quality, safety, and patient privacy are not compromised.

HIMSS does not want providers and health systems that are acting in good faith to then be penalized with CMS negative payment adjustments because of insufficient implementation time due to compounding delays associated with standards development, vendor implementation timelines, and staffing shortages that are impacting the whole community. The current timeline and resulting penalties may disproportionately impact end-users who care for underserved, Tribal, and rural communities. These providers are already disproportionately subject to negative payment adjustments by CMS reporting programs, and potential penalties caused by mechanism outside of their control would further disrupt the goals of digital transformation.

Observations on USCDI V4 and other new and revised Certification Criteria

USCDI V4 Implementation

HIMSS has been a long-time advocate for the healthcare industry to universally adopt and expand USCDI as a mechanism for facilitating interoperability. Seamless, secure, and ubiquitous data access and interoperable health information exchange should ensure the right people have the right access to the right health information in a usable format at the right time. HIMSS applauds ASTP/ONC's leadership in advancing the vision of nationwide interoperability by leveraging a standard core data set for interoperable data exchange. HIMSS supports the timely and equitable incorporation of the USCDI v4 and future versions into certified health IT and Health IT modules with a deadline for implementation of December 31, 2027.

In addition to the adoption of USCDI v4, HIMSS strongly encourages ASTP/ONC to present a pathway to the adoption of USCDI+ in future iterations of certified Health IT to support

CMS goal of transitioning quality measurement programs to digital quality measures (dQMs.) Clinical quality measures, particularly measures used in specialty practice, include layers of clinical context. The data needed to populate dQMs will require much more clinical context than can be supported by the capabilities of USCDI V4 and QI Core for the foreseeable future. Additional layers of context are being added to USCDI+, which in turn will need to be harmonized with the Quality Data Model (QDM) and QI Core. Implementors and software developers need stability in specific standards that they can work with over a three-to-five-year time horizon. Standards impacting electronic clinical quality measures (eCQMs) and dQM's are changing often, which does not allow sufficient time to be vetted in a consensus-driven way or implemented as part of HL7 implementation guides.

Properly testing Bulk FHIR v2.0 against all needed use cases

FHIR APIs do not have the ability to transmit the large volumes of patient data needed for managing the health of populations, support clinical research, or facilitate the core functions of public health. HIMSS supports the continued advancement of Bulk FHIR standards to facilitate the exchange of large volumes of data.

However, HIMSS membership has raised significant concerns regarding the adoption deadline of January 1, 2028, for the use of HL7® FHIR® Bulk Data Access v2.0.0 as part of certified Health IT and Health IT modules. Both HIMSS membership and participants at the August Workgroup for Electronic Data Interchange (WEDI) meeting have shared that Bulk FHIR 2.0 has performed poorly in testing environments. Bulk FHIR 2.0 is also still in trial phase, and developers of Health IT can't initiate the implementation of the standard in their systems until the specifications are finalized. HIMSS membership has also noted that to date the standard has not been tested in many important real-world environments, including clinics, payer applications, and public health settings.

Ensuring appropriate testing in diverse settings validates that the bulk data transmission capabilities will meet the needs of users is critical before requiring a standard as part of a certified module. HIMSS recommends the following:
- CMS and ASTP/ONC should collaborate to launch a "sandbox" for conducting real world testing of Bulk FHIR v2.0 in all impacted care and administrative settings, including clinical inpatient, outpatient, public health, and payer end-users. The CMS Centers for Medicare and Medicaid Innovation can facilitate a framework.
- ASTP/ONC should collaborate with CMS to develop a legal agreement for standards development organizations and developers to test with providers as close to as possible production data.
- ASTP/ONC should continue to use Bulk FHIR v1.0 through December 31, 2028, with Bulk FHIR v2.0 becoming a required part of certification on January 1, 2029. This additional year will allow Bulk FHIR 2.0 to complete trial phase and rigorous real-world testing in all key healthcare ecosystem environments before developers and end-users initiate their processes for implementing Bulk FHIR v2.0 into their health IT modules.

Digital Imaging Certification Criteria

HIMSS supports ASTP/ONC's proposal to revise the requirements for Health IT and Health IT modules certified to provide "imaging links" to analyze and share digital images. This proposal clarifies that imaging links specifically enable electronic viewing or retrieval of one or more images over a network and must be made available via hyperlink. This would end reliance on the patient to share digital images with different providers using CD-ROM technology.

HIMSS notes that, while some specialties will be well prepared for this change (particularly radiology), other specialties, which regularly utilize digital imaging but historically have not offered images via hyperlink, will struggle to implement these changes in their practices. HIMSS recommends ASTP/ONC convene subject matter expert groups of these specialties and developer/market suppliers to develop implementation playbooks for implementing the required digital imaging specifications and incorporating them into the workflows for these specialties.

Other New and Revised Certification Criteria

After extensive review, HIMSS supports the addition of the proposed new certification criteria and revised criteria and the supporting standards and specifications. The timeline for adoption continues to be the greatest concern for our membership. There are challenges with alignment and with the readiness of several new criteria. A couple of examples:

1. Many of the criteria required for transmitting data to public health agencies, for example, HL7 Version 2.5.1 IG: Laboratory Orders (LOI) from EHR, Release 1, STU Release 4 – US Realm and HL7 Version 2.5.1 IG Laboratory Results Interface, Release 1 STU Release 4, are still in trial phase. Developers can't initiate implementation until the new standards have completed trials and the final specifications are available. HIMSS strongly recommends additional time for any new standards still in trial phase to not be included in rulemaking until they have completed trial phase and have been validated.

Public Health Data Exchange and Certification

HIMSS supports the electronic sharing of information with public health partners. However, implementing new requirements for providers if public health agencies can't receive public health data in the prescribed manner creates additional burden and little value. After extensive conversations with our public health constituencies HIMSS recommends the following changes to ASTP/ONC's proposals for certification geared towards driving data sharing with public health agencies.

1. HIMSS supports the adoption of the proposed new public health reporting certification criteria where the standards are well established and in use in public health settings using the proposed December 31, 2026, and December 31, 2027, implementation deadlines. These include:
   a. Immunizations (f)1- end of 2026
   b. Syndromic surveillance (f)2-end of 2026
   c. Anti-microbial Use and Resistance (f)6- end of 2026

d. Healthcare Surveys (f) 7- end of 2026
e. Prescription Drug Monitoring (f)9- end of 2027
2. HIMSS recommends the following certification criteria be added to the certification program via rulemaking after they have completed trial phase and have been validated.
a. Electronic lab reporting (f)3
b. Cancer registry reporting (f)4
c. Electronic case reporting (f)5
d. Birth reporting (f)8
  a. HIMSS notes that ASTP/ONC is proposing to only require the adoption of Birth reporting (f)8 Transmission of a birth report according to the Birth and Fetal Death Reporting FHIR IG: Vital Records Birth and Fetal Death Reporting–1.1.0 - STU 1.1. HIMSS Public Health partners have noted that their vital records work also requires the transmission of adult death records. HIMSS recommends that ASTP/ONC revise this criterion to include adult death records.

HIMSS calls for ASTP/ONC to set the deadline for all public health reporting-related certification criteria which have not completed trial phase to December 31, 2029. This will allow additional time for testing and finalizing all the proposed standards, as several are currently still in trial phase. Implementation of these standards can't begin until the specifications are finalized, and the final rule is in place, and these extra implementation time will ease the burden on developers and providers. HIMSS strongly encourages ASTP/ONC to launch alpha pilots with public health partners to validate these new standards. Many state level agencies currently utilize other required methods of data transmission outside of the proposed standards and the standardized API for public health data exchange. These pilots are critical to aid public health in creating the appropriate infrastructure to receive data from providers in the prescribed matter. Without a proof of concept, encouraging state and local investment in public health data modernization and the adoption of the certification requirements to receive electronic health data will be challenging. If states systems that utilize central systems that are not easily replaced cannot participate in receiving data, it could lead to significant health equity challenges.

HIMSS also notes that the lack of adoption by public health partners can place a cost and implementation burden on providers. HIMSS reminds ASTP/ONC that providers must attest to the capability of reporting public health data as a requirement for both CMS Promoting Interoperability Program and the Merit-Based Incentive Payment System (MIPS) program. The adoption of criteria, in this case, the Standardized API for Public Health Data Exchange, represents additional cost and implementation burden, without being widely adopted yet by public health partners. HIMSS encourages ASTP/ONC to consider removing Standardized API for Public Health Data Exchange (g)20 from the Base EHR definition and make it a modular certification option.

Comments on Proposed Information Blocking Changes, Including Protecting Care Access Exception

HIMSS supports the proposed Protecting Care Access Exception, which would prevent actors' limiting EHI sharing to reduce a risk of exposing patients, providers, or persons who facilitate care to legal action because they sought, obtained, provided, or facilitated

lawful reproductive health care from being found to be information blocking by the Office of the Inspector General. HIMSS recommends ASTP/ONC simplify the six conditions under the exemption. Actors who can demonstrate they are acting in good faith when information blocking to protect their patients from legal reprisals for seeking lawful reproductive care should meet the exception. Given that the actors most likely to meet the exception will be providers, simplifying the conditions will allow providers to make the best decision in the interest of their patients.

HIMSS also supports the proposal that if the patient requests the information to be shared, even if there is risk of legal reprisal for seeking or facilitating legal reproductive care, the actor must comply or will be found to be information blocking. This proposal is consistent with HIPAA mandates for patient requested information sharing, as indicated in the proposed rule.

HIMSS supports the clarification in the rule that defines "healthcare providers" to include "laboratory" and "pharmacist" and revised language to clarify which labs and pharmacies would be included. HIMSS continues to emphasize that all parties that access and have the capability of exchanging and utilizing identifiable patient information should be subject to the same information sharing and privacy protection requirements. However, HIMSS members expressed concerns that laboratory and pharmacy systems do not need to be certified, which means those systems are not required to have the same privacy and security standards as certified health IT. Certified health IT would also improve the quality of data submitted by labs and pharmacy to public health partners. HIMSS encourages ASTP/ONC to explore expanding certification into the laboratory and pharmacy space.

HIMSS supports the proposal to clarify that contracts which encourage information blocking behavior are consider information blocking under the "interference" definition.

Certification of Health IT Modules Used in Public Health Agencies

HIMSS supports the adoption of standards and specifications to facilitate the appropriate and ubiquitous exchange of electronic health information across all sectors within the United States healthcare ecosystem. HIMSS emphasizes the importance of bidirectional exchange between clinical care and public health agencies using standards-based solutions in the Integrating the Healthcare Enterprise (IHE) Quality, Research, and Public Health domain with the plan to evolve to FHIR-based APIs. Such an exchange could improve patient care outcomes and facilitate automated data queries. Variation in the reporting specifications across different states and public health jurisdictions for submitting health data to public health agencies leads to significant errors and gaps in the information available to public health partners. ASTP/ONC's proposal to require the same standards and specifications built into health IT used in public health settings as clinical end users utilize in their certified health IT systems and modules would facilitate much more effective and meaningful exchange of information.

However, unlike the old Meaningful Use program, the voluntary certification doesn't address the business case for public health agencies to adopt certified health IT. Public health agencies struggle with budgetary limitations and human resources to implement and sustainably maintain health IT technologies capable of electronic exchange of data with the rest of the healthcare ecosystem. In 2009, the HITECH Act allocated $27 billion in

funding to build healthcare information technology infrastructure around the United States. Public health was left out, and as result, outside of a handful of forward-thinking state public health agencies, the health IT infrastructure for public health to electronically receive data and share insights back with clinicians is woefully inadequate to facilitate appropriate electronic health information exchange. And, in the case of some more advanced public health jurisdictions, the adoption of the standards proposed for certified health IT modules would be a step backwards from the more advanced standards and specifications they currently use for data exchange. Sustainability of funding to pay for infrastructure, staff retention, licensing, system updates, and continuing education are critical. HIMSS also notes that ASTP/ONC's proposed cost analysis neglected to estimate the costs for software development, business development, testing environments for public health, and the additional staffing with the subject matter expertise to implement and utilize the systems. HIMSS strongly encourages ASTP/ONC to convene public health partners to get a better understanding of the real costs of adopting IT with the proposed certification requirements. HIMSS collaborates with The Data: Elemental to Health Campaign to promote data modernization. The members of the campaign have invaluable expertise and experiential learning to share with ASTP/ONC. HIMSS would welcome the opportunity to facilitate engagement between ASTP/ONC and these important subject matter experts.

Sustainable funding is the most important key to widespread adoption and use of these certified modules in public health settings. Creating the appropriate public health IT infrastructure baseline to support public health information exchange across all public health jurisdictions is critical to improving public health response and strengthening public health's ability to provide critical insights to decision-makers. In HIMSS's [Public Health Information and Technology Infrastructure Modernization Funding Report](#), HIMSS estimates that the nation's state, local, and territorial public health agencies would require an investment of over $36 billion dollars over the next ten years to have the infrastructure (hardware, software, interoperability, staffing, and sustainability) needed to accept the data elements required for reporting by the Promoting Interoperability Program in a standardized, FHIR-enabled manner (along with supporting other critical public health functions.) HIMSS continues to encourage HHS and the underlying agencies to invest in data modernization and encourage state and local PHAs to improve capabilities to electronically receive data from hospitals and providers.

HIMSS has a suite of digital health [maturity models](#), packages of on-sight assessments, consultancy, and advisory services through the [Digital Health Technology Partners Program](#) (DHTP), and an enterprise-wide digital health assessment of an enterprise's governance and workforce, analytics capability, interoperability, and person-enabled health tools (the [Digital Health Indicator](#)) to aid PHAs (and all healthcare delivery sites) in achieving the digital maturity required to maximize a PHA's ability to receive, analyze, and leverage data to improve public health.

Finally, HIMSS encourages ASTP/ONC to adopt provisions in certification that allow public health agencies who have adopted more advanced standards than what is required in the certification to continue to use the advanced standards. For example, one HIMSS public health constituencies noted that their state utilizes an advanced IHE standard and implementation guide for the transmission of syndromic surveillance data. The proposed rule would require that state, if they sought the adoption of certified IT modules, to utilize

secure FTP, a version which they consider to be significantly less effective than the IHE IG currently in use.

APIs for Payers

HIMSS supports the intent of the CMS Final Rule requiring payers to adopt standards and specifications to support payer-to-payer, payer-to-provider, payer-to-patient, and prior authorization information exchange. The technical specifications and standards proposed in the proposed rule support these mandated functions.

As noted earlier in the letter, the proposed implementation timelines present challenges for the industry. HIMSS comments that, for example, Bulk FHIR v2.0 has not been effectively tested with payer data use cases. HIMSS recommend ASTP/ONC focus on high value use cases for the adoption of these APIs by payers. Based on HIMSS member feedback, payer to provider and payer to payer functionality are heavily demanded, while patients rarely access their claims data history. There is an opportunity for ONC/ASTP to stagger adoption requirements to help pace the industry during rapid change, and staggering implementation deadlines to focus on payer-to-provider and payer-to-payer first would create the most value for partners in the healthcare ecosystem for inclusive language (individuals impacted) interested, affected, relevant parties impacted, collaborators.

HIMSS notes that the deadline for certified health IT being used in clinical settings to adopt the standards and specifications to receive and exchange data with payers doesn't go into effect until January 1, 2028. As proposed, payers are required to adopt the same standards and specifications January 1, 2027. HIMSS recommends ONC revise the proposed implementation deadline to January 1, 2028, to align with the standards and specifications being used in clinical settings.

HIMSS also notes that only payers impacted by their participation with CMS programs (Medicare Advantage, state Medicaid and CHIP programs, etc.) are required to adopt these standardized APIs. Specifically, "Prior Authorization API 170.315(g)(34) is required for all eligible hospitals and clinicians, but is only required for adoption by impacted payers, specifically payers who support Medicare Advantage, state Medicaid and chip programs, etc. We have heard concerns that including Prior Authorization API provider in the "Base EHR" when some providers may not engage these impacted payers and would not utilize the functionality and would represent a cost and implementation burden with no value. Instead, HIMSS recommends ASTP/ONC make Prior Authorization a modular functionality and consider adding Prior Authorization (g)34 to the Base EHR definition once the standard has been more widely adopted by the payer community.

Staging Updates to the ONC Certification Program and Improving Sub-regulatory Guidance

During the development of public comments from HTI-2, many eligible hospitals and eligible clinicians expressed concerns regarding the volume of new certification requirements and the resources, cost, and effort for compliance by hospitals and providers to make the required updates. The number of mandated changes to certification in back-to-back rulemaking cycles puts health systems and providers in constant state of customizations and updates for health IT systems and modules to the extent that they are reporting struggles to really create efficiencies and innovate care

delivery. Many healthcare leaders, particularly those from smaller health systems, commented that they are struggling to bring the resources to bear to be compliant with the number of systems updates and new requirements mandated through HTI-1, and HTI-2 will require another resource-heavy update to their systems in 2028. HIMSS has concerns that patient care will suffer at the expense of compliance.
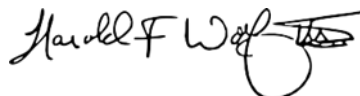
HIMSS makes two recommendations to ASTP/ONC to mitigate the concerns of end-users regarding the health IT certification program.

1. HIMSS recommends ASTP/ONC commit to a regular cadence for producing updates to the ONC Certification Program. These updates should, at minimum, only occur every two calendar years. Once final rulemaking has been published, EHs, CAHs, and ECs should have at least two years to implement the required changes.
2. End-users struggle to understand the impact of proposed certification updates will impact their resources and workflows. HIMSS calls for ONC to convene a group of end-users to develop end-user friendly sub-regulatory guidance for implementing the latest changes to certification. This group should include end-users from diverse clinical settings, including large and small health systems and a variety of distinct types of physician practices, along with market suppliers subject to certification. The end-product of the group would be to produce a standardized "playbook" for end-users to comply with certification changes, including details on the resources required, timelines, cost, and impact on clinical workflows.

We look forward to discussing these issues in more depth. Please feel free to contact Jonathan French Senior Director of Public Policy and Content Development, or David Gray, Director of Government Relations, with questions or for more information.

Thank you for your consideration.

Sincerely,

Harold F. Wolf III, FHIMSS
President & CEO