Micky Tripathi, Ph.D., M.P.P.
National Coordinator
U.S. Department of Health and Human Services
Washington, DC 20201

Dear Dr. 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: Certification Program Updates, Algorithm Transparency, and Information Sharing (HT1-1 RIN 0955–AA03.) 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 the Office of the National Coordinator 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, stakeholders, 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 is in Rotterdam, The Netherlands and our Americas headquarters is in Chicago, Illinois.

For our public comment, HIMSS offers the following thoughts and recommendations on the NPRM. HIMSS is advocating for a one-year delay for the implementation of all new certification requirements other than criterion for Decision Support Interventions (DSI), which we are recommending delaying two years. HIMSS supports the advancements to nation-wide interoperability that the proposed certification criterion and Insight's Reporting Program will facilitate. However, implementing these new criteria in a rushed manner presents risks.

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 careful consideration, HIMSS recommends changing the deadline of December 31, 2024, for incorporating the complete set of new and revised certification criteria. The Office of the National Coordinator's proposed date 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 acting in good faith to be penalized by the Promoting Interoperability Program because of insufficient implementation time due to cascading delays associated with standards development, vendor implementation timelines, and staffing shortages that are impacting the whole community. Such a scenario would be more likely to negatively impact end-users who care for underserved and underinsured communities.

HIMSS also calls on ONC to weigh the impact on healthcare sectors that are vital components to interoperability yet are poorly positioned to take on additional cost and regulatory burden, including behavioral health, long-term post-acute care, community organizations that address health-related social needs, and public health, to ensure those organizations are fully incorporated into an interoperable care delivery ecosystem.

In addition, HIMSS has concerns with proposed changes to certification that haven't been fully addressed in the proposed rule. Many of the new data elements required for capture, particularly associated with social determinants of health, are particularly sensitive. Appropriate real-world testing is needed to ensure their security. There is a lack of consensus on how to ensure end-user and third-party cooperation with meeting certification reporting requirements, particularly associated with DSI source attribution and risk mitigation. There is a lack of consensus about the methods for facilitating data segmentation to ensure patient choice for how their data is shared. The proposed deadline shift should be utilized to start implementing new certification requirements and to develop consensus-based, standards-driven solutions to address these challenges.

In summary, in addition to more detailed recommendations found below, HIMSS recommends the following implementation timeline:

- Year1 Certification Deadline
    - All certification criterion other than DSI must be implemented in certified Health IT no later than December 31, 2025
    - Insight reporting on Stage 1 certification criterion will kick off in October 2026
    - Move FHIR and Bulk FHIR certification criterion reporting from Year 2 to Year 1 (reporting in October 2026)
- Year 2 Implementation Deadline
    - DSI and Predictive DSI certification criterion must be implemented in certified Health IT no later than December 31, 2026
    - Insight reporting on Stage 2 (DSI/Predictive DSI) Criterion will kick off in October 2027

Comments on USCDI V3 and other new and revised Certification Criteria

USCDI V3 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 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 v3 and future versions into CEHRT.

However, during discussions with our membership, HIMSS has learned that two significant challenges exist, which make a December 31, 2024, implementation deadline of USCDI v3 for all certified modules across the United States in a safe and effective matter very challenging. Based on feedback from our membership, HIMSS is concerned that incorporation of USCDI V3 into CEHRT and implementing these data into clinical workflows will require additional time beyond the deadline posed by ONC in the NPRM. Because this is the first update to USCDI since the 2015 certification edition, HIMSS supports a modest delay of the implementation of certification criteria. HIMSS recognizes that ONC published USCDI v3 in July of 2022 and encourages ONC to work closely with SDOs, market suppliers, and other partners to ensure the HL7 US Core Implementation Guide is updated in in a timely manner. HIMSS applauds ONC's ONDEC system, which provides a transparent, predictable, and collaborative process to expand USCDI and is provides the industry with sufficient visibility to upcoming USCDI elements. HIMSS recommends putting mechanisms in place so that future updates can be accomplished within one year after requirements are formalized.

In addition, USCDI v3 includes many data elements often considered sensitive, such as social determinants of health, sexual orientation, and gender identity. Sharing of such data without guardrails can pose significant patient safety issues for some individuals.

Accordingly, HIMSS recommends a December 31, 2025, deadline for the adoption of USCDI v3. HIMSS feels this delay is appropriate to ensure a thoughtful, complete, and realistic implementation cycle for all healthcare providers utilizing certified Health IT and will facilitate the real-world testing and appropriate activities needed to develop and implement granular data segmentation techniques to protect sensitive data elements. In addition, these deadlines should align with CMS new compliance activities to minimize implementation and compliance burdens and re-work.

Please note, HIMSS recommendation of a modest delay is to accommodate the volume of work required to fully develop, implement, and test these certification changes across the healthcare ecosystem successfully, without risks to quality, safety, and patient privacy. HIMSS recommends the healthcare community initiate the work to implement certification changes as soon as the final rule and the appropriate implementation guides are published.

Finally, HIMSS is concerned about the potential lack of alignment for certification with the transition of CMS quality reporting programs to using digital quality measures (dQMs) in the future. The proposed rule does not indicate a pathway to the adoption of USCDI+ in future iterations of certified Health IT. 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 V3 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.

HL7® CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide, Release 3 – US Realm (C-CDA Companion Guide R3)
HIMSS supports the proposal to adopt the HL7 CDA R2 Implementation Guide as outlined in the NPRM, with a revised implementation deadline of December 31, 2025.

New Versions of Minimum Standard Code Sets
HIMSS generally supports the updating of code sets to newer versions and encourages ONC to align updates with the USCDI process. In alignment with HIMSS recommendation for a USCDI v3 implementation deadline of December 31, 2025, HIMSS recommends the same deadline for code set updates.

Adoption of consensus-based, industry-developed electronic standards and implementation guides (IGs) for Electronic Case Reporting
HIMSS supports the adoption of consensus based, industry developed electronic standards and implementation guides for Electronic Case Reporting to state, local, and territorial public health entities. HIMSS recommends the adoption of the Electronic Case Reporting criterion with an implementation deadline of December 31, 2025. HIMSS notes, the industry made great strides in implementing electronic case reporting during the pandemic and hopes ECR will be one of the first new criteria to be rolled out in new implementations of the certification package.

In addition, HIMSS strongly encourages ONC to collaborate with other federal agencies and Congress to address the infrastructure gap in Health IT for many state, local, and territorial public health agencies. We are encouraged by the work by ONC and CDC to develop a North Star Architecture and work with a broad range of stakeholders through the Data Modernization Consortium meetings. The resulting dialogue has created a much more workable environment, which is fostering greater coordination across the healthcare ecosystem.

As demonstrated by the pandemic, there is little value in requiring health systems and providers to have the capability to transmit electronic case public health data if their public health partners do not have the capability to receive the data electronically, use health IT tools to analyze the data, and share their insights with clinical leaders to drive effective public health response. HIMSS has published a funding recommendation to modernize public health information technology infrastructure at a state and local level, with an estimated cost of approximately $36.7 billion over ten years, with investments split between providing state, local, and territorial agencies the hardware and software required and the sustainable funds to build the public health workforce and subject matter expertise to sustain the modernization efforts.

Standardized API for Patient and Population Services
HIMSS supports this proposal to align with general industry standards. HIMSS recommends the deadline for implementation should be December 31, 2025, to allow for proper testing and evaluation.

FHIR US Core Implementation Guide STU version 5.0.1/ US Core IG v6 if published before the Final Rule
HIMSS supports the adoption of FHIR and US Core. However, the industry should have adequate time to test and implement v6 to ensure a successful implementation, especially with concerns regarding ensuring the protection of sensitive data elements. HIMSS strongly recommend that US Core IGv6 should be added, at minimum, one full regulatory cycle after publication. With the publication of US Core IG v6 in spring of 2023, HIMSS recommends a December 31, 2025, deadline for implementation of US Core v6.

Publishing service base URLs for Certified API Developers with patient-facing apps
HIMSS supports this proposal, noting earlier recommendations that the timeline for industry to make this update and others should be December 31, 2025, for the adoption of new and updated certification criteria.

SMART v2 Guides Standard
HIMSS supports this proposal and recommends adopting the current release SMART v2.1. Noting earlier recommendations, the timeline for industry to make this update and others should be December 31, 2025, for the adoption of new and updated certification criteria.

Patient Demographics and Observation
HIMSS recommends aligning this requirement with the USCDI v3 process and implementation deadline. As noted earlier in our public comments, this deadline should be December 31, 2025, for the adoption of new and updated certification criteria.

Replace Sexual Orientation and Gender Identity Code Sets with SNOMED CT code set on December 31, 2025
HIMSS supports the proposal to replace Sexual Orientation and Gender Identity code sets with SNOMED CT to provide adequate time for health IT systems to transition to the updated terminology standards. HIMSS notes that industry will need similar time to transition to other proposed recommendations. HIMSS recommends the implementation deadline for the SNOMED CT sexual orientation and gender identity code set be scheduled for December 31, 2025.

Add Sex for Clinical Use" (SFCU), "Name to Use" and "Pronouns"
HIMSS supports the inclusion of SFCU criterion to certification. HIMSS recommends aligning the SFCU criterion with the recommended USCDI v3 implementation timeline of December 31, 2025.

Patient Requested Restrictions Certification Criterion
HIMSS believes it is critical to protect the confidentiality, integrity, and availability of patient information and other sensitive information and assets of stakeholders while ensuring the continued and effective delivery of patient care and coordination of care.

Without appropriate privacy mechanisms, sensitive data elements could trigger unwarranted engagement with other entities.

ONC policy must identify a method to ensure the safe exchange of potentially sensitive personal health information in a manner compliant with HIPAA, using a rule based, standardized approach that eliminates manual and costly data segmentation exercises.

HIMSS recommends ONC convene the industry through connectathons and other consensus driven methods to develop prioritized use cases, and a rules-based method for segmenting data to ensure patient privacy while minimizing the costly burden manual data segmentation of patients requesting restrictions places on the industry.

Updated "Transitions of Care" Certification Criterion
HIMSS supports the proposed change of the Transitions of Care certification criterion to ensure that certified Health IT Modules can access, exchange, and use USCDI v3 data elements. However, as noted earlier in the comments, the USCDI v3 data elements will require additional time to implement because of the need for additional testing and the development of the appropriate safeguards for sensitive personal health information. HIMSS recommends ONC change the implementation deadline for USCDI v3 and the change to the Transitions of Care certification criterion to December 31, 2025.

Comments on Decision Support Interventions (Clinical Decision Support Criterion for Certification)

Definition of "Decision Support Interventions"
Core to the HIMSS mission is promoting the use of health information and technology to improve the quality of healthcare delivery through effective performance measurement and decision support. HIMSS believes that the use of digital health information can and should be utilized to identify gaps in care, optimize clinical care delivery, and improve patient outcomes. As a foundation for any regulatory oversight for clinical decision support, HIMSS strongly recommends that all CDS technologies support "the CDS Five Rights,"

1. The right information
2. To the right person
3. Via the right CDS intervention format
4. Through the right channel
5. At the right point in workflow

HIMSS defines clinical decision support as, "a process for enhancing health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery." Numerous technologies fall under this broad definition. Information recipients can include patients, clinicians, and others involved in patient care delivery; information delivered can include general clinical knowledge and guidance, intelligently processed patient data, or a mixture of both; and information delivery formats can be drawn from a rich palette of options that include data and order entry facilitators, filtered data displays, reference information, alerts, and others.

ONC is proposing to adopt a new terminology and definition for clinical decision support, namely "decision support interventions" or DSI. ONC is defining DSI as, "Technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis." HIMSS feels the inclusion of "algorithms" in the definition of DSI potentially adds more clinical decision support mechanisms than intended by legislative and regulatory scope, creating confusion in the marketplace. HIMSS recommends ONC refine DSI's definition by removing "algorithms" to limit scope specifically to decision support driven by models using example data.

DSI Criterion Implementation Timeline

Accuracy of clinical decision support tools is negatively impacted by rushed implementation timelines. As noted below when discussing the Real-World Testing component of the DSI criterion, current challenges in the healthcare ecosystem limit the available resources required to implement new clinical decision support functionality while not adversely impacting clinical care workflows and other processes. In cases of infrequent substantive changes, the industry normally requires a minimum of 18 months from the moment that newly required standards, specifications, and code sets are available to implement a new regulatory requirement in technology. The scope of these proposed changes is substantial and requires more than the usual time to implement a substantive change.

Given the wide-ranging changes, the current lack of standards-based method for collecting and presenting source attribution updates from third parties and end-users, and the additional time required to work with end users to change workflows to meaningfully utilize these new functionalities, HIMSS believes DSI will need more time to safely implement DSI and predictive DSI criterion than the other proposed components of certification. HIMSS recommends that the Office of the National Coordinator shift to a December 31, 2026, implementation deadline for implementing the criterion related to the adoption and use of decision support interventions and predictive decision support interventions. This recommendation allows for robust field testing, the safe implementation of both the criterion and new workflows required to accommodate the new requirements.

Source Attributes and User Feedback

The accuracy and credibility of the information provided in decision support interventions are critical in successful adoption of those tools in clinical workflow. At a high level, HIMSS supports ONC's desire to improve transparency by requiring the publication of source attributes for decision support interventions as part of certification.

However, the broad definition of decision support interventions proposed by ONC creates significant potential areas of confusion. Most notably, many of the decision support interventions currently in use by healthcare delivery sites are created by end users or by third-party market suppliers who may or may not be subject to certification requirements. In addition, while market supplier EHRs may have specific decision support intervention functionality, end-users often use their own data, clinical best practice guidance, and other drivers to optimize algorithms driving the decision support interventions provided by the market supplier.

These realities raise significant questions-

1. What mechanism exists to ensure that end users and/or third parties market suppliers provide the appropriate source attribution information? This is a significant issue because currently, even federal agencies like the CDC don't always provide source attribute information for recommended best practice guidance supporting care pathways and order sets.
2. How will end-user and/or third-party market supplier submitted source attributes be validated? Who ultimately has liability if bad actors submit source attributes that generate guidance inconsistent with clinical best practices?

For HIMSS recommended DSI criterion implementation deadline of December 31, 2026, we request ONC limit source attribution requirements specifically to decision support interventions provided by the certified Health IT developer, while exempting the certified developer from capturing end-user and third-party source attributes. HIMSS recommends ONC leverage its power to convene the industry to develop a consensus-based, standardized approach for identifying the required elements and method of capture for source attributes.

In addition, HIMSS recommends ONC conduct feasibility testing regarding the implementation of a user interface for decision support interventions to provide feedback. Over the years, a primary pain point with the adoption of clinical decision support has been the increased occurrence of alert fatigue. An extra click, especially when said click is not associated with clinical workflow, is disruptive. Decision support interventions must be designed to be impactful on the delivery of care, without negatively impacting clinical workflow to the point where clinicians start to circumvent the clinical guidance. The perceived value of the clinical guidance being provided must be complimented with a high degree of usability.

Real World Testing and DSI

One of the greatest challenges to federal regulatory oversight of health information technology, including decision support interventions/CDS, is the lack of participation in real world testing initiatives for regulatory-driven requirements. For example, in the 2024 IPPS proposed rule published in April 2023 by the Centers for Medicare and Medicaid Services, each of the proposed new clinical quality measures had only been field tested at twenty or fewer healthcare delivery sites and using a small sample of the available certified health IT products available in the industry. While there are only a handful of electronic health record vendors in the marketplace, health systems, hospitals, and providers often have unique configurations despite using the same electronic health record. As result, there is significant variation in clinical documentation workflows from one EHR to another and from one healthcare organization to another. Field testing a more diverse and larger cohort of care delivery sites is critical to ensure safe and reliable clinical decision support functionality when implemented.

This is endemic to a larger issue; healthcare delivery sites are not incentivized properly to participate in real world testing. Real world testing of clinical decision support functionality is a multifaceted process requiring significant resources with complementary skill sets including clinical guidelines, CQL, data and terminology standards, Clinical/EHR workflows, data capture, mapping to local codes and data quality. Participation in testing is costly, labor intensive, and has very little return on

investment for the participating health system. As a result, most hospital participation in testing programs comes from large, well-resourced organizations that may not reflect the configurations and support capabilities of all care delivery settings and providers.

Addressing the need for more robust and diverse participation in testing will be critical for the new DSI criterion. In addition to extending the implementation deadline to December 31, 2026, for all decision support interventions criterion to accommodate more robust field testing to ensure safe implementations of the new criteria, HIMSS recommends that ONC collaborate with the Centers for Medicare and Medicaid Services and other federal partners to take the following actions:

1. Ensure that the testing cohort for the DSI criterion include a significant sample size, including large and small hospitals, untethered ambulatory care networks, federally qualified community health centers, and other care delivery sites across a wide geographic and patient demographic spectrum.
2. Provide a significant scoring bonus for hospitals and providers participating in testing in the Inpatient Quality Reporting program, the Merit Based Incentive Payment System (MIPS) program, and other value-based care reporting programs in the federal ecosystem. This heightens critical access, rural, and community hospitals opportunities to receive incentive program dollars.

"Insights"- Comments on the proposed ONC EHR Reporting Program

Multiple Numerators and Denominators for Insight's Measures
For the EHR Reporting Program, five of the nine measures in the proposed rule have "options" for the numerator and/or denominator. HIMSS presumes that the specific options offered for both the numerator and the denominator are designed to help ONC and the market better understand how information is being exchanged, shared, and used. For example, numerator and denominator options in the proposed Individual Access to Electronic Health Information Supported by Certified API Technology Measure will help ONC and the market better understand patient behavior and preferences. Specifically, the numerator options will allow ONC to parse utilization data into the three primary avenues for accessing electronic health information (EHI.) HIMSS supports ONC's proposal to all numerator and denominator options for all Measures with multiple numerators and/or denominators.

Adoption of FHIR and Bulk FHIR Timeline
In the proposed rule, ONC proposes that the adoption and reporting of the use of the FHIR and Bulk FHIR standards should be adopted in Year two of the Insight's Program (October 2026 reporting period.) With HIMSS recommending that the implementation of new certification criteria other than DSI be completed by December 31, 2025, HIMSS recommend that FHIIR and Bulk FHIR be moved to Year 1 of Insight's reporting, which would, under HIMSS recommendation, initiate in October 2026.

Comments on Information Blocking
HIMSS supports the proposed definition of "Offer Health IT" as any individual or entity that under any arrangement makes certified health IT available for purchase or license, even if they are not responsible for certifying the HIT, will "offer HIT." HIMSS agrees that healthcare providers or third parties that offer self-developed software to others should meet the same regulatory requirements directed to health IT developers.

HIMSS members have raised concerns that the Infeasibility Exception requirement mandating the actor provides the reason for a request being infeasible within 10-business days. The HIMSS Electronic Health Record Association indicates that there may be some additional time needed to exhaust potential options when the requested manner can't be accommodated. Accordingly, HIMSS supports the EHRA recommendation that the policy be revised to indicate that the10-business-day timeframe for responding to the requestor should begin once the actor has received sufficient information to fulfill the request.

Discontinuing Yearly Editions

HIMSS supports the transition away from year themed editions of certifications to one set of certification criteria, in agreement with the justification provided by ONC. However, while HIMSS feels regular progress is important, update cycles must be tied to real-world conditions such as standards availability, business and economic challenges, and provider capacity to implement upgraded technology. The cadence for making changes to current criteria must align to the normal standards development cycle.

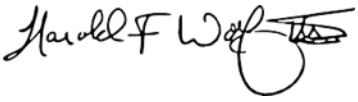
Accordingly, HIMSS recommends that, once the requirements for certification and the corresponding Insight's EHR reporting program go-live, ONC should establish a regular cadence for certification updates that allows market suppliers to implement the required changes safely and effectively. As noted above, most industry testing and development cycles need a minimum of two years, and in some cases like DSI, 3-5 years.

In addition to updates being on a regular cadence with at least a two-year gap, HIMSS also recommends ONC establish a regular cadence as an appropriate timeline for market suppliers to implement required changes in certification. For example, if new criteria are finalized in 2026, these criteria should not be required until at least 2028.

We look forward to the opportunity to discuss 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
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