June 19, 2023

Micky Tripathi, National Coordinator for HIT
Office of the National Coordinator
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0955-AA03; Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

Submitted electronically via http://www.regulations.gov

Dear Mr. Tripathi,

Trinity Health appreciates the opportunity to comment on policies set forth in the proposed rule. Our comments and recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 123,000 colleagues and more than 26,000 physicians and clinicians caring for diverse communities across 26 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 135 continuing care locations, the second largest PACE program in the country, 136 urgent care locations and many other health and well-being services. Trinity Health has 15 medical groups with 1,324 primary care providers and 4,193 specialty care providers. Based in Livonia, Michigan, its annual operating revenue is $21.5 billion with $1.4 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 17 Clinically Integrated Networks (CINs) that are accountable for approximately 2 million lives across the country through alternative payment models. Our health care system participates in 14 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes eleven markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. All of these markets participated in the "enhanced track", which qualifies as an advanced alternative payment model (AAPM). Two of the 14 markets also participate in CPC+. In addition, we have participated since 2014 in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative and the Comprehensive Care for Joint Replacement (CJR) program across 37 hospitals. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

Editions terminology
ONC proposes to discontinue year-themed editions and establish a single set of certification criteria, renaming all certification criteria within the Program simply as "ONC Certification Criteria for Health IT."

Trinity Health supports this proposal and agrees it will further institutionalize the EHR certification program.

Applicability and Expiration Timelines for Certification Criteria and Standards
ONC proposes to establish dates by which a prior version of a criterion is no longer applicable when a new, revised, or updated version of that criterion is adopted. ONC also proposes to establish applicable timelines, including expiration dates, for the adoption of standards when a new, revised, or updated version of the standard is adopted for the same purpose.

Trinity Health supports this proposal and recommends ONC finalize.

New and Revised Standards Criteria
USCDI is the standard for data required to be accessible through certified health IT for numerous certification criteria, expanding the data elements and data classes included in the USCDI increases the amount of data available to be used and exchanged for patient care. To advance interoperability, ONC proposes to add USCDI v3 to the regulation, proposing that the USCDI v1 expire on January 1, 2025 and both versions be referenced as applicable in the USCDI standard for the time period up to and including December 31, 2024.

Trinity Health supports this proposal and urges ONC to finalize.

Patient Restriction Criterion
The proposed rule includes several policies in support of the HIPAA Privacy's Rule's individuals' "right to request a restriction" on certain uses and disclosures of their PHI, including proposals to:
- Adopt a new certification criterion
- Add to ONC's Privacy and Security Certification Framework under the Program (add the proposed new criterion and require it by Jan 1, 2026, or 24 months after the effective date of the final rule)
- Revise existing criterion to support additional tools for implementing patient requested information privacy restrictions

It is imperative for providers to have complete medical histories for patients to coordinate care and provide the most effective treatment. Further, it is critical that population health entities, such as accountable care organizations (ACOs), have access to patient medical records. ACOs and coordinated care models are held accountable by CMS for coordinating care and outcomes of beneficiaries and they cannot do this without access to full patient data. Understanding a patient's full health and access is key to supporting a comprehensive patient-centered care plan that improves outcomes for overall health and experience of care.

If this provision is finalized, HHS should ensure patient restriction criterion aligns with requirements finalized for HIPAA.

Information Blocking, Manner Exception: Trusted Exchange Framework and Common Agreement (TEFCA) Condition
ONC proposes to add a TEFCA condition to the proposed revised and renamed Manner exception. The TEFCA condition would offer Qualified Health Information Networks (QHINs), participants, and subparticipants in TEFCA the ability to fulfill EHI request from and QHIN participant, or subparticipant using TEFCA means, even if the requestor would have preferred to use another means.

Trinity Heath supports this proposal as it would recognize and support actors that adopt and comply with the Common Agreement by providing certainty and burden reduction for those actors when it comes to information blocking and requests for access, exchange, or use of EHI by QHINs, Participants, or subparticipants.

Conclusion
We appreciate ONC's ongoing efforts to implement the Cures Act. If you have any questions on our comments, please feel free to contact me at jennifer.nading@trinity-health.org.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health