ADA American Dental Association®

1111 14th Street, N.W.
Suite 1200
Washington, DC 20005

T 202.898.2400
F 202.898.2437
www.ada.org

June 20, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
330 C Street SW
Washington, DC 20201

Re: RIN 0955–AA03, Proposed Rule, Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing.

Dear Secretary Becerra:

On behalf of the 159,000 members of the American Dental Association (ADA), we are pleased to provide comments on the Proposed Rule on Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing. The ADA commends HHS and ONC for continuing to promote interoperability to facilitate the exchange of information between providers, patients, and payers. We recognize that the work of the Office of the National Coordinator for Health Information Technology (ONC) has been vital in the progress that has been made in achieving healthcare interoperability and transforming health information access and exchange.

ADA thanks HHS and ONC for its helpful proposals in this rule, most importantly moving to US Core Data for Interoperability (USCDI) Version 3 and adopting the Code on Dental Procedures and Nomenclature, or Current Dental Terminology (referred to as CDT throughout the rest of these comments) among minimum standards and code-sets in the Certification Program. ADA urges HHS and ONC to remember the crucial importance of adopting standards that are compatible with dentistry. Further, while the ADA supports ONC certification for dental vendors, most dental practices use electronic dental records and practice management systems that are unlikely to be ONC certified. Thus, connecting changes in standards to the ONC Certification Program would not benefit dental providers, nor remove barriers to the exchange of dental clinical or administrative data.

The absence of dental subject matter experts on the HIT Advisory Committee (HITAC) has created an advisory environment which fails to consider and address the needs of the dental sector. While no changes to HITAC are proposed here, we believe that the 21st Century Cures Act (P.L. 114-255) sections (d)(2)(b) and (d)(3), under which HITAC was established, clearly intend to ensure inclusivity among all healthcare sectors. **The ONC and HITAC have a responsibility to acknowledge the gap in subject matter expertise and to work with industry stakeholders to identify opportunities within the nomination and selection process for dental inclusivity.**

<u>Minimum Standards Code-Sets Updates</u>
§ 170.207(a)—Problems

We propose to remove and reserve § 170.207(a)(3), IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release. We propose to revise § 170.207(a)(1), which is currently reserved, to reference SNOMED CT US Edition March 2022 and incorporate it by reference in § 170.299.

• § 170.207(d)—Medications (pg 23768)
We propose to revise § 170.207(d)(1), which is currently reserved, to reference RxNorm July 5, 2022, Full Monthly Release and incorporate it by reference in § 170.299. We propose to reference the code sets specified in 45 CFR 162.1002(c)(1) which include International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM); International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) (including The Official ICD–10–PCS Guidelines for Coding and Reporting); National Drug Codes (NDC); the combination of Health Care Financing Administration Common Procedure Coding System (HCPCS), as maintained and distributed by HHS, and Current Procedural Terminology, Fourth Edition (CPT–4), as maintained and distributed by the American Medical Association, for physician services and other healthcare services; Health Care Financing Administration Common Procedure Coding System (HCPCS) as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in healthcare services; and Code on Dental Procedures and Nomenclature, in § 170.207(d)(4).

ADA strongly supports this proposal to make CDT a minimum standard code-set. CDT is the only code set used in dentistry to document and report dental procedures. The CDT is a HIPAA-named standard and is mandated for use by dental providers and payers for dental claims. CDT is also the only code set used to document dental procedures that have been performed on patients in a dental record.

New and Revised Standards and Certification Criteria
"To advance interoperability, in section III.C.1, ONC proposes to add the newly released USCDI v3 in § 170.213(b)."
The ADA supports updating Certification Program requirements to USCDI Version 3. For "Procedure" data elements, USCDI Version 3 would specify that CDT is the applicable standard for technology developed to record dental procedures. ADA also thanks HHS and ONC for updating USCDI Version 3 so that CDT is no longer preceded by limiting language suggesting that CDT is optional for technology which records dental procedures. This also improves on USCDI Versions which lists CDT as an optional vocabulary standard. Use of USCDI version 1 leads to confusion between the use of the CDT codes that are appropriate for dental procedures and SNOMED codes which are inadequate for dental procedures. USCDI version 2 (and version 3 b) named CDT a vocabulary standard for technology primarily developed to record dental procedures, but is nevertheless often interpreted by certain software vendors to be "optional." ADA believes that CDT is the only appropriate vocabulary standard for dental procedures and should be present to accurately represent dental clinical procedures in all health information technology.

The inclusion of dental terminology and standards will promote our shared goals of a robust interoperable health information technology landscape through acknowledging the differing needs of dentistry and medicine.

Decision Support Interventions and Predictive Models

Artificial Intelligence (AI) and Augmented Intelligence has been used in the dental industry for several years, and its use is expanding in dental practice. Integrating AI and augmented intelligence in dental practices can assist in clinical and administrative functions including:

- Image analysis and assisted diagnosis;
- Treatment planning and prosthesis designing;
- Robotic and automation;
- Virtual reality and augmented reality;
- Claim processing; and,
- Data analysis and predictive analytics.

ADA's Standards Committee on Dental Informatics (SCDI) recently developed a white paper, "Overview of Artificial and Augmented Intelligence Uses in Dentistry."[1] SCDI is in the process of developing two new standards regarding "Image Analysis Systems" and "Validation Dataset Guidance for Image Analysis Systems using Artificial Intelligence." The ADA is also developing the U.S. position for the first international standard on AI and augmented intelligence in dentistry, ISO 18374 Dentistry – Artificial intelligence (AI) based 2D X-ray analysis — Data generation, data annotation and data processing.

Given ADA's attention to, and standards work on, AI and augmented intelligence in dentistry,[2] the ADA welcomes ONC's work to improve transparency to enhance the trustworthiness of "predictive DSIs," or decision support interventions, defined 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." As always, ADA would call attention to the specific needs of dentistry and the specific uses DSIs in dentistry. ADA's white paper on AI and augmented intelligence provides the best available information as of early 2022 on AI available in dental imaging and other areas of dentistry where imaging may impact the use of AI (or vice versa). Currently, the primary use of DSI in dentistry is in the analysis of dental images to assist clinicians in diagnosis, and ADA's white paper details how DSIs might be used for dental image analysis.

ADA commends HHS and ONC's efforts in this proposal to increase transparency of DSIs by requiring reporting on how DSI is designed, developed, trained, evaluated, and should be used, as well as its promotion of DSI in ONC Certified Health IT that is fair, appropriate, valid, effective, and safe (FAVES). **Data privacy and security, ethical considerations, interoperability and integration, and training and education are priorities for ADA as it develops standards for AI and augmented intelligence, and ADA urges that ONC continue to prioritize these concerns as it encourages the development of FAVES DSI. ADA would also remind HHS and ONC that more may need to be done to incentivize dental vendors to develop DSI that is FAVES, as dental vendors are generally not pursuing ONC Certification**.

FHIR United States Core Implementation Guide Version 5.0.1

[1] Dentistry — Overview of Artificial and Augmented Intelligence Uses in Dentistry

[2] In addition to the above white paper, the Journal of the American Dental Association (JADA) has published a series of articles: How Artificial Intelligence Works In Dentistry.

"Health IT systems that adopt the latest version of US Core can therefore provide the latest consensus-based capabilities for providing access to USCDI data classes and elements using FHIR APIs."

The ADA applauds HHS and ONC's efforts to promote the adoption of FHIR-based APIs and has worked closely with Health Level 7 (HL7) to develop dual Clinical Development Architecture (CDA) and FHIR implementation guides. The ADA is also working with several HL7 workgroups on developing the dental content in various FHIR standards. **ADA strongly supports incentives and significant investment in dental-specific FHIR-based pilots and technology to move the dental industry towards FHIR-based APIs for real-time exchange.**

Next Steps

We would like to thank HHS and ONC once again for its commitment to interoperability, and for the proposals in this rule that acknowledge the importance of adopting standards that are compatible with dentistry. Requiring USCDI Version 3 for ONC's Certification Program and adopting CDT as a minimum standard code set are big steps towards the inclusion of the dental industry in the progress of the medical industry.

As HHS and ONC continue to advance interoperability, **we urge you to continue the encouraging efforts to expand domain-specific datasets through USCDI+ as these are vital for public health reporting and alignment of quality measures across entities.** America's dentists have been committed to pursuing coordinated, meaningful, and parsimonious measurement through the Dental Quality Alliance (DQA), convened by the ADA at the request of CMS. DQA is the only comprehensive multi-stakeholder organization in dentistry that develops dental quality measures through a consensus-based process. Thirty-eight organizations with oral health experience participate in the DQA along with a public member. **ADA would welcome a partnership with ONC to ensure that tested measures and datasets developed by the DQA are implemented within the USCDI+ program.**

We also would urge the ONC to work with other federal offices such as the Centers for Medicare and Medicaid Services (CMS) and the Bureau of Primary Health Care to identify a roadmap for alignment of measures and reporting as a key element which will advance dental interoperability and data exchange. As it stands, dental vendors have no obligation or incentive to use FHIR-based standards and there has been a proliferation of proprietary APIs which are creating data silos and are in direct opposition of the fundamental goals of information blocking mandates. **This proposal, and others focused on adoption of standards and promoting interoperability, will be much more effective for dental data exchange if federal agencies work together to focus on educating, engaging, and incentivizing business partners to facilitate the move toward adoption of the standards discussed in this rule.**

Thank you again for the opportunity to comment on the proposed rule. The ADA looks forward to continuing to work with HHS and ONC. Should you have any questions, please do not hesitate to contact Corey McGee at mcgeec@ada.org.

Sincerely,

George R. Shepley, D.D.S.
President

Raymond A. Cohlmia, D.D.S.
Executive Director

GRS:RAC:cm