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Don Rucker, M.D.
National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street, SW
Washington, DC 20201

RE: RIN 0955-AA01 21st Century CURES Act Interoperability, Information Blocking, and ONC Health IT Certification Program Proposed Rule

Dear Dr. Rucker:

The American Dental Association (ADA) is the world's oldest and largest professional dental association with over 163,000 members. We are a leader in the development, publication, and implementation of interoperability standards in the oral health care setting. The ADA is named in HIPAA as an organization that the Secretary of Health and Human Services (HHS) is required to consult when new or revised standards are being developed. The ADA is also an American National Standards Institute (ANSI) Accredited Standards Development Organization for dental information technology through its Standards Committee on Dental Informatics (SCDI). The SCDI membership consists of a broad range of stakeholder interests, including technology vendors, dental plans, clearinghouses, national dental specialty organizations, practicing dentists, and academics. Among the SCDI's many accomplishments are a data content standard for structured periodontal and orthodontic claim attachments (ADA Standard No.1079), which has been developed into two Health Level 7 Implementation Guides in their Clinical Document Architecture (CDA) base standard. The SCDI also recently completed ANSI/ADA Standard No.1084: Reference Core Data Set for Communication among Dental and Other Health Information Systems, which the ADA hopes to develop in partnership with Health Level 7 into further joint work products designed to fuel dental interoperability across electronic health care technology platforms and care settings.

Most significantly, the ADA continues to maintain its ANSI/ADA Standard No. 2000, Systematized Nomenclature of Dentistry (SNODENT®), a standard that has been recognized as an American National Standard by the American National Standards Institute, and which is a recognized subset of SNOMED CT concepts, with annual updates. SNODENT and SNODENT subsets provide dentists and developers with a standard, structured, clinical terminology that can work independently of platform or care setting to facilitate information exchange. SNODENT also enables data aggregation for quality assessment, quality improvement, and longitudinal studies.

General Comments

The ADA agrees in spirit with the Proposed Rule's stated purpose of implementing new provisions to advance interoperability that supports the access, exchange, and use of electronic health information. New and improved certification criteria for health information technology (health IT) developers can, and should, be used to help drive better information exchange in the health care sector that improves outcomes and lowers the overall cost of health care. Health care providers in general need to be able

to purchase new health IT systems with confidence that those systems will perform as advertised, delivering the necessary interoperability, ease of use, security and privacy.

The ADA has comments that include some areas of concern with the Proposed Rule.

Lack of 2015 Edition Certified Health IT Products

At the time of writing, there were no Dental Electronic Health Record products or modules that had been certified to 2015 Edition Criteria. Although the Dental Software Industry did participate significantly in the creation of 2011 and 2014 Edition Certified Health IT products for use by dentists participating in the CMS Promoting Interoperability (formerly Meaningful Use) programs, they have not certified a single 2015 Edition product since the publication of the 2015 Edition criteria.

Participation in the Office of the National Coordinator (ONC) Health IT Certification is voluntary, and dental IT vendors appear unlikely to certify 2015 Edition products without wider market demand; presently, only about 10% of dentists are eligible to participate in the Promoting Interoperability program; the numbers currently using a 2014 Edition Certified Health IT product are likely somewhat lower. Since, at this time, dental IT developers have not modified any of their products to meet 2015 Edition Criteria, if dental IT vendors were to attempt to bring a product into conformance with the Proposed Rule's Modifications to the 2015 Edition Criteria, then they would be farther behind than their medical IT vendor counterparts, requiring more time than medical vendors to bring products to market.

Unless this situation changes, this will prove a very significant, if not insurmountable barrier to dentists' ability to participate in information exchange. This alone should earn any dentist subject to the Proposed Rule an exemption from Information Blocking provisions that require the use of 2015 Edition Certified Health IT in order to comply.

The language surrounding the "infeasible" exemption from Information blocking provisions would appear to apply, but further clarification surrounding this exemption is necessary in any final rule. Specifically, the clarification should include an exemption for infeasibility where the provider cannot send or receive electronic health information due to the unavailability of Certified Health IT products for the provider's care setting and/or area of specialization.

Inclusion of SNODENT in Modified 2015 Edition Certification Criteria

The ADA also urges the National Coordinator to include the SNODENT terminology standard (ANSI/ADA Standard No. 2000 Systematized Nomenclature of Dentistry) as a criterion in the modified 2015 Edition Criteria. SNODENT will facilitate information sharing between physicians and dentists, should dental system vendors decide to certify their products to the modified 2015 Edition Criteria proposed in this rule, and may help with information exchange via the proposed Certified Application Program Interfaces (APIs) by giving dentists in the Federally Qualified Health Center (FQHC) and hospital settings a means of capturing, and sharing, useful clinical details relevant to the practice of dentistry in those settings.

Electronic Health Information (EHI) Export

The proposed EHI Export criterion at 170.315(b)(10), intended to empower consumers by supporting providers' ability to export a patient's entire health record at the valid request of the patient or a user

on the patient's behalf and to support migration of data when a provider transitions to a different system, is highly commendable and the ADA supports the Export criterion. However, the ADA urges HHS to require testing for performance, security and privacy by an ONC-Accredited Certification Body as a condition of certification of this criterion.

APIs

The ADA does not object to including API criteria in the proposed modified Certification Criteria. The ADA agrees that there is potential for these tools to empower consumers and improve information sharing. The ADA also agrees strongly that health care providers should have sole authority and autonomy to unilaterally permit connections to their health IT through Certified API technology that those health care providers have acquired.

This capability can help alleviate some of the problems dentists face with the lack of 2015 Certified Health IT products for the dental practice setting, as it will help them in obtaining patients' health information from patients themselves or from other health care providers who are able to acquire Certified Health IT with API interfaces. When implemented appropriately, patients will be able to access their health information from their physicians' Electronic Medical Records via API interfaces, and share that information with their dentists, as needed. Likewise, a dentist should be able to use similar APIs to access information from their patients' physicians as well. ADA data content standards, such as ADA Standard No. 1084, and as yet unnamed related joint HL7 work products should be supported by APIs if they are to exchange standard dental content across platforms and care settings.

We do note, however, that dentists may not be able to share information in this manner without access to appropriately Certified Health IT products that can interface with certified API technology. Both the Certified Health IT and APIs will need to be rigorously tested for performance, security and privacy before they are released to the market. The ADA urges HHS to allow sufficient time for development, testing, and certification of APIs.

United States Core Data for Interoperability (USCDI)

The ADA supports adoption of core data standards to support the interoperability of electronic health records in general. Indeed, such interoperability as envisioned by previous legislative and regulatory efforts is not possible without it.

As such, the ADA strongly agrees with the decision to name the US Core Data for Interoperability, or USCDI, as a standard, and also agrees that USCDI can and must be expanded in future versions, particularly to include core data standard sets for dentistry as well.

As noted above, the ADA SCDI recently completed a core reference data content standard for dentistry, ANSI/ADA Standard No. 1084. An investigatory effort is already under way to determine how best to implement ANSI/ADA Standard No. 1084 using Health Level 7 base standards such as HL7 CDA.

The ADA urges HHS to include ANSI/ADA Standard No. 1084, and/or joint ADA/HL7 work products derived from current and future versions of Standard No. 1084, for inclusion in the USCDI at the appropriate time(s). ADA Standard No. 1084 should also be the core content standard for dental information sharing via APIs.

To further support its core reference data standards and ongoing work with HL7 to create implementable data interoperability standards for dentistry and the rest of the US health care continuum, the ADA also urges inclusion of SNODENT in the USCDI at the earliest possible time specifically for dental encounter diagnoses and problems. SNODENT is a subset of SNOMED CT concepts constrained to terminology that is relevant to dentistry for findings, disorders and diagnoses. SNODENT is fully interoperable with SNOMED. SNODENT's inclusion is necessary to bring dental systems, and dentists that use them, into sync with the rest of the health care provider community in the use of interoperable, certified EHRs.

The ADA's Code on Dental Procedures and Nomenclature (CDT) is the appropriate standard to use for identifying dental procedures in the USCDI. The CDT is a federally required code set for dental procedures named in the HIPAA Regulations. SNODENT, as identified in the USCDI procedure data class can remain as an optional applicable standard for procedures, however, CDT should be identified as the required applicable standard for dental procedures. In addition, CDT, as specified in 45 CFR 162.1002 should be the only applicable standard for exchange of data between plans and between plans and patients as noted in our comments to the CMS interoperability proposed regulation (RIN 0938-AT79).
The ADA also urges the ONC to seek the ADA's input when considering adoption of standards impacting dentistry in a direct manner.

Provenance

The ADA agrees that the inclusion of the "Provenance" data class in the USCDI is good and necessary. The inclusion of data provenance is vital for providers to have so that they may understand the source of data shared via APIs, how much trust may be placed in that data (based on author and the date stamp), and whom to contact if they have questions about an item of shared data.

Clinical Quality Measure Reporting

The ADA has no objections to the proposed requirements but reminds HHS that there are no 2015 Edition Certified Health IT products with a dentistry orientation listed on the ONC Certified Health IT Products List (CHPL).

Privacy and Security Transparency Attestations

The two proposed Certification Criteria, (1) Encrypt Authentication Credentials, and (2) Multi-Factor Authentication, appear reasonable and sound in judgment, with one suggestion.

With regard to these criteria, the ADA requests that the ONC Accredited Certifying Bodies (ONC-ACBs) be required to test products before granting certification, instead of allowing health IT vendors to merely attest that their products meet these criteria. This will slow the certification process down, no doubt, but will ensure that these products *actually provide necessary security and privacy*, instead of inviting deception, which would leave clients and consumers to deal with the aftermath (and costs) of the inevitable breaches. The ADA would like to see that some of that inevitable cost to the public invested in more rigorous, careful software development and testing, along with a higher bar for certification rather than a lower bar that will invite greater security problems than those we have at present.

Health IT and Opioid Use Disorder Prevention and Treatment-Request for Information

Prescription drug monitoring programs are a crucial part of helping prescribers keep opioids from getting into the wrong hands. Unfortunately, many of these state-based reporting systems are cumbersome to use and the data are not always consistent or reliable. Universal data standards would help states collect and report data that are more relevant, reliable, timely, and ineroperable across state lines.

Comments Detail

Page 7434 and following of the six proposed deregulatory actions, we disagree with the following:
(1) The removal of randomized ONC-ACB surveillance requirements, as this will contribute to a "Wild West" environment wherein some developers may knowingly and willingly rush untested health IT to market with false attestations. Why have a certification program at all if ONC is not going to subject the items certified to testing or subsequently follow up to ensure maintenance of certifications?

(2) Removal of the 2014 Edition Certification Criteria **in the absence of a plan for small providers** who are limited to 2014 Edition Certified Health IT to participate in information sharing (due to health IT developers' inability or unwillingness to seek 2015 Edition Certification), which will present significant problems for dental providers.

The ADA proposes that the ONC examine the information exchange requirements of those eligible professionals who are unable to obtain a 2015 Edition system for purposes of the following:

(1) Determining whether certification to ALL 2015 Edition Criteria is necessary in all care settings; in many respects, most of the 2015 edition criteria are of no use in dentistry and this may have been a contributing factor in developers' decisions to pursue certification beyond the 2014 Edition
(2) Determining the feasibility of an ancillary professions Health IT Certification program that is scaled appropriately for the types of systems employed in those care settings
(3) Identifying an appropriate path for those professions left out by the unavailability of appropriately certified health IT
(4) Creating incentives to drive developers to bring appropriately certified (whether 2015 Edition, Modified 2015 Edition, or some as yet unnamed edition) products to market for use by eligible professionals who cannot otherwise obtain them

Page 7446, Upper Right Column:

In the proposed changes to the 2015 criteria, on page 7446, where the Proposed Rule's authors ask for comments on the use of Fast Healthcare Interoperability Resources (FHIR)-enabled APIs replacing HL7 Quality Reporting Document Architecture (QRDA)-based reports for quality reporting and improvement, the ADA has the following comment:

Dentists will only be able to report any sort of care quality data manually through an API if their health IT does not support the HL7 QRDA. The latter seems likely, since the market has not provided a 2015 Edition certified dental EHR and seems unlikely to do so, even when this Proposed Rule becomes final.

In the absence of certified health IT products for their specific care setting, dentists will only be able to participate in electronic information exchange by APIs, including quality reporting. Certified APIs developed for this purpose will have to be enabled to permit manual data entry by professionals who do not have access to a certified health IT product. Many may see this as "special effort," and a barrier, however, and a certified health IT product enabled for this type of data reporting via automated processes would be preferable.

Pages 7477-7479 Which FHIR Standard(s)?

Regarding standardization of API capabilities, the ADA agrees that the APIs certified for electronic health information exchange must be standardized for technical consistency, ease of implementation, and scalability if this regulatory effort is to be successful in achieving the desired goals.

Of the 4 options discussed regarding which version(s) of the FHIR standard(s) to use, the ADA believes Option 3, which proposes that FHIR Release 2 and Release 4 both be named in the Certification Criteria, represents the best choice for dentistry and the health care space in general. This would permit lagging developers, such as those who have certified 2011 and 2014 Edition Health IT products, but not 2015 Edition, to meet a baseline standard for information exchange via Release 2 and yet permit innovators to forge ahead and develop Release 4 capable products that meet proposed requirements.

In response to the Secretary's request for comments on cutover timelines from Release 2 to Release 4, the ADA asks that the cutover timelines allow time for developers and clients using Release 2 to spread out the costs of this proposed two step approach, so that they are not staggered by the burden of two massive upgrades in quick succession.

Pages 7509-7510 Information Blocking

The ADA agrees with the need for carefully defined exceptions to the Information Blocking Provisions in this proposed regulation.

In response to the Secretary's request for comments on whether to expand Information Blocking provisions to all HIPAA covered health care providers, the ADA must oppose such a suggestion without qualification. Even though a large (in excess of 70%) majority of dental practices are HIPAA covered health care providers through their completely voluntary use of HIPAA standard

transactions, more than 90% of all dental practices **do not participate in the Promoting Interoperability program and do not have, or use, Certified Health IT.**

This lack of participation is due to the following factors:

1. Medicare does not cover typical dental services, so dentists' participation in Medicare and the Medicare portion of the Promoting Interoperability program is extremely limited.

2. The threshold for eligibility to participate in the Medicaid portion of the Promoting Interoperability is quite high and most dentists do not see enough Medicaid enrolled patients to qualify.
3. Based on the points above, one may conclude that there are poor financial incentives for dental practices to participate in Promoting Interoperability.

4. In the absence of demand, health IT developers with a dentistry orientation find their market for certified health IT products very limited.

The ADA asks that the Secretary limit the scope of enforcement of Information Blocking provisions to Promoting Interoperability program participants, which in all cases ensures that the exemption for technical infeasibility specifically excuses health care professionals who cannot obtain a certified health IT product for their care setting.

Additionally, ONC should not limit the requirement to prevent information blocking **to ONLY the vendors that participate in the certification process**. If the intent is truly to improve care coordination, then ONC or CMS **must** extend these requirements to **all vendors whose software is used to serve publicly insured patients**, or dentists will continue to be unable to participate in information exchange among themselves and with other health care professions.

The ADA also strongly supports information blocking provisions that would enable reporting to registries on an individual basis, by patients themselves or by their health care providers, in order to facilitate the building of new patient registries in addition to population-based reporting for existing registries.

Page 7519 Limiting or Restricting the Interoperability of Health IT

The ADA also finds that some of the proposed information blocking provisions are duplicative of the HIPAA Privacy Rule, particularly with regard to individuals' Rights of Access and Communication, and offer little value in that regard.

Specifically, the following is among the examples cited on page 7519:

> "A health care provider has the capability to provide same-day access to EHI in a form and format requested by a patient or a patient's health care provider, but takes several days to respond."

The implied timeline for compliance with the information request is more stringent than that specified in the HIPAA Privacy Rule, and although the ADA does not want to leave room for information blocking in life or death situations, the ADA is concerned that dentists with limited staffing and technical capabilities could be unfairly punished in a situation such as this. We would urge the Secretary to use great care to make clear the need for fact-finding specific to each allegation and to allow some room for exemptions where technical, staffing, and other resource limitations delay information exchange, but do not ultimately inhibit it, and in all cases complies with extent provisions of the HIPAA Privacy Rule.

Page 7523 Exemption for Situations Where Disclosure of EHI is Likely to Endanger Life or Safety

The ADA agrees that an exemption from information blocking provisions is necessary in situations where a Licensed Health Care Professional determines that disclosure of EHI is likely to endanger the life or physical safety of a patient or others. The ADA agrees that avoiding conflicts with HIPAA Privacy at 164.502(g)(5) is wise and necessary for the autonomy of health care professionals and for the safety of their patients.

The ADA also agrees that the proposal to establish an exception from the information blocking provisions in instances where an individual has specifically requested a restriction against providing access to EHI or sharing EHI is sound and reasonable, and aligns with a similar provision in the HIPAA Privacy Rule. A reasonable time frame to provide documentation of the request for restriction should probably be consistent with requirements found in HIPAA Privacy and Security Enforcement regulations, as this would not disrupt existing practices and still ensure timely responses.

Page 7539 Method to Recover Costs

The ADA urges HHS to use care in determining whether or not an exemption applies when a fee restricts access or sharing of EHI and, possibly, implicates information blocking. Fees need to be affordable for health care providers and consumers alike or they simply will not use APIs, and this regulatory effort will have failed. Dentists in particular will not pay exorbitant subscriptions or fees for access to information by APIs and will be discouraged from information exchange unless fees are constrained and reasonable. Large numbers of small providers across multiple disciplines refusing to pay fees for access should be a red flag to enforcement officials.

The ADA agrees that costs due to Non-Standard Design or Implementation Choice should not be exempted. Driving standardization is the point of the Proposed Rule and non-standard designs and implementations should not be rewarded.

Page 7554 FHIR Release 4 for Bidirectional Information Exchange with Registries

The ADA believes that the most mature iteration of the FHIR standard, which is currently Release 4, should be used for bidirectional communications with registries. The ADA asks only that developers, health care providers, and the owners of various registries affected by the adoption of this standard be granted adequate time to implement. The ADA suggests a minimum two years lead time from publication of any regulation where this standard, or a successor version, is named for this activity. The ADA again asks that the information blocking provisions facilitate the building of new registries on a case by case basis in addition to population-based reporting

The ADA thanks ONC and HHS for the opportunity to comment on these proposed regulations. Please do not hesitate to contact Ms. Jean Narcisi at narcisij@ada.org regarding any part of these comments.

Sincerely,

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