

June 3, 2019

Seema Verma, M.P.H.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS Proposed Rule RIN 0938-AT79

Dear Administrator Verma:

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, 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 a Core Reference Data standard, ANSI/ADA Standard No.1084, which it hopes to develop in partnership with Health Level 7 (HL7) into further joint work products designed to fuel interoperability across technology platforms and care settings.

Most significantly, the ADA continues to maintain ANSI/ADA Standard No. 2000, Systematized Nomenclature of Dentistry (SNODENT®), 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, with annual updates. SNODENT and its 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 is in favor of the proposal to empower patients by requiring payers to make their enrollees' data available via Application Program Interfaces (APIs) through which third party

software applications may connect. The ADA agrees this should give patients the ability to take charge of their health care and could help to improve outcomes.

The ADA is also in favor of proposed measures to prevent information blocking with qualifications.

The ADA is also in favor of the proposal to require payers to make data they hold available through APIs and new software developed for the purpose of ensuring enrollees' data moves with them as they transition from plan to plan, or provider to provider. The ADA especially encourages the Centers for Medicare and Medicaid Services (CMS) to require payers to make it easy for current and prospective enrollees to identify which providers are within a given plan's network in a way that is easy for them to access and to understand.

The Universal Patient Identifier Problem

The ADA supports the Office of the National Coordinator for Health IT (ONC) and CMS in their ongoing efforts to solve the patient matching problem in the absence of a Universal Patient Identifier (UPI) standard that is unlikely to ever happen. We would urge ONC and CMS to consider the following:

- Prioritize identifying the best possible algorithms for patient matching through HHS-funded studies and pilots, either with grants or with awards. The 2017 ONC Patient Matching Algorithm Challenge was a step in the right direction, but the fruits of that effort should be studied and piloted, along with other as-yet unidentified algorithms

- Determine whether a single algorithm is robust and consistent enough to be adopted as a standard by the ONC

- Seek industry feedback about the matter prior to, during, and after proposed rulemaking, and produce the best possible final rule. Feedback should be obtained via the National Committee on Vital and Health Statistics (NCVHS) or the Workgroup for Electronic Data Interchange (WEDI)

This approach seems likely to produce a satisfactory result in the long run by creating a consensus around a standard algorithm that is sufficiently robust and consistent.

Maturity of API Functionality, Timelines, and Resources

While the ADA agrees in principle that API technology can, and should, play a significant role in solving interoperability problems, caution is needed in setting too aggressive a timeline for implementation.

The HL7 Fast Healthcare Interoperability Resources (FHIR) standard that enables the creation of the proposed standard APIs has some challenges.

Although very promising, Release 4 of the FHIR standard has only been available since late 2018 and may have as-yet unknown problems that need time to be identified and fixed. Prior releases may not be sufficiently robust for purposes of the CMS Proposed Rule.

Presently there is a shortage of workforce sufficiently trained in FHIR implementation. Naming the FHIR standard in federal rulemaking will drive recruiting and training of the needed workforce, but there still needs to be sufficient time allotted between publication of a final rule and any implementation deadline to allow for this workforce to be trained and deployed to good effect. Additional time for testing should be factored into any final rulemaking as well.

There will also need to be a significant amount of money earmarked for implementing these technologies if historically under-resourced payers, e.g. State Medicaid Organizations, are to participate in this effort successfully.

As noted in the ADA's comments regarding RIN 0955-AA01, the 21st Century CURES Act Interoperability, Information Blocking, and ONC Health IT Certification Program Proposed Rule, ADA data content standards, such as ADA Standard No. 1084, and as yet unnamed related joint ADA SCDI/HL7 work products should be supported by APIs if they are to exchange standard dental content across platforms and care settings. In particular, ADA Standard No. 1084 (and as-yet unnamed HL7 derivative work products) should also be the core content standard for dental information sharing via APIs.

Information Blocking

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 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.

Additionally, HHS 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 support reporting to registries on a case-by-case basis in order to support the building of new patient registries in addition to population-based reporting.

Privacy Concerns and HIPAA

The ADA wishes to add that meeting the regulatory requirements of the HIPAA Privacy and Security Rules is a significant challenge for small provider offices such as the typical dental office, and that dental practices will be dependent on their API vendors (and their information trading partners' vendors) for technical aspects of security. These APIs must be tested rigorously for conformance to information security best practices, and maintained in an optimal configuration for security purposes by the vendors themselves, not the providers, if there is to be any confidence in them. All dental practices can do is seek appropriate business associate agreements with their vendors and trust that their vendors are adhering to the HIPAA security regulations. Small providers such as dental practices need to have confidence that the systems they will use for information exchange are secured in a sufficiently robust manner, or they will not use them. The ADA asks that the regulatory compliance burden for meeting HIPAA security requirements reside primarily with the developers, and that a rigorous program of accreditation and testing ensures that products brought to market will perform as advertised.

Innovation Centers as Models for Interoperability

The ADA agrees that the proposed Innovation Center models can offer a test bed for better integration across the health care spectrum, and would ask that participating dentists be included in the Innovation Center's programs. The ADA recommends that the program findings, successes, and challenges be shared with the public so that the industry may learn and grow from them as well. We would ask that the Innovation Center be particularly mindful of the implementation challenges in the dental provider sector and look for ways to avoid burdening participating dentists while still meeting program goals.

These implementation challenges are:

- Cost

- Availability of suitable technologies from mainstream dental information system vendors; typically, mainstream dental information systems are not enabled for information exchange and there is little market incentive to change this
- Integration within optimized workflows

We would also ask that the Innovation Center avail itself of the SNODENT® terminology standard (ANSI Standard No. 2000) as well as ADA SCDI/HL7 joint standards work products for purposes of interoperability testing, problem solving, and improvements in the multi-specialty provider setting.

Privacy and Security Concerns in the Context of APIs

The ADA has some concerns related to the proposed Open APIs as information sharing tools that will be used by consumers to access and to share their electronic health information.

First, although a covered health care provider is not responsible for the security of HIPAA Protected Health Information (PHI) once it has been received by a third-party application chosen by an individual, HHS will need to publish very clear guidance and decision trees on when it is, or is not appropriate to disclose PHI to a third party application in the proposed new API environment. Such distinctions are quite nuanced and providers without a full-time legal analyst on staff need resources to help them adjust to their changing environment.

Secondly, although the ADA has no wish to disparage the Federal Trade Commission or its enforcement authority, relying on after-the-fact enforcement action by an agency that is constrained by a limited budget is an unsound approach to ensure that API developers adhere to the law. Rather, the ADA and its members would prefer to see a high bar for entry into the direct-to-consumer health information sharing API market. This high bar would include strict criteria and testing by independent accredited certifying bodies, in much the same manner the ADA proposed for the Certified Health IT developers, in comments regarding the proposed companion ONC Interoperability Rule (RIN 0955-AA01). This will slow developers' ability to bring their products to market, and will cost more money up front; however, it is money well spent if it prevents some avoidable security breaches.

The ADA also agrees that both providers and health plans regulated by this Proposed Rule should have sole authority to permit third party applications to access electronic health information via their APIs.

Content and Vocabulary Standards

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, 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).

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 Electronic Health Records (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** 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 ONC Interoperability proposed regulation (RIN-0955 AA01).

The ADA also urges CMS to seek the ADA's input when considering adoption of standards impacting dentistry in a direct manner.

Open APIs and Payers

The ADA supports the implementation of Open APIs by payers to make claims, medication, and lab test results data available to consumers so that they may share this information with their health care providers. The burden placed on payers initially is significant, but will arguably save them money in the long run as information sharing helps eliminate duplicative services, reduces re-admissions, and improves outcomes. Dentists and their patients will

certainly benefit from being able to obtain medication and other health care claims data to prompt follow-up questions to patients' primary care physicians for better care coordination.

The ADA asks that the time frame be realistic and that payers are given sufficient time to implement these technologies. Too little time has been allotted for all of this change to take place. An additional 12-24 months lead time is necessary, more so for the State Medicaid and Children's Health Insurance Program (CHIP) organizations that are historically under-resourced. State Medicais in particular must be sufficiently resourced for this implementation to work as intended.

In addition, the ADA requests that Standalone Dental Plans (SADPs) be included in this requirement as it will help dentists and their patients make better informed decisions about treatment plans and how to best use available benefits.

Provider Directory Data

Dentists do participate with some Medicare Advantage (MA) plans that offer coverage for dental services, and as such, will be required to update their credentialing information so the MA plans' Provider Directories are current. The same may be said of State Medicaid and Children's Health Insurance Plan participating dentists, whose information will be made public via these plan directories. While the ADA agrees that the proposal to make provider directory data public via Open API technology will help enrollees to find providers, dentists included, the ADA urges CMS to ensure that State Medicaid and CHIP organizations are appropriately resourced to support implementation of this technology.

Routine Testing and Monitoring of Open APIs

CMS proposes to require regulated entities to monitor and test their Open APIs to ensure they're functioning properly as well as ensuring their security. This requirement is essential to ensure the confidence of the public. **This regulatory effort will fail if it is not included in a final rulemaking.**

Applicability and Timing of MA, QHP, Medicaid, and CHIP Deadlines for Open APIs

The proposed deadlines for implementation of Open APIs by MA organizations and Federally Qualified Health Plans (QHPs), of January 1, 2020, and Medicaid FFS and CHIP by July 1, 2020, are extremely aggressive. It is doubtful that these organizations are positioned to implement such a massive technological change on such short notice, and the shortage of information technology workers with sufficient knowledge of, and familiarity with the FHIR standard, will delay implementation for some time as well as inflate costs that will only be passed on to consumers through various means.

The ADA proposes that any final rulemaking for Open API implementation by these plans allot sufficient time for training and certification of a FHIR-literate workforce of sufficient size

to meet demand in a timely way, and to extend the deadline at least 12-24 months beyond what is proposed currently. Medicaid and CHIP organizations in particular, will likely need more time.

Information Sharing Between Payers and Providers through APIs

The ADA agrees that effective care coordination best occurs when health care providers have access to the most relevant information in the timeliest manner possible. Payers can assist dentists with effective care coordination by making claims, encounter, medication, and lab test claims data available to providers via Open APIs.

A large percentage of the dental profession will not be able to make use of Open APIs for some time. It is unlikely that dentists will be requesting a download of shared patient data from another provider, especially a physician, until dental information systems support the interoperability features named in this Proposed Rule and the ONC Interoperability Rule (RIN 0955-AA01).

MA, QHP, Medicaid, and CHIP participating dentists will probably need these payer organization types to go the extra mile in support of care coordination by implementing feature-rich APIs that support care coordination with their patients' primary care physicians, specialists, and pharmacies. Sufficient time to devise, implement, and test this technology is badly needed, and the January 1, 2020, and July 1, 2020 implementation deadlines proposed here are far too aggressive. As previously noted, a minimum of 12-24 additional months may be required, and possibly a considerable amount more, for the under-resourced Medicaid and CHIP programs.

As for the usefulness of obtaining patients' utilization history, it is doubtless dentists will find this helpful in avoiding drug/drug interactions and duplicative services.

Comprehensiveness of the USCDI Data Set

The ADA wishes to emphasize that the USCDI is sufficient enough to support the envisioned information sharing, save for the omission of SNODENT for documentation of findings, disorders and diagnoses. SNODENT is referenced in ANSI/ADA Standard No. 1084 and two joint ADA/HL7 standards work products based in the HL7 Consolidated Clinical Data Architecture standard. As noted above, ANSI/ADA Standard No. 1084 will be developed into one or more joint ADA/HL7 work products to facilitate information sharing across platforms and care settings. The two existing joint work products represent efforts to create structured documents for reporting of periodontal exams and orthodontic findings as claim attachments, **but the most clinically significant parts of them can be leveraged and re-purposed for provider-provider information sharing.** The ADA urges ONC and CMS to include these standards in both the Interoperability Standards Advisory and the USCDI in the near future, as well as SNODENT in its proper role, as a clinical terminology for documenting findings, disorders, and diagnoses.

Trusted Exchange Networks

The proposal to require MA, Medicaid managed care plans, CHIP managed care entities, and QHPs (excluding SADPs) to participate in a trusted exchange network is likely to be beneficial to patients and providers, but the timeline for implementation by January 1, 2020, is far too aggressive. Because Medicaid and CHIP organizations will have the most difficulty meeting the proposed deadlines it is recommended they be granted at least 12-24 months additional time.

Public Reporting of Negative Attestations on Physician Compare

It is unclear whether MA participating eligible professionals will be subject to the proposed information blocking attestation requirement on Physician Compare. If they are, the ADA urges CMS to exempt eligible MA participating dentists for as long as there are no suitable Certified Health IT products for the dental setting. By “suitable,” the ADA means products that are certified as supporting the interoperability requirements, including API interfaces, data export, and other proposed requirements described in the proposed ONC Rule RIN 0955-AA01.

Provider Digital Contact Information

The proposal to publicly report the names and National Provider Identifiers (NPIs) of individuals and organizations who do not have digital contact information in the National Plan and Provider Enumeration System (NPPES) is unreasonably aggressive in its timing. While the ADA agrees that including digital contact information in providers’ NPI associated data maintained by NPPES and making that information available to the public is likely to support better information exchange, there is a significant education and outreach challenge that must be met in order to be successful. The proposal to begin reporting the names of providers who have supplied digital contact information in the second half of 2020 fails to take into account the difficulty of reaching small providers and getting a message across successfully. Extending the deadline for providers to update their NPI associated data to include digital contact information would be just as successful without needlessly harming providers who are perfectly willing to cooperate but are focused on other activities. The ADA suggests a minimum of 12 additional months are necessary for a successful outreach effort, forestalling publication until the second half of 2021 or even 2022.

The ADA thanks CMS 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,

Jeffrey M. Cole, DDS, MBA
President

Kathleen O'Loughlin, DMD, MPH
Executive Director