

June 30, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: [Docket No. FDA-2014-N-0339]

The over 157,000 members of the American Dental Association (ADA) have confidence in their ability to deliver safe, effective, quality dental care and rely on the strong ADA commitment to the development and use of voluntary consensus standards for dentistry. The ADA is a national and international leader in the development of consensus standards and guidelines for materials, instruments, equipment, digital devices, and health information technology software impacting the safety and health of the public and the practice of dentistry.

The ADA is actively engaged in the development and maintenance of information technology standards for dentistry. The ADA's leadership role with regard to standards was recognized by the HIPAA legislation naming the ADA as an entity to be consulted when the HHS Secretary is considering adoption of a new or modified HIPAA administrative simplification standard. The ADA is the only professional association so named.

The ADA is also an American National Standards Institute-accredited standards organization. The ADA Standards Committee on Dental Informatics (SCDI) develops and maintains dental information system, data architecture, functional model, and interoperability standards through a consensus-based process involving a balance of stakeholder interest groups. The SCDI has a Statement of Understanding with Health Level 7 (HL7) that permits dental domain-specific HL7 work products to originate in the SCDI. SCDI also has a similar arrangement for dentistry-specific Digital Imaging and Communication (DICOM) work products.

The ADA has developed a subset of the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) called the Systematized Nomenclature of Dentistry (SNODENT). SNODENT® is a clinical terminology designed for use in the electronic health and dental records (EHR) environment. As SNOMED CT is a recognized clinical terminology for Meaningful Use Stage 2 and beyond, it is the ADA's opinion that being fully interoperable with SNOMED CT makes SNODENT the best choice for a clinical vocabulary required for dental systems.

The ADA recognizes that solving patient safety problems associated with the three types of HIT described in the FDA report is, and should be a national priority.

The ADA agrees that medical devices which incorporate HIT in their designs, work without need for human oversight or intervention, and have potential to harm or even kill patients should be subject to FDA regulation.

The ADA also agrees that Health Care Management software should not be subject to FDA regulation. Instead, the ADA agrees in principle with the proposed strategy of leveraging standards, voluntary product certification programs, knowledge building, and knowledge sharing in a non-punitive atmosphere. The ADA agrees that this approach can create favorable conditions for market based solutions to emerge.

The ADA agrees that clinical decision support (CDS) systems require careful design, implementation, and end user training to best assist dentists and dental specialists without interfering with their professional autonomy.

The ADA acknowledges that dentists or dental specialist professionals making patient care decisions may require additional training in the use of CDS tools.

The ADA believes that input sources regarding the extent and content of the prescription for additional training must include, but not necessarily be limited to state dental boards and dental educators.

The ADA believes many of its internal agencies and partner organizations possess relevant expertise and sufficient breadth and depth of knowledge to make valuable contributions in this arena. These include agencies such as the Commission on Dental Accreditation (CODA), the Council on Dental Education & Licensure (CDEL), the Council on Scientific Affairs (CSA), the Dental Science Institute (DSI) Center for Product Evaluation, Professional Product Review (under the Center for Scientific Information), the Information Technology Committee (ITC), the Dental Practice Institute (DPI), the Dental Quality Alliance (DQA), the Dental Content Committee (DeCC), and the Center for Evidence-Based Dentistry.

As such, the ADA requests appropriate opportunity for comment on any proposed or final federal regulations with implications for dentistry-related educational measures.

The ADA recognizes that CDS software by definition supports professional decision making, and does not interact with the patient without professional oversight and control. Hence the responsibility for the safety and efficacy of those care decisions

RE: [Docket No. FDA-2014-N-0339]
June 30, 2014
Page 3


rests on the provider and not the system. Professional decisions that have a CDS component are professional decisions, and are still subject to regulation by existing state and professional mechanisms. The ADA believes that clinical decision support tools that are designed to support the professional practice of dentistry do not pose a risk sufficient to warrant direct FDA regulation, and should not be subject to such regulation.

The ADA firmly believes the software functional and technical standards and criteria for sound clinical decision support tools in dentistry are best developed by existing standards organizations such as the ADA, DICOM, and Health Level 7; and, that technical methods for software development and testing are subject to standards and best practices prepared by standards organizations such as IEEE. The ADA also believes that these organizations should have a key advisory role with the ONC concerning matters of dentistry, HIT, and patient safety, and any federal regulation of software as a medical device.

The ADA would also request more details regarding the proposed Health IT Safety Center, particularly how it will interact with private and public entities, and which organizations will participate in its activities.

The ADA respectfully offers these ideas and opinions for consideration. Thank you for the opportunity to comment.

Sincerely,



Charles H. Norman, III, D.D.S.
President



Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director/Chief Operating Officer

CHN/KTO:PC

cc: David M. Preble, D.D.S., J.D., C.A.E., vice president, Practice Institute