

March 11, 2026

The Honorable Thomas Keane, M.D., M.B.A.
Assistant Secretary for Technology Policy
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

ATTN: RIN 0955-AA11: Request for Information: Diagnostic Imaging Interoperability Standards and Certification

Dear Assistant Secretary Keane:

On behalf of the members of the American Dental Association (ADA), the nation's leading authority on oral health, we appreciate the opportunity to comment on the "Request for Information: Diagnostic Imaging Interoperability Standards and Certification". The ADA is encouraged by the efforts of the Secretary of Health and Human Services (HHS) and the Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) to improve interoperability in the area of imaging data exchange, which gives us renewed hope towards emphasizing the need to adopt standards for imaging interoperability.

In preparing these comments, the ADA convened an open information gathering session with broad participation from software vendors, dental imaging experts, clinicians, academic researchers, and standard development specialists. The insights gathered, such as the widespread reliance on proprietary imaging formats, inconsistent Digital Imaging and Communications in Medicine (DICOM) implementations, fragmented exchange pathways, and the lack of standardized metadata and structured findings, helped illuminate systemic challenges across the dental imaging ecosystem. While this input informed our understanding of current barriers and opportunities, the ADA has prepared its responses specifically to address the needs of dentists and their patients, ensuring that national imaging interoperability efforts reflect the unique clinical workflows, safety considerations, and care coordination requirements of the dental profession.

Diagnostic imaging plays a foundational role in dentistry, supporting comprehensive assessment, diagnosis, and treatment across a wide range of clinical specialties. Imaging modalities such as intraoral and extraoral radiographs, cone-beam computed tomography (CBCT), and digital photographic records are integral to evaluating oral structures, monitoring disease progression, and evidence-based clinical decision-making. Despite their centrality to patient care, dental diagnostic images are often stored in systems that operate independently of electronic dental records, restricting efficient exchange between dentists. Proprietary software limits accessibility and interoperability necessary to coordinate patient-centered care and lack of standardization increases the cost of providing care.

In collaboration with industry stakeholders and imaging vendors, the ADA has developed standards for imaging in dentistry that are universally applicable to any digital imaging system, providing a scientifically validated process from image capture to image display to achieve an optimal balance between image quality and radiation dose. Other widely used standards in dentistry, such as DICOM, an international standard that the ADA has recognized since the early 2000's, provide guidelines for the formatting, storage, and exchange of digital radiography files to ensure interoperability across all types of imaging systems, practice management systems, and health care networks. By requiring conformance to DICOM, the dental industry can ensure that systems remain interoperable. The ADA has been actively promoting the use of DICOM in dentistry; however, implementation has largely been limited to universities and institutional dental facilities. To see widespread implementation of interoperable imaging and file exchange to support small and rural dental practices, several key issues need to be addressed. These are identified in the detailed sections in this letter.

The standards on Imaging interoperability developed by the ADA Standards program and accepted as American National Standards are listed below for consideration:

ADA Standard No. 1110 for Validation Dataset Guidance for Image Analysis Systems Using Artificial Intelligence. This standard will help ensure confidence in image analysis systems using artificial intelligence by providing a validation dataset to measure their performance.

ADA Standard No. 1114 for Implementation Requirements for the Effective Use of DICOM in Dentistry. This standard will provide dental requirements for DICOM conformance to achieve interoperability through networking infrastructure, storage and archiving, data security and privacy, and integration among systems

We are pleased to enclose our detailed responses to questions posed by ASTP/ONC. We respectfully offer the following considerations to help dental offices overcome hurdles in diagnostic imaging interoperability.

Transition From Physical Media to Electronic Access, Exchange, and Use

PM- 1. What barriers do patients experience with electronic access to diagnostic images? Are there examples today where patients can successfully access, exchange, and use diagnostic images outside of a particular hospital or network system without use of physical media?

Dentists are one of the highest-volume users of imaging in the healthcare system. Imaging is the fundamental adjunct to the clinical examination in the diagnosis and management of patients. Despite the frequency and availability of imaging, dental patients face significant barriers to electronic access to dental diagnostic images such as X-rays and CBCT scans. This is largely due to the failure to implement standardized data formats, poor interoperability between systems, and limited patient portal functionality in the tools used by independent practices. Without patient-facing digital tools (e.g. robust patient portals), patients frequently serve as intermediaries, transporting CDs, emails, or paperwork between care locations, because automated workflows are not available across systems.

The patient portals for dental data access may provide reports and limited records, but not viewable diagnostic images, compliant with DICOM for interoperability. Images are often transmitted as

screenshots, PDFs, or secondary captures, stripping essential metadata (acquisition parameters, exposure, timestamps), and compromising diagnostic value. Exchanging files using non-standardized methods can degrade data quality, leading to repeat imaging that increases radiation exposure, delays care, and adds avoidable costs for patients. When provenance (details on creation, editing, and distribution) information is missing or unreliable, the care team cannot determine whether an image is diagnostically valid or altered, further driving unnecessary retakes and additional radiation exposure.

These challenges persist despite evidence that patients are interested in digital access to dental clinical records and that such access would increase their engagement with their dental health¹.

PM- 2. What existing policies do you believe limit or interfere with diagnostic image access, exchange, and use? What policies would you introduce to accelerate the transition to electronic, standards-based diagnostic image access and exchange and to reduce the practice of imaging silos that impede electronic access, exchange, or use of diagnostic images?

PM-2a. What other policy or financial barriers do providers face in accessing diagnostic images from outside facilities? For example, are there concerns about compliance with health care facility policies or procedures (e.g., security or overall policies on data sharing outside the facility), state laws, or malpractice liability?

Dentistry was largely excluded from HITECH incentives, so dental EHRs and imaging systems never had to adopt interoperability standards, unlike medical systems. The lack of regulatory incentives led to outdated systems, proprietary formats, and minimal electronic exchange. Since federal attachment standards have not yet been finalized, healthcare attachments, including images, are still exchanged primarily by manual methods, such as mail, fax, through clearinghouses and web-based portals. Dentists must navigate multiple payer-specific workflows and proprietary transmission channels for sending required images; each workflow has different file requirements, formats, and proprietary portals. Dental offices spend significant time gathering, formatting, and submitting images. The variability in transmission requirements results in incomplete or delayed claims until the imaging requirements are met, resulting in longer payment cycles and an increased likelihood of claim denials due to insufficient imaging documentation.

There is growing recognition of the oral-systemic link, specifically the connection between oral health and overall wellness. Evidence has shown that treating specific dental services prior to treating certain medical conditions (e.g., organ transplants, cardiac valve replacements, and treatment for head/neck cancer) may improve the clinical success of the primary medical treatment^{2,3}. However, communication between dental and medical systems remains a barrier to achieving patient outcomes. Medical and dental facilities and health information exchanges need to be able to trust incoming data and lack of confidence leads to blocked exchanges or burdensome manual workarounds. Some systems may require restrictive filtering or quarantine processes

¹ CareQuest Institute for Oral Health. Patient Portals: Patient Perspectives and Opportunities for Practices. Boston, MA; January 2022. Copyright © 2022 CareQuest Institute for Oral Health, Inc.

² Integration of Medical and Dental Care and Patient Data. 2ed. Springer International Publishing; 2019

³ Beaumont S, Liu A, Hull K. A retrospective cohort study of the oral healthcare needs of cancer patients. Support Care Cancer. 2025 Mar 22;33(4):314. doi: 10.1007/s00520-025-09314-y. PMID: 40119964; PMCID: PMC11929681.

⁴American Dental Association Health Policy Institute. (2024). Distribution of dentists according to size of dental practice and affiliation with a Dental Support Organization (DSO) [Data file]. American Dental Association

for imaging files from dental offices or outright refuse system-to-system connections with dental imaging platforms that use proprietary file exchange or APIs.

Dental offices, 73% of which are small businesses⁴, report challenges that impede the adoption and maintenance of new technologies, including digital imaging systems, cybersecurity controls, and integrated clinical software. The proliferation of dental imaging vendors with proprietary software solutions adds financial complexity and staff burden. When images are not stored and exchanged according to standards, downstream systems cannot reliably ingest, render, or route them, forcing offices to use vendor-specific viewers, export to physical media, or re-capture data, creating workflow disruption and requiring additional staff time. These issues are exacerbated when images need to be accessed by non-office-affiliated dental or medical teams.

Policies to support open APIs or export specifications, and to support export to standards-based DICOM formats, will help ensure that image metadata is preserved. This creates interoperability without forcing all vendors to rewrite their systems at once. *ANSI/ADA Standard No. 1114 for Implementation Requirements for the Effective Use of DICOM in Dentistry* defines the DICOM requirements for dentistry, outlining how dental images should be acquired and stored to support full interoperability across care teams. It expands beyond CBCT to include intraoral radiographs, panoramic and cephalometric images, and visible-light orthodontic photos, ensuring consistent formatting and proper display, such as through standardized hanging protocols to enable reliable sharing and use across dental systems.

PM-2b. What technical/interoperability concerns exist, such as compatibility between systems, authorization issues from external sources, or issues with the provenance of diagnostic images?

Dental imaging systems frequently use proprietary, non-DICOM formats, making it difficult or impossible to import images into other systems without converting or manually reformatting them. Even when DICOM is used, systems may not implement consistent or reliable metadata such as standardized tooth numbers, series layout, or anatomical references, making it difficult to correctly interpret, organize, and display images across platforms and increasing the risk of misplacement, mislabeling, or loss of clinical context during exchange. Hanging protocols and multi-image series layouts are often not preserved or are unsupported, so the receiving site cannot view images in the same structured layout intended by the original system. Many existing systems store decades of images in non-interoperable proprietary formats that require extensive, custom conversion work to migrate. Even with specialized tools, some image data cannot be fully recovered. Converting legacy images to DICOM often results in secondary captures that lose diagnostic metadata and reduce clinical utility. Unlike the Picture Archiving and Communication System (PACS) used by health systems, dental imaging platforms have no consistent external access mechanism—there is no dental equivalent of the IHE XDS-I profile in widespread use.

Intraoral scanners present additional interoperability challenges. Many vendors restrict access to full datasets, exporting only partial representations (e.g., STL surface files) that exclude color texture maps, occlusal relationships, margin annotations, scan path data, or device calibration metadata. The absence of standardized metadata and structured descriptors prevents seamless integration into broader electronic health records, prosthodontic workflows, or cross-platform visualization tools.

Image fidelity is another significant concern. Diagnostic quality depends on preserving original bit depth and raw acquisition data. However, many systems downgrade 12–16-bit images to 8-bit for storage efficiency, reducing grayscale resolution, and potentially masking subtle pathology. Vendor-specific image enhancement filters such as sharpening, contrast adjustments, or noise reduction are often applied without documentation or transparency. Without visibility into the processing pipeline, receiving systems cannot determine whether images are raw, enhanced, or degraded. Reapplying additional filters (“filters on filters”) may further compromise image quality, limit a dentist’s ability to reprocess images appropriately, and reduce AI model performance due to inconsistent input characteristics.

More broadly, persistent nonconformance to standardized data models and terminology, inconsistent adoption of healthcare informatics standards such as DICOM®, and reliance on proprietary APIs fragment the dental technology ecosystem. Dental imaging platform vendors frequently use proprietary formats as a means of customer retention. Practices that wish to switch imaging systems or share images externally face significant technical and contractual obstacles. This dynamic mirrors the information-blocking behavior that the 21st Century Cures Act sought to address in the EHR context, but dental imaging has not received equivalent policy attention. As a result, interoperability frequently depends on extensive third-party data brokers, adding cost, complexity, and security considerations while slowing innovation and limiting scalable, standards-based exchange across dental and medical environments.

PM-3. What technical, operational, and policy approaches can best support health care providers in transitioning from physical media (e.g., CDs and DVDs) to secure, electronic exchange-based methods for sharing diagnostic images outside of their operating environment/health care organization system? If possible, please be detailed in your response.

To accelerate the transition from CDs and other physical media to secure, electronic image exchange, federal policy should prioritize a coordinated, standards-driven approach supported by targeted financial and regulatory levers. Policymakers can drive meaningful progress by establishing clear requirements for dental imaging interoperability, creating incentives for adoption, and reducing operational barriers for practices—particularly small and resource-limited ones. Therefore, the ADA offers the following policy recommendations:

- **Strengthen technical requirements.**
Adopt ANSI-accredited ADA Standard No. 1114 DICOM® requirements for dentistry, supported by clear implementation guides, conformance criteria, and testing programs. Systems should be required to preserve and transmit essential metadata, including bit depth, acquisition parameters, processing history, standardized tooth identifiers, anatomical references, and series layout or hanging protocols, to ensure diagnostic fidelity and consistent display across platforms. Vendors should also publish open export specifications and interoperable APIs so that images, annotations (e.g., cephalometric measurements), and structured findings can move with full fidelity between systems and into payer workflows without data loss or proprietary constraints.
- **Provide financial and operational support.**
Many dental practices operate in siloed environments with limited IT resources. Providing targeted financial incentives, technical assistance, and operational support would help these

practices implement secure patient and payer portals that enable authorized, bidirectional image exchange—eliminating the need for patients to physically transport CDs and reducing administrative burden. Additional federal support, such as HRSA grants, Medicaid meaningful use—equivalent programs, or tax incentives for technology modernization, would further accelerate the adoption of standards-based dental imaging systems.

- **Align regulatory policy with exchange outcomes.**
Regulatory frameworks should focus on measurable outcomes related to access, usability, and seamless exchange rather than on minimum technical compliance alone. Establishing a uniform, standards-based attachment pathway for payers would reduce reliance on proprietary submission channels, fragmented workflows, and administrative burden for small practices. Strengthening identity and access management frameworks is also essential to enable trusted exchange among dental, medical, and payer systems.
- **Ensure image quality and fitness for use.**
Exchanged images must meet dental-specific diagnostic requirements. ANSI-accredited ADA standards on image quality *ANSI/ADA Standard No. 1094, Quality Assurance for Digital Intra-Oral Radiographic Systems*, *ANSI/ADA Standard No. 1099, Quality Assurance for Digital Panoramic/Cephalometric Radiology*, *ANSI/ADA Standard No. 1098, Quality Assurance for Cone Beam Computed Tomography CBCT* should guide minimum thresholds for resolution, bit depth, and preservation of raw data and processing transparency to ensure images remain clinically reliable for diagnosis, treatment planning, and secondary uses such as AI.
- **Strengthen dental image capture and exchange in federally funded programs.**
Establish minimum interoperability requirements for dental practice management systems as a condition of participation in federal programs, including Medicaid, CHIP, and Medicare Advantage dental benefits.
- **Encourage dental-vendor certification through inclusion of dental-specific certification criteria.**
Federal policy should establish dental-specific certification criteria within the ONC Health IT Certification Program, recognizing that dental practice management systems may function as the de facto imaging platforms and must meet interoperability requirements currently applied only to medical PACS. In parallel, ONC should expand USCDI to include dental imaging data classes—such as intraoral radiographs, panoramic images, CBCT, clinical photographs, and AI-generated findings—and update the View/Download/Transmit (VDT) criterion to enable patients to electronically access and share their dental images through certified health IT. Together, these actions would ensure that dental imaging is fully integrated into national interoperability policy and that patients benefit from consistent, standards-based digital access to their diagnostic images.

PM-4. Do health care providers and/or patients (including patient-facing apps) need access to the full resolution diagnostic images stored in PACS or is a reference image (e.g., a DICOM image rendered as a JPEG) sufficient for clinical decision-making and use by health care providers and patients? Does this vary by clinician specialty or by type(s) of care provided to the patient? Please feel free to elaborate with rationale.

Dentists generally require access to full-resolution diagnostic images, not reference JPEGs, because dental imaging systems often acquire data at higher bit depths and apply specialized processing, which is lost when reduced to reference formats; this affects diagnostic accuracy and eliminates the ability to reprocess images for clinical use or specialty preferences. Full-resolution images are also

essential for AI-enabled tools trained on high-fidelity datasets, which show reduced accuracy when applied to compressed or filtered derivatives. Certain clinical specialties, including oral surgery, endodontics, and orthodontics, as well as others that rely on cephalometric or implant measurements, require precise quantitative data and structured metadata that are not preserved in JPEG renditions. While some routine viewing scenarios may allow patients or general dentists to use reference images for education or basic review, consistent clinical decision-making, accurate diagnosis, and specialty treatment planning depend on the availability of full-resolution DICOM images with complete metadata and display integrity.

PM-5. Do health care providers and/or patients need access to quantitative parameters ^[3] derived from images for clinical decision-making and use by providers and patients? Please feel free to elaborate with rationale.

Dentists do need access to quantitative parameters derived from diagnostic images, as these measurements are essential for accurate clinical decision-making across multiple dental specialties. For example, oral surgeons rely on quantitative implant planning data embedded in CBCT studies, and orthodontists routinely exchange cephalometric landmarks, angles, and linear measurements that must accompany the image itself to support treatment planning and continuity of care. These data are increasingly represented through structured DICOM reports, which allow precise measurements to be transmitted as structured data and validated by receiving dentists and medical colleagues without altering the original image. Quantitative image-derived parameters also support emerging AI-enabled diagnostic tools, which require access to the underlying numeric data to maintain accuracy and clinical validity. While patients may not always interpret these measurements directly, they benefit when quantitative data are included because it prevents retakes, improves care coordination among specialists, and enhances the reliability of clinical decisions.

Standards and Certified Health IT Functionality

SC-1. What technical approaches are currently in use to enable access and/or exchange of diagnostic images between health care systems and health information networks? To what extent are these methods based on standards (e.g., DICOM, DICOMwebTM, FHIR[®], IHE[®] XDS-I, IHE[®] XCA-I) versus proprietary or custom integrations?

Current technical approaches for accessing and exchanging diagnostic images rely primarily on physical media, such as CDs containing DICOM viewers, which remain the most common method for transferring images between clinics due to limited electronic interoperability. In some integrated environments (hospital systems, FQHCs), dentists use centralized PACS systems that support internal exchange, but most dental practices still operate standalone, proprietary imaging systems that lack standardized export capabilities and therefore resort to emailing non-DICOM formats or PDFs, which reduces diagnostic quality. ADA has been a strong advocate for DICOM-based exchange of diagnostic images. Many practice management systems offer “plug and play” support for imaging devices via proprietary APIs or vendor-specific formats. Proprietary methods prevail in vendor ecosystems, leading to silos without DICOM export.

SC-2. What metadata and other information is currently associated with diagnostic images for purposes of access and exchange, including images exchanged using different standards and custom integrations? Please feel free to elaborate on the use of artificial intelligence tools in adding metadata to images and additional information to accompany an image.

Diagnostic images today typically carry limited and inconsistent metadata, especially in dentistry, where many systems store images in proprietary or non-DICOM formats that omit key information such as acquisition parameters, bit depth, processing history, and structured identifiers like tooth numbers or anatomical references. Even when DICOM is used, metadata essential for interoperability, such as raw image exposure values, compression details, filtering steps, or the intended hanging protocol for multi-image intraoral series, are often missing or improperly populated, leading to loss of diagnostic value and inconsistent presentation across systems. More advanced metadata, such as structured measurement data (e.g., cephalometric landmarks) or implant planning parameters, is increasingly available through DICOM structured reports but is not widely implemented by vendors. Artificial intelligence tools rely heavily on complete, high-fidelity metadata to ensure accurate model performance, and AI workflows may generate derived metadata, such as annotations, segmentation overlays, or quality assessment indicators, that must accompany the original image without altering it to support clinical validation and downstream use. The ADA Standards Program published the first U.S. standard in AI in dentistry, approved by the American National Standards Institute. ANSI-accredited ADA Standard No. 1110-1 for Dentistry—Validation Dataset Guidance for Image Analysis Systems Using Artificial Intelligence, Part 1: Image Annotation and Data Collection establishes requirements for the content, collection, and metadata of validation datasets to ensure they are representative, secure, ethically sourced, and aligned with each AI system’s intended use. It defines standards for qualified image acquisition and annotation, documentation of diagnostic or treatment findings and their provenance (details on creation, editing, and distribution), patient permissions, data security, and structured processes for validating AI performance and calculating results. The standard also sets expectations for confidence and transparency, including rigorous ground-truth methods, the sequestration of validation datasets from system development, and public reporting of dataset composition, intended uses, and performance metrics to promote trust and reproducibility.

SC-3. What technical barriers, such as proprietary interfaces or ambiguous standards, limit the access, exchange, and use of diagnostic images across health IT systems (including by patient-facing apps), and should existing technical standards be further modified (please identify the standard)?

Major technical barriers to image interoperability include proprietary formats and closed ecosystems (especially with intraoral scanners) that block standards based export; inconsistent or missing DICOM metadata for dental needs (tooth identifiers, intraoral series layout/hanging protocols, bit depth, compression and processing history), which prevents faithful rendering and reuse; unclear provenance due to down sampling and vendor filtering that recipients cannot verify; gaps for newer dental modalities (e.g., surface scans, fluorescence/transillumination) that lack clear encodings; and legacy data silos where conversion to interoperable formats is costly and often degrades diagnostic context. To address this, existing standards should be operationalized and extended: broadly adopt *ADA Standard No. 1114* with implementation guides and conformance

tests; refine DICOM to require dental series layout and robust metadata for fidelity and processing provenance; add explicit modality/semantic support for newer dental imaging types; promote DICOM structured reports/overlays so quantitative measurements travel without altering source pixels; and require vendors through outcome based policies to publish open export specifications/APIs so dentists, payers, and patient facing apps can access complete images and metadata through secure channels without resorting to physical media

SC-4. Should there be a focus on particular, individual diagnosis and treatment use cases (e.g., ocular imaging)? Are there specific requirements that need to be considered for use cases in other fields?

Yes—there should be focused attention on specific, high-value diagnostic and treatment use cases, because different clinical specialties require distinct levels of image fidelity, metadata completeness, and structured quantitative information to ensure accurate diagnosis and care coordination. In dentistry, specialties such as endodontics, oral surgery, and orthodontics rely on precise measurements, cephalometric landmarks, implant planning parameters, and standardized series layouts—requirements that cannot be met by generic or reference–image–only exchange methods. These needs parallel other domains, such as ocular imaging, where specialty-specific metadata and measurement standards are essential for clinical validity.

Emerging dental imaging modalities—including intraoral scanners, fluorescence imaging, and transillumination—also lack consistent standardization, reinforcing the importance of incorporating modality-specific requirements into national interoperability frameworks. To ensure images remain diagnostically reliable and interoperable across systems, any national imaging standard should include use -case-specific requirements for modality definitions, metadata completeness, quantitative reporting, provenance, and display semantics, with patient safety as the guiding priority.

Within dental imaging, the following use cases should be prioritized:

- **Caries detection and monitoring:** Requires exchange of intraoral radiographs with structured findings across general dentists, specialists, and payers.
- **Periodontal disease assessment:** Requires interoperable transmission of radiographic bone level measurements and full-mouth series to support staging and longitudinal care.
- **Orthodontic treatment planning:** Requires exchange of panoramic radiographs, cephalometric studies, and CBCT datasets across orthodontists, oral surgeons, and referring providers.
- **Medical–dental integration:** Requires sharing of panoramic images with medical clinicians for identification of systemic indicators such as carotid artery calcifications and airway considerations.

Together, these specialty-focused requirements can support real clinical workflows, prevent degradation of diagnostic accuracy, and reduce unnecessary radiation exposure through avoidable retakes.

In closing, the ADA’s recommendations aim to strengthen imaging interoperability in ways that meaningfully improve the patient experience by ensuring that dental images follow patients seamlessly, support timely care, and eliminate the burden of transporting physical media.

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By advancing standards-based exchange and reducing the fragmentation that drives repeat imaging, we believe our recommendations will help avoid unnecessary costs for patients, providers, and the healthcare system while supporting more accurate diagnosis and better health outcomes. Together, these efforts position dental imaging as a fully integrated component of a modern, patient-centered health information ecosystem.

Thank you for the opportunity to share our recommendations. If we can provide any further information or assistance to the ASTP/ONC as it considers diagnostic imaging exchange, please do not hesitate to contact Rebekah Fiehn, Director, Dental Benefits, Coding, and Data Exchange, at fielnr@ada.org.

Sincerely,

/s/

Richard J. Rosato, D.M.D.
President

/s/

Elizabeth Shapiro, D.D.S., J.D., C.A.E.
Interim Executive Director