March 12, 2026

Thomas Keane, MD
Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building, Mail Stop: 7033A
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Washington, DC 20201

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

Submitted electronically via http://www.regulations.gov

Dear Dr. Keane,

The American Academy of Dermatology Association (AADA) appreciates the opportunity to provide comments to the Health and Human Services (HHS) in response to the Request for Information (RFI): Diagnostic Imaging Interoperability Standards and Certification.

The AADA represents over 18,000 dermatologists nationwide who are committed to excellence in the medical and surgical treatment of skin disease; advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of disease.

Dermatology and Dermatopathology represent a unique intersection of clinical and pathologic imaging. Many dermatologists, particularly those dual board-certified in dermatology and dermatopathology, interpret their own images as part of routine clinical practice. Although the RFI appropriately recognizes that diagnostic images are often stored in systems external to electronic health records (EHRs) (e.g., picture archiving and communication systems [PACS] and

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vendor neutral archives [VNAs]), dermatologic imaging presents distinct characteristics that warrant specific consideration, as discussed below.

A. Transition From Physical Media to Electronic Access, Exchange, and Use
PM-2 What existing policies do you believe limit or interfere with diagnostic image access, exchange, and use?
Standard best practice for using diagnostic images in dermatopathology inherently limits how images can be used, but this limitation supports accurate clinical use. Dermatopathology diagnostic images are used to supplement clinical notes, rather than serve as a primary diagnostic test. Digitization of dermatopathology slides are not part of the clinical workflow for most practices. Glass slide reading is still the standard of care and dermatopathology slides are not easily scannable and available in EHRs due to technical barriers and security concerns related to the large size and storage requirements of high resolution digital data.[1] For example, dermatopathology diagnostic images require strict image quality parameters such as 40x magnification for dermatopathology whole slide imaging (WSI)[2] and a recommended minimum resolution for diagnostic clinical images.[3] These requirements pose significant barriers to physicians seeking to access, exchange, or use such images to provide optimal patient care.

There is also a lack of unified standards for data exchange, which limits interoperability between vendor systems. As a result of these challenges, implementing digital pathology in a dermatopathology practice would present a significant financial and administrative burden to buy equipment, train staff, and purchase adequate technology storage and maintenance systems for the digitized slides. As a workaround to these challenges, many small dermatology practices already successfully access subspecialty dermatopathology expertise through commercial laboratories that provide digital pathology services and remote interpretation by board-certified dermatopathologists, particularly benefiting underserved and rural areas. These small practices are able to access digital pathology services either through their EHR, if interoperability exists, or through the laboratory information system (LIS).

To support transition to electronic standards-based diagnostic image access and exchange, the Academy recommends HHS consider policies that:

- **Ensure interoperability solutions enable pathologists to access clinical and dermoscopic images when interpreting tissue specimens, which has been shown to improve diagnostic accuracy and reduce false-negative melanoma diagnoses.**
- **Enable dermatologists to share clinical images with pathologists, other dermatologists, and primary care providers. Dermatopathologists need access to clinical and dermoscopic images; and clinicians need access to WSIs for correlation and education.**
- **Recognize the full spectrum of dermatologic imaging. Explicitly acknowledge both clinical imaging (photography, dermoscopy) and histopathologic imaging (WSI) and**

recognize that optimal care requires integration of these complementary modalities—including longitudinal access for surveillance and monitoring, not only episodic diagnostic imaging.

- **Support teledermatology and telepathology, facilitate secure transmission of clinical and pathologic images with associated clinical data for remote consultation, maintaining HIPAA compliance.**

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?

Since FDA approval of whole slide imaging systems for primary diagnosis in 2017, digital pathology has become clinically validated for diagnostic use, making interoperability standards essential for current practice models. Clinical dermatologic images exist across diverse platforms, including specialized dermatology imaging systems, standalone dermoscopy devices, mobile device cameras, and dedicated total body photography (TBP) systems (2D and 3D).[4,5] Dermatopathology images are typically stored in integrated EHR, digital pathology platforms, laboratory information systems, vendor-neutral archives, and specialized dermatopathology software. To support interoperability, the Academy recommends that HHS:

- **Develop standards that accommodate non-Digital Imaging and Communications in Medicine formats, as well as emerging digital pathology standards, while maintaining clinical utility. Non-DICOM formats are primarily used by dermatopathologists, therefore interoperability framework should accommodate multiple image formats, while ensuring adequate quality and associated metadata are preserved.**
- **Engage specialty societies in developing technical standards and implementation guidance that address specialty-specific requirements for image metadata, quality, clinicopathologic correlation workflows, and integration of multiple image types.**

We appreciate the opportunity to provide comments to support the access, exchange, and use of diagnostic images by physicians and patients. If you have any questions regarding this letter, please contact Elizabeth Boyes, Senior Manager, Health Policy & Payment, at eboyes@aad.org or 847-240-1289.

Sincerely,

Susan C. Taylor, MD, FAAD

Susan C. Taylor, MD, FAAD
President, American Academy of Dermatology Association

[1] Biswas N, Berg H, Shukla SK. Digital pathology: Barriers to transitioning to the digital age. *Digit Health*. 2026;12:20552076261418364. Published 2026 Feb 12. doi:10.1177/20552076261418364

[2] Patel A, Balis UGJ, Cheng J, et al. Contemporary Whole Slide Imaging Devices and Their Applications within the Modern Pathology Department: A Selected Hardware Review. *J Pathol Inform*. 2021;12:50. Published 2021 Dec 9. doi:10.4103/jpi.jpi_66_21

[3] American Academy of Dermatology Position Statement on Teledermatology PS-Teledermatology

[4] Schneider SL, Kohli I, Hamzavi IH, Council ML, Rossi AM, Ozog DM. Emerging imaging technologies in dermatology: Part I: Basic principles. *J Am Acad Dermatol*. 2019;80(4):1114-1120. doi:10.1016/j.jaad.2018.11.042

[5] Schneider SL, Kohli I, Hamzavi IH, Council ML, Rossi AM, Ozog DM. Emerging imaging technologies in dermatology: Part II: Applications and limitations. *J Am Acad Dermatol*. 2019;80(4):1121-1131. doi:10.1016/j.jaad.2018.11.043