

February 23, 2026

The Hon. Robert F. Kennedy, Jr.  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC 20201

**Re: RIN 0955-AA13: Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as part of Clinical Care**

Dear Secretary Kennedy,

The American Society of Retina Specialists (ASRS) is the largest retina organization in the world, representing over 3,500 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

Thank you for the opportunity to provide feedback on the adoption and use of artificial intelligence (AI) in clinical care.

**Executive Summary**

ASRS supports HHS's goal of fostering a regulatory, payment, and research environment for rapid, responsible adoption of AI in clinical care that improves patient outcomes and augments the services retina specialists provide. For retina specialists, AI already demonstrates meaningful potential for clinical value, particularly in image-based diagnoses and disease monitoring. However, its broader adoption and impact are fundamentally constrained by systemic barriers that HHS is uniquely positioned to address.

**The most significant barrier to accelerating AI innovation and deployment is lack of interoperable, standardized clinical and imaging data.** This barrier is created by conflicting proprietary data formats, incomplete implementation of existing standards, and misaligned vendor incentives. These challenges limit competition, raise costs, slow research progression, and reduce the real-world effectiveness of AI tools.

ASRS urges HHS to prioritize:

- Stronger enforcement and maturation of existing data standards, including Digital Imaging and Communications in Medicine (DICOM), Fast Healthcare Interoperability Resources (FHIR) and Observational Medical Outcomes Partnership Common Data Model (OMOP);

- Payment policy modernization that recognizes AI as clinical infrastructure capable of improving outcomes;
- Federal research and development oversight that promotes open, sharable data and accelerates real-world implementation of validated AI tools;
  - In particular, **NIH should withdraw or significantly modify its proposed Controlled-Data Access policy**, which could have a chilling effect on the dissemination of imaging data for clinical research.
- Preventing private payer use of AI to deny care through prior authorization or recoup payments to physicians through auditing.

By aligning policies around interoperability and value, HHS can unlock AI's full potential to improve patient outcomes, not only for those being cared for by retina specialists, but across medicine. Our full comments and responses to selected, specific questions from the RFI are below.

### **Background**

Retina specialists are board-certified ophthalmologists who have completed an additional 1–2-year fellowship focusing on the medical and surgical care of the vitreous body of the eye and the retina. This includes surgical care for conditions such as retinal detachment and chronic care management for diseases such as age-related macular degeneration (AMD), diabetic retinopathy, retinal vein occlusion, and inherited retinal diseases. Retina specialists have pioneered treatments for these diseases that include injectable medications, surgical techniques, and advanced imaging. Without these advances, millions of Americans would go blind every year.

In the spirit of that innovation, the first AI-enabled medical device cleared by the Food and Drug Administration (FDA) is used for screening for diabetic retinopathy. Retina specialists are eager to continue that innovation and harness AI's potential to speed access to new cures and treatment protocols. AI-assisted analyses of retinal and ocular data hold promise for diagnosing and treating systemic disease, ranging from cardiovascular to autoimmune to neurodegenerative diseases. To meet this opportunity, ASRS has created an AI Task Force charged with identifying key opportunities to integrate AI into retinal care and providing leadership with guidance on the society's role in fostering it. This comment letter is based on the task force's guidance.

### **Lack of Standardized Data**

The ASRS AI Task force has identified the greatest regulatory challenge facing AI adoption in retinal care as a lack of standardization to facilitate data access and interoperability. Numerous data standardization criteria and formats exist—among them FHIR, DICOM and OMOP—but there is a gap between their existence and their implementation making it nearly unworkable

for retina specialists and researchers to create large, aggregated, high-quality datasets essential for robust and generalizable AI.

At the heart of this disconnect in retina, and ophthalmology as a whole, is the widespread use of proprietary imaging formats and incomplete implementation of existing standards by device manufacturers. For example, advanced imaging devices, such as optical coherence tomography (OCT), fundus cameras, and automated visual field analyzers often store data in proprietary formats or, even when using standardized formats, fail to standardize the reporting of crucial metrics, such as central subfield thickness, geographic atrophy (GA) lesion size, and subretinal fluid volume quantification.

Beyond devices, non-structured or non-standardized data extracted from EHRs lack the common nomenclature and coding necessary for reliable dataset aggregation. Clinical metrics, such as visual acuity (VA), lack standardized definitions across systems.

ASRS is advocating to vendors and manufacturers that their proprietary and siloed approach to storing and sharing clinical data (where data is held in isolated, non-interoperable systems that prevent it from being shared or aggregated) is hampering needed innovation. There are private companies and programmers currently engaged in efforts to develop systems that will bridge this gap by converting the proprietary data outputs into standardized formats. If HHS were to echo the need for standardization, this crucial message would be greatly amplified, giving vendors and manufactures more incentive to make their products and data interoperable.

ASRS recommends that HHS enforce and strengthen existing data standards for EHRs, as well as imaging and diagnostic equipment manufacturers, to ensure that retina specialists and developers can harness and aggregate the data to advance patient care and develop new treatments and cures.

We recommend HHS identify and create incentives for vendors and manufacturers to accomplish this, rather than implement punitive measures that would likely cause these companies to pass on significant costs to retina specialists and other end users, increasing costs across the system. Without addressing this underlying data bottleneck, HHS will not be able to achieve its goals of advancing AI in clinical care.

### **Barriers to Implementation in Physician Practices**

As data sets become more standardized and retina specialists and other physicians begin integrating more AI-enabled or assisted technologies into practice, it is imperative that payment systems, particularly Medicare, adapt to meet these changes and keep practices viable. Implementing AI tools in an independent practice may require a significant initial capital outlay and their ongoing use could create additional work for physicians as they analyze additional data and consider differential diagnoses current tools and equipment do not provide. Current reimbursement structures for physician work and practice expense are not designed to reflect these emerging technologies. HHS should collaborate with the medical community to prevent

promising technology from failing because physicians and other providers cannot make a financial case for it.

This inadequate reimbursement barrier is already coming to fruition. Medicare has struggled over the last several years to develop a consistent strategy to code for and value AI-enabled clinical tools. For example, the AI-enabled diabetic retinopathy screening device mentioned above has seen limited uptake by physician practices because the current system lacks a viable payment pathway for its use. Because the device makes the initial diagnosis, Medicare assigns no physician work to the CPT code for the service (92229) and only reimburses for the practice expense of the nurse or technician who assists the patient at the terminal. Primary care physicians, who would be most likely to purchase the device to ensure diabetic patients can receive timely referrals to retina specialists, have no way of covering the initial cost of the device, and CMS has been reluctant to reimburse for equipment start-up costs. Without any incentive to implement the technology, patients—and the Medicare system—do not have the opportunity to benefit from lower treatment burden and cost of care when their disease is caught early.

As the basis for coding and valuation across all payers, the Medicare payment system must be modified to account for AI in a way that encourages physicians to adopt new technologies or care patterns that can improve outcomes without financially penalizing the physician or provider. We strongly recommend HHS and the Centers for Medicare and Medicaid Services (CMS) work with the physician community to develop a framework for valuing physician work and practice expense when using AI technologies in direct patient care or supporting clinical and administrative work. A potential starting point for retina would be to consider a set of billing modifier codes for using AI to help interpret images, similar to those used by radiology when the physician is using computer-aided detection (CADx) tools.

If CMS fails to develop a workable framework, it is likely private payers will develop their own systems, leading to fragmentation across the healthcare system and likely inadequate physician reimbursement. By providing adequate reimbursement, HHS can assist physicians and providers adopt and continue to use these technologies. Without it, HHS will not meet its goal of improving patient outcomes.

### **Clinical Research**

ASRS' AI Task Force has identified the above recommendation of data standardization as critical for clinical research. By enabling AI to aggregate and analyze a broad set of standardized clinical data, retina specialists and researchers may unlock even more answers to better treating, curing or preventing blinding retinal disease. With this analytic capability, retina specialists will align with this administration's goals for a healthier America where retina patients experience less treatment burden, rely less on caregivers, and remain productive members of the economy. ASRS is pleased HHS is prioritizing AI for its role in advanced clinical research.

### ***Opposition to Proposed NIH Controlled-Data Access Policy***

ASRS is concerned, however, that HHS has not fully integrated this strategy across all its agencies or contemplated how it will interact with other simultaneous initiatives. In particular, **we are greatly concerned about the National Institutes of Health’s (NIH) December 2025 RFI on the proposed Controlled-Access Data Policy and its potential chilling effect on imaging-based clinical research and AI development, particularly in retina.** While ASRS strongly supports appropriate protections for human participant data, the draft policy’s broad treatment of personal health data and imaging modalities risks unintentionally restricting responsible data sharing that has historically driven innovation. Retinal imaging—including fundus photography, OCT/OCTA, and ocular ultrasound—can, in certain contexts, become re-identifiable through metadata, rare diagnoses, or linkage with other datasets. However, mandating that all such imaging require controlled access will detrimentally slow research progress.

Of particular concern is NIH’s explicit statement that user registration alone does not constitute controlled access. Many NIH-funded investigators currently share research-grade retinal image datasets through professional society portals such as ASRS’s Retina Image Bank; despite enacted robust data use requirements, they do not meet the proposed full technical requirements of NIH-approved controlled-access. Requiring universal controlled-access could have the unintended consequence of preventing the development and implementation of new AI-enabled technologies HHS seeks in this RFI. ASRS will also be commenting on NIH’s RFI, but given its relationship to this topic, we recommend that HHS provide oversight of the new policy and work with professional societies and other institutions to develop a more workable, risk-based policy for sharing potentially identifiable data.

### **Oversight of Private Payers**

ASRS is also concerned about the use of AI by commercial payers for physician auditing and prior authorization—often in ways that lack transparency, clinical nuance, or meaningful human oversight. In retina care, where treatment decisions are frequently time-sensitive, payer-deployed AI tools risk denying medically necessary care, delaying treatment, and undermining the physician–patient relationship. ASRS has long-standing opposition to payer utilization management tactics, such as prior authorization and step therapy, that nearly every retina patient, except those with original Medicare Part B, must endure. Without clear guardrails from HHS on the use of AI in utilization management, private payers will likely significantly increase their use of them. This will ultimately limit medically necessary care for patients and further add to already significant physician administrative burden.

Research bears out patients’ concern with these potential tactics. A recently published study found that of 291 retina patients surveyed on a 5-point Likert scale, the mean response was 4.2 when asked whether they agreed patients should be given the choice when AI tools are used. In

addition, both patients and retina specialists disagreed with the notion of trusting AI tools over the clinical judgement of a physician.<sup>1</sup>

ASRS urges HHS to exercise oversight authority and restrict or prohibit the use of AI by payers for prior authorization and punitive physician auditing, particularly when such tools operate without transparency, appeal rights, or accountability for clinical harm.

### Responses to Specific Questions

*Questions 1&2: What are the biggest barriers to private sector innovation in AI for health care and its adoption and use in clinical care? What should HHS prioritize to overcome them?*

As noted above, the single largest barrier to AI innovation is lack of interoperable, standardized clinical and imaging data. The main contributors to this barrier are proprietary ophthalmic imaging formats that limit reuse and secondary analysis; inconsistent or absent standards for key clinical variables (e.g., visual acuity); and high costs and contractual barriers to extracting data from EHRs and imaging platforms.

HHS should prioritize incentives for vendors that encourage full adoption of already existing interoperable standards. As a specific example, HHS should not permit imaging vendors to state they have adopted DICOM simply if they have file transfer capabilities. To be considered compliant with DICOM, imaging equipment must have:

- **Equivalence in Imaging Storage:** Images viewed for clinical care on proprietary viewing systems should be stored identically in the PixelArray in DICOM.
- **Standardized Reporting:** Mandatory and uniform reporting of specific, quantitative metrics (e.g., GA lesion size, fluid quantification) using established DICOM Structured Reporting templates across all imaging platforms.
- **Open API for Extracted Metrics:** Imaging devices must provide a non-proprietary export interface for “outside” AI algorithms to securely access and utilize standardized, extracted findings without needing to process raw images themselves.

In addition, HHS should enforce FHIR and OMOP standards for clinical data. HHS should encourage the development of standardized clinical terminology, such as for eye exam findings across all EHRs. It should continue to support full and robust implementation of FHIR standards for all relevant ophthalmic data elements, including a consensus standard for visual acuity (VA).

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<sup>1</sup> Garcia, E, et al. “Artificial Intelligence in Clinical Care: Perceptions of Retina Specialists and Patients Gathered Through a Multicenter Survey,” *Journal of Vitreoretinal Disease*; Vol.10, i 1, <https://journals.sagepub.com/doi/10.1177/24741264251381990>

*Question 3: For non-medical devices, we understand that use of AI in clinical care may raise novel legal and implementation issues that challenge existing governance and accountability structures (e.g., relating to liability, indemnification, privacy, and security). What novel legal and implementation issues exist and what role, if any, should HHS play to help address them?*

ASRS shares the concerns articulated by the American Medical Association (AMA) regarding physician liability related to the use of AI in clinical care. The introduction of AI into clinical workflows should not create expanded malpractice exposure for physicians beyond existing standards of care, nor should physicians be held accountable for errors attributable to algorithm design, training data deficiencies, or vendor-controlled system updates. While current AI tools may assume liability for errors, physicians and patients need to understand the medicolegal implications of these new technologies.

HHS should promote a clear, risk-aligned liability framework that assigns responsibility to the party best positioned to manage and mitigate harm. Developers and vendors of clinical AI systems—particularly those with autonomous or semi-autonomous functions—should bear appropriate responsibility for system performance, including maintenance, updates, and known limitations. Payers who use AI-driven utilization management should bear responsibility for any harm they cause. Physicians should retain clinical judgment and oversight, but should not be penalized for reasonable reliance on validated tools, nor for choosing not to use AI where standards of care remain unsettled. HHS guidance clarifying these principles would reduce adoption barriers, support responsible innovation, and help preserve the physician–patient relationship as AI becomes more widely used.

Furthermore, physicians must not be held liable for harm resulting from private payer utilization management decisions—such as prior authorization or step therapy—which may increasingly be "super-charged" by AI to prioritize cost over what the physician determines is most appropriate for the patient. Consequently, HHS should promote a risk-aligned framework where developers, vendors, and payers bear responsibility for the performance and decisions of the systems they control, ensuring physicians are not penalized for the "blind reliance" on, or the systemic failures of, validated tools.

### **Conclusion**

Thank you again for the opportunity to provide comments on the Administration's goals for integrating AI into clinical care. ASRS stands ready with HHS to promote the development and full implementation of standardized clinical and imaging data to speed access to AI-enabled technology, while also ensuring physician practices remain viable and patients retain access to the care their physicians prescribe. If you have questions or need additional information, please contact Allison Madson, vice president of health policy, at [allison.madson@asrs.org](mailto:allison.madson@asrs.org).

Sincerely,



Geoffrey G. Emerson, MD, PhD, FASRS  
President, ASRS