



February 27, 2026

U.S. Department of Health and Human Services  
Assistant Secretary for Technology Policy  
200 Independence Ave SW  
Washington, DC 20201

On behalf of the American College of Physicians (ACP), we appreciate the opportunity to comment on the proposed rule from the Office of the Assistant Secretary for Technology Policy (ASTP) and the Office of the National Coordinator for Health IT (ONC) regarding Health Data, Technology, and Interoperability (HTI-5). We thank ASTP/ONC for its commitment to advancing interoperability, transparency, and secure data exchange across the health care ecosystem. ACP members include 163,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

At the same time, ACP has significant concerns regarding the scope, structure, and timeline of several proposals. While modernization of health IT policy is essential, reforms must be implemented in a manner that is clinically practical, operationally sustainable, and aligned with patient-centered care. Without appropriate safeguards, the proposed changes risk destabilizing clinical workflows, increasing regulatory uncertainty, shifting liability to physicians, and exacerbating burdens on small, independent, and rural practices. To ensure reforms align with clinical realities and patient needs, physicians and frontline clinicians must be actively involved in developing and implementing health IT policies. ACP urges ASTP/ONC to establish mechanisms for ongoing physician engagement to ensure HTI-5 reforms achieve their goals without unintended negative harm.

ACP further cautions against a regulatory environment marked by continual structural change. Constant changes to certification expectations diminish long-term planning stability for both vendors and physicians and may ultimately stifle rather than promote sustained innovation. To mitigate these risks, ACP urges ASTP/ONC to adopt a phased, predictable transition strategy that includes adequate testing periods, preservation of core accountability mechanisms, clear implementation guidance, and sufficient time for practices to adapt workflows without compromising patient care. We offer the following comments and recommendations to promote interoperability in a sustainable and patient-focused manner.

### **Certification Stability and Clinical Impact**

ACP supports the agency's goal of advancing interoperability and modernizing the certification program. However, we are concerned that the breadth, pace, and cumulative impact of the proposed changes are

overly aggressive and risk destabilizing clinical systems. Frequent and rapid shifts in certification criteria, data standards, compliance obligations, and transparency requirements create regulatory uncertainty and operational strain. Certified health IT systems are deeply embedded in care delivery and patient safety; modifications to certification requirements, exchange mechanisms, transparency standards for artificial intelligence (AI), or data governance frameworks directly affect how physicians document care, make clinical decisions, and coordinate with other clinicians and patients.

While certain proposals may appear manageable from a developer perspective, their real-world impact on physician practices can be substantial. Small, independent, and rural practices, many of which lack dedicated IT staff and rely heavily on vendor support, are particularly vulnerable to accelerated implementation timelines and shifting technical requirements. Without sufficient transition periods and usability safeguards, these changes risk increasing administrative burden, contributing to physician burnout, and introducing patient safety risks through workflow disruption or poorly aligned system design.

ACP is also concerned about proposals to remove certain certification criteria based on “broad industry adoption,” including the proposed elimination of the decision support intervention (DSI) transparency requirements. Although widespread uptake may suggest market maturity, certification criteria serve as critical regulatory guardrails that promote consistency, accountability, and baseline functionality. They also ensure that data, including AI-enabled clinical decision support outputs, is effectively managed, shared, and understood by end-users. Eliminating certification criteria and transparency requirements without adequate replacement safeguards may create financial and operational consequences for physician practices, particularly if vendors repackage previously required capabilities as optional, fee-based enhancements.

In the context of AI and advanced DSI tools, the removal of transparency standards may further limit physicians’ ability to understand how these tools function, what data they rely on, and whether they are appropriate for their patient populations. This lack of clarity could undermine clinician trust, increase liability expense, and erode the patient-physician relationship. If ASTP/ONC determines that the current DSI framework requires refinement, ACP recommends developing an alternative transparency framework that uses a risk-based oversight model, incorporates physician leadership and education, and establishes due accountability for developers.

ASTP/ONC’s proposal to remove certain patient demographics requirements from the United States Core Data for Interoperability (USCDI) and the certification program is also concerning. While many of the proposals in this rule are technology-driven and aimed at improving health IT efficiency, we urge ASTP/ONC, CMS, and other regulators to keep patients affected by their decisions in mind. The removal of sexual orientation and gender identity, critical elements of human dignity and respect, threatens patient autonomy and the broader patient-physician relationship. These data elements are essential for providing effective and meaningful clinical care, and removing them puts patients at risk.

### **USCDI Expansion and FHIR**

ACP supports the development of a robust and clinically meaningful USCDI. However, we are concerned that continuously expanding or changing data collection without appropriate clinical prioritization could

overwhelm physician workflows and diminish the clinical or patient-centric value of the required data elements. Data standards should be based on patient care needs rather than solely on technical feasibility. ACP urges ONC/ASTP to ensure that future USCDI expansions are grounded in demonstrated clinical and societal relevance, accompanied by clear implementation guidance, and supported by adequate transition periods.

Additionally, while we acknowledge the potential of Fast Healthcare Interoperability Resources (FHIR)-based exchange to enhance interoperability, we caution against a rigid or accelerated transition to FHIR without giving sufficient attention to real-world clinical readiness and implementation challenges. A premature approach could worsen disparities in health IT adoption and may unintentionally disadvantage practices that are already under-resourced. The clinical utility of FHIR-based exchange relies not only on technical standards but also on data quality, adequate testing, guidance, and reasonable transition periods. Since FHIR standards and exchange development have not progressed consistently, there are outstanding questions on how FHIR will function at scale. Data exchange must still be supported by C-CDA exchange functionality. Rural, less-resourced physician practices utilizing certified health IT from smaller developers still rely on C-CDA as the primary exchange modality. If these changes move forward as proposed, ASTP/ONC risks breaking the current data exchange landscape by excluding many physician settings from exchanging data unless they pay additional fees or adopt new technologies. ACP strongly urges ASTP/ONC to preserve policies that maintain the current level of interoperability while providing robust incentives for the adoption of new technologies and standards.

ACP is also concerned about the proposal to remove the real-world testing condition and the maintenance-of-certification requirement from the certification program. Real-world testing plays a critical role in ensuring certified technology performs as intended once deployed in clinical environments. Eliminating this requirement risks increased adoption of immature or insufficiently tested standards. This may lead to workflow disruptions requiring extensive workarounds, increased burden and cost for physician practices, and failure to achieve intended policy outcomes. While we recognize that aspects of enforcement discretion have previously been exercised, formal removal of the requirement would weaken an important accountability mechanism. ACP urges ASTP/ONC to preserve and strengthen real-world testing requirements to ensure health IT innovation translates into practical, safe, and effective clinical implementation.

### **Information Blocking**

ACP supports efforts to promote appropriate data sharing and prevent unjustified information blocking. We are also concerned that certain aspects of these proposals transfer compliance burdens and legal risks onto physicians, even when they have little control over the technical architecture or operational policies of health IT systems. Physicians should not be held accountable for decisions made at the vendor or system level, especially when compliance with information-blocking requirements depends on complex technical infrastructure that is beyond their control. ACP urges ASTP/ONC to ensure that enforcement frameworks clearly delineate responsibilities among developers, health systems, and individual clinicians. This will help prevent physicians from inadvertently being exposed to regulatory risks for situations outside their control.

### *"Access" and "Use" Definition Changes*

ACP supports the proposed changes to the definitions of "access" and "use" to explicitly include automated means of accessing, exchanging, or using electronic health information, including autonomous and AI-enabled systems. As AI and other emerging technologies become increasingly integrated into health care systems and data exchange, regulatory frameworks should be put in place to ensure these tools are implemented safely, transparently, and in ways that protect patients and end users.

### **Privacy and Security Concerns**

ACP has significant concerns regarding privacy, security, and the transfer of risk to physicians amid the expansion of data exchange and API-based access. While increased interoperability offers important benefits, it also brings new vulnerabilities. The growth of data flows, reliance on third-party applications, and API-driven ecosystems raises critical issues related to data governance, patient consent, cybersecurity, and HIPAA liability. Physicians are increasingly placed in positions of legal and ethical responsibility for data exchange practices over which they have limited visibility or control. This shift in risk is troubling, especially given the escalating cybersecurity threats and growing patient concerns about data misuse. ACP strongly urges the ASTP and ONC to prioritize practical and security safeguards, clarify liability frameworks, and avoid policies that implicitly transfer compliance risk from technology developers to clinicians and patients.

### **Conclusion**

ACP appreciates the opportunity to provide feedback on HTI-5 and looks forward to continued collaboration with ASTP/ONC on future rulemaking, including HTI-6. As the health care system moves toward an FHIR-enabled, API-driven approach, ACP urges ASTP/ONC to offer clear guidance on implementation, workflow integration, and liability issues. Future policies should define how FHIR-based APIs will underpin a robust interoperability framework with consistent standards and accountability. They must also ensure responsible use, privacy protections, and cybersecurity resilience to enhance patient trust and clinical care. ACP is committed to working with ASTP/ONC to ensure that interoperability policies are practical, ethical, and support high-quality patient-centered care. Please contact Dejah Johnson, JD, MPA, Manager, Regulatory Affairs for the American College of Physicians, at [djohnson@acponline.org](mailto:djohnson@acponline.org) or (202) 261-4506 with comments or questions about the contents of this letter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ross W. Hilliard".

Ross W. Hilliard, MD, FACP  
Chair, Medical Informatics Committee  
American College of Physicians