ConnectedHealthInitiative

February 27, 2026

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

RE: ***Comments of the Connected Health Initiative,*** **Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity** ***[RIN 0955-AA09; 90 FR 60970]***

I. Introduction, Statement of Interest, and Summary of Views

The Connected Health Initiative[1] represents stakeholders from across the healthcare community who share your goals of driving the development and adoption of digital health management and care navigation applications and strengthening interoperability and secure access to health data through open, standards-based technologies. We appreciate the opportunity to respond to your proposed rule[2] focused on deregulatory actions identified in HHS regulations regarding Health information technology standards, implementation specifications, and certification criteria and certification programs for health information technology, and information blocking. We are committed to increasing beneficiary access to effective digital capabilities needed to make informed health decisions and increasing data availability for all stakeholders contributing to health outcomes.

CHI's membership spans the full digital health continuum, including developers of digital health management applications, connected devices, remote patient monitoring solutions, AI-enabled clinical decision support tools, telehealth platforms, and health IT infrastructure. All are committed to advancing digital healthcare policies that improve patient outcomes, reduce costs, augment population health management, and support the healthcare workforce (the Quadruple Aim[3]). The free and secure flow of health information, and true interoperability, are central to achieving improved outcomes for all patients. CHI is deeply committed to advancing health data interoperability, responsible AI adoption, and a vibrant competitive marketplace for health IT throughout the continuum of care.

CHI shares ASTP/ONC's commitment to the necessary expanded use of digital and connected health technologies. A growing evidence base continues to demonstrate that the responsible use of safe and effective digital health solutions produces better patient outcomes, reduces costs, augments population health management, and improves the healthcare workforce experience. Digital health tools, increasingly powered by artificial intelligence (AI), leverage patient-generated

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[1] www.connectedhi.com.
[2] 90 FR 60970.
[3] Bodenheimer T, Sinsky C. "From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider." *Annals of Family Medicine*. 2014;12(6):573-576.

health data (PGHD) and include cloud-enabled solutions, to reduce administrative burden, support medical and clinical decision-making, and chronic and acute care management. The use of these tools is also vital in supporting unserved and underserved populations' access to prevention, diagnosis, and treatment for both acute and chronic conditions.

CHI generally supports ASTP/ONC's deregulatory direction in this Proposed Rule. The healthcare technology sector will benefit from a regulatory-level recalibration to reduce unnecessary regulatory burden, reflect the maturation of the market, and enable the FHIR-based interoperability future that American patients and providers deserve.

We offer the following detailed comments and recommendations to help ASTP/ONC finalize a rule that maximally serves these goals. Key recommendations we make include:

ONC Health IT Certification Program

- Support removal of 34 legacy criteria and revision of seven others; appreciate the strategic FHIR-forward reset of the Certification Program.
- Support removal of AI "model card" requirements; urge future AI certification requirements align with NIST's AI Risk Management Framework and CPT Appendix S.
- Support descoping Real World Testing and Insights conditions; support USCDI v3.1 adoption with appropriate SDOH data segmentation safeguards.
- Urge clear transition guidance, consistent ONC-ACB application of the deregulatory framework, and vigilance against compliance gamesmanship and anticompetitive fee practices.

Information Blocking

- Support revising "access," "use," and "exchange" definitions to cover automated and AI-mediated access.
- Support removing the third-party modification condition and revising or removing the manner exception exhausted condition from the Infeasibility Exception.
- Support clarifying the Manner Exception cannot be satisfied by non-market-rate, adhesion, or unconscionable contracts; urge companion guidance with concrete examples.
- Support removal of the TEFCA Manner Exception; urge robust OIG enforcement and pro-innovation guidance on AI and real-world data access scenarios.

Additional Recommendations

- Urge action to address SEP licensor abuses threatening open health IT interoperability; coordination with CMS on payment policies rewarding digital health innovation; and establishment of API response time standards with payer-provider symmetry requirements.

Across all of our recommended actions, coordination across HHS, and the federal government and states, will be critical to accomplishing meaningful improvements to the U.S. health technology ecosystem.

II. CHI Views on Proposed Deregulatory Reforms to the ONC Health IT Certification Program

a. Removal and Streamlining of Certification Criteria

CHI supports ASTP/ONC's proposal to remove 34, and revise seven, of the current 60 certification criteria. The Proposed Rule's recognition that many of these longstanding functionality-oriented and non-FHIR-based certification criteria are no longer necessary to advance interoperability and no longer serve as meaningful market drivers for initial adoption is well-founded. CHI agrees that these legacy requirements can be costly compliance obligations that consume engineering and testing resources without commensurate patient benefit. Removing them will allow developers to redirect resources toward innovation and toward meeting the genuine interoperability needs of providers and patients.

With respect to specific proposed removals, CHI notes its support for removing the following categories of criteria:

- Legacy non-FHIR transport criteria, including the Direct Project (§ 170.315(h)(1)) and Direct Project, Edge Protocol, and XDR/XDM criteria (§ 170.315(h)(2)), which are superseded by FHIR-based exchange standards now well-established in the market.
- Several design and performance certification criteria, including Safety-Enhanced Design, which ASTP/ONC has identified as no longer meaningfully driving improved product safety given widespread market adoption of safety by design practices.
- Public health certification criteria that are redundant with, or superseded by, other reporting channels and programs, including certain Cancer Registry and Health Care Surveys transmission criteria.

CHI further supports ASTP/ONC's strategic vision of "resetting" the Certification Program to establish a new foundation on which to build FHIR-based API requirements. As ASTP/ONC notes, prioritizing FHIR-based APIs that enhance automation and API performance, move beyond read-only interactions, and expand the scope of data available to support clinical, patient-centered, and public health use cases is the right long-term direction. CHI's members have invested in, and benefit from, FHIR implementation.

b. Proposed Removal of AI Model Card Requirements for Decision Support Interventions

CHI supports ASTP/ONC's proposal to revise the Decision Support Interventions (DSI) certification criterion (§ 170.315(b)(11)) to remove the AI "model card" requirements. As CHI has previously raised before ASTP/ONC and across HHS, overly prescriptive DSI reporting mandates could lock in certain capabilities, create an artificial ceiling on AI innovation, and generate compliance costs, including by effectively limiting integration of third-party AI tools to avoid liability for disclosures about proprietary third-party systems. Transparency in health AI remains essential, and CHI recommends a scaled, risk-tiered approach to AI transparency requirements rather than uniform mandates. Removing the model card requirements is consistent with this approach.

More specifically, this Proposed Rule would remove requirements for health AI capabilities to disclose "source attributes," including information about training data. CHI agrees that these existing requirements have been unhelpful on net by adding compliance costs and development overhead for AI developers without meaningfully enabling providers to evaluate the tools they use. CHI supports their removal, but at the same time urges ASTP/ONC not to abandon the underlying goal of helping providers understand and evaluate health AI tools. Rather than prescribing specific disclosure fields, ASTP/ONC can and should continue to work collaboratively with impacted stakeholders to develop a voluntary common format for communicating to providers the information they actually need to conduct their own independent evaluation and review of AI tools. This need is especially acute for smaller provider practices, which typically lack the resources to evaluate AI tools and systems and would benefit from accessible, standardized information to make informed decisions about the AI tools they deploy in clinical settings.

As ASTP/ONC rebuilds certification requirements on a FHIR-forward basis, CHI urges ASTP/ONC to develop any future AI transparency certification requirements in close partnership with technology developer, provider, patient, and other stakeholders and in alignment with the broader federal AI governance landscape, including alignment with NIST's AI Risk Management Framework[4] and other cross-sectoral standards such as ISO/IEC 42001[5]. CHI also recommends that ASTP/ONC leverage CPT Appendix S[6] (AI taxonomy for medical services and procedures) to advance common terminology across certification, coverage, and regulatory purposes.

Finally, CHI has worked with the broader community to develop, and strongly encourage the ASTP strategy to align with, healthcare ecosystem-wide consensus recommendations on the use of AI in healthcare:

- **CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem***, a proposal on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients (https://connectedhi.com/wp-content/uploads/2022/02/AdvancingTransparencyforArtificialIntelligenceintheHealthcareEcosystem.pdf); and
- **CHI's *Health AI Roles & Interdependency Framework***, which proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use; and suggests roles for supporting safety, ethical use, and fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept (https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf); and
- **CHI's *Value-Based Payment Reform: Leveraging SaaS Technologies for Care Model Innovation*,** a report offering leading recommendations for payment reforms to enable and incentivize the adoption of modern software and AI technologies and care model innovation

[4] National Institute of Standards and Technology, *Artificial Intelligence Risk Management Framework (AI RMF 1.0)*, NIST AI 100-1 (Jan. 2023), https://doi.org/10.6028/NIST.AI.100-1.
[5] ISO/IEC 42001:2023, *Information Technology — Artificial Intelligence — Management System* (Dec. 2023), https://www.iso.org/standard/81230.html.
[6] American Medical Association, *CPT Appendix S: AI Taxonomy for Medical Services and Procedures*, https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures (eff. Jan. 1, 2022).

(https://connectedhi.com/value-based-payment-reform-leveraging-saas-technologies-for-care-model-innovation/).

c. Conditions and Maintenance of Certification: Real World Testing and Insights

CHI supports ASTP/ONC's proposals to descope the Real World Testing Condition and Maintenance of Certification requirements (§ 170.405) and to remove and descope measures associated with the Insights Condition (§ 170.407). These changes are consistent with ASTP/ONC's enforcement discretion positions and reflect the practical reality that Real World Testing plans and results reporting and the current Insights reporting framework impose significant administrative burdens with limited marginal benefits at this stage of the program. Limiting the Insights condition to reporting on "use of FHIR in apps through certified health IT" is appropriately targeted at the key metric that will support the FHIR-forward future.

CHI has consistently advocated for ASTP/ONC and CMS to work together to advance joint agency goals of gaining insight into interoperability and reducing provider reporting burdens, including by allowing provider reporting to be accomplished through simplified attestation approaches wherever feasible. The Proposed Rule's approach to Insights is a notable step in this direction.

d. USCDI v3.1 and Standards Updates

CHI supports ASTP/ONC's proposal to adopt USCDI v3.1 in § 170.213. CHI has long supported USCDI expansion consistent with technology and competitive neutrality principles. As USCDI continues to mature, CHI encourages ASTP/ONC to continue the predictable, collaborative approach to USCDI updates that has established the U.S. as a world leader in FHIR-based data standardization and exchange. We reiterate our prior recommendation that, where it is appropriate, any future USCDI updates be accompanied by adequate privacy and security safeguards and by granular data segmentation policies that protect sensitive information in accordance with patient preferences and applicable law.

CHI supports the removal of outdated and no longer referenced standards from the Certification Program. Maintaining accurate, current standards references reduces confusion and unnecessary compliance work for developers.

CHI also applauds ASTP/ONC's broader focus in this Proposed Rule on FHIR as the foundation for health IT interoperability. As the Certification Program is reset on a FHIR-forward basis, CHI encourages ASTP/ONC to enable hyperlinks to diagnostic medical images within transitions-of-care and patient access workflows. The ability for providers and patients to access diagnostic imaging through FHIR-based API links, rather than requiring large, cumbersome file transfers, is an important practical advance for clinical workflows and patient engagement. CHI had expressed support for this proposal previously, and believes it remains a valuable and achievable interoperability improvement that is fully consistent with the FHIR-forward direction ASTP/ONC is now pursuing.

e. Request for Transition Period Clarity and Stakeholder Guidance

While CHI supports the deregulatory thrust of the Proposed Rule, we urge ASTP/ONC to provide clear guidance on transition periods and compliance expectations as it finalizes and implements

the rule. The Proposed Rule references a transition period through January 1, 2027, for certain standards removals. CHI generally recommends that ASTP/ONC:

- Publish clear guidance documents, as early as possible, detailing what health IT developers must do (and by when) as legacy certification criteria are removed, and how existing certified products will be treated during and after the transition.
- Engage ONC-Authorized Certification Bodies (ONC-ACBs) proactively to ensure that certification bodies are not applying legacy requirements in a manner inconsistent with ASTP/ONC's deregulatory intent during the transition.
- Ensure that health IT developers and ONC-ACBs do not use the certification program architecture to extract excessive fees, impose compliance gamesmanship, or otherwise undermine the program's pro-patient, pro-innovation goals. The deregulatory direction of this Proposed Rule should be accompanied by vigilance against such anticompetitive practices, and CHI encourages ASTP/ONC and ONC-ACBs to remain attentive to this issue.

III. Proposed Revisions to the Information Blocking Regulations

A truly interoperable healthcare ecosystem must be inclusive and welcoming of data from a range of sources through open APIs that allow the safe and secure introduction of patient-generated health data (PGHD) into electronic health records (EHRs). CHI has long encouraged robust information blocking enforcement and has consistently called on HHS to take steps to end information blocking practices that actively harm patients by disrupting the connected care continuum. We are therefore supportive of the Proposed Rule's efforts to address documented misuse and abuse of information blocking exceptions.

CHI emphasizes that the deregulatory reforms in this Proposed Rule should not come at the expense of robust enforcement of the information blocking rules. Vigorous enforcement of the information blocking prohibitions is not in tension with the Administration's deregulatory goals, and is essential to achieving them. A connected, competitive healthcare technology ecosystem cannot exist where certain actors face no meaningful consequences for systematically and unreasonably withholding patient data from providers, patients, and innovators. The Administration's vision of an open, interoperable health data ecosystem depends on enforcement, not merely on removing regulatory burdens from developers. CHI therefore calls on ASTP/ONC and the OIG to treat information blocking enforcement as a top priority and to make clear through visible enforcement actions that the rules carry real consequences.

a. Clarification of "Access" and "Use" Definitions to Include Automated Means and AI Systems

CHI supports ASTP/ONC's proposal to revise the definitions of "access" and "use" in § 171.102 to clarify that these definitions include automated means of access, exchange, or use of electronic health information (EHI), including autonomous AI systems. CHI has advocated across HHS for policies that recognize the central role of AI in healthcare and that facilitate, rather than impede, AI-driven innovations that improve patient outcomes.

Information blocking of EHI that is accessed or used by AI systems represents a meaningful and growing concern for CHI members developing AI-enabled healthcare tools. Expressly addressing

AI-driven access in these foundational definitions will provide important clarity for the ecosystem. The recognition of autonomous AI agents, including AI systems that independently query, retrieve, or process patient data without direct human initiation of each transaction, as covered by the access and use definitions is particularly important and timely given the rapid expansion of agentic AI in healthcare workflows.

CHI also supports ASTP/ONC's alternative proposal to revise the "exchange" definition in a similar manner. In CHI's view, the alternative proposal ensures full symmetry across the access, use, and exchange definitions and eliminates any ambiguity that could be exploited by information blocking actors seeking to argue that AI-mediated exchange falls outside the rules' coverage.

b. Removal of the Third Party Seeking Modification Use Condition from the Infeasibility Exception

CHI supports ASTP/ONC's proposal to remove the third party seeking modification use condition from the Infeasibility Exception (§ 171.204(a)(3)). As ASTP/ONC observes, this condition has proven susceptible to misuse by actors seeking to withhold EHI and unnecessarily inhibit access, exchange, and use of EHI by third parties that patients and providers want to work with. The CHI community's experience reflects frustrations arising from certain health IT actors invoking this condition to block third-party application developers from receiving data to which patients and providers have authorized access. Removing this condition is consistent with the overarching policy goal of the Cures Act that EHI be accessible without "special effort" and that patients and providers control how their data is used.

c. Revision or Removal of the Manner Exception Exhausted Condition

CHI supports ASTP/ONC's proposal to revise or, in the alternative, remove the manner exception exhausted condition (§ 171.204(a)(4)) from the Infeasibility Exception. Like the third party seeking modification condition, this condition has been invoked in ways that conflict with the underlying purpose of the information blocking rules. CHI notes that ASTP/ONC's preferred approach is to revise this condition to narrow its application and better align it with the original intent. We support that approach as a targeted, proportionate response. However, CHI also supports the alternative of full removal if ASTP/ONC concludes that the condition cannot be sufficiently narrowed to prevent continued abuse. In all events, the priority must be ensuring that actors cannot use this condition as a shield to withhold data that patients and providers need.

d. Revisions to the Manner Exception's Manner Requested Condition

CHI supports ASTP/ONC's proposal to revise the Manner Exception's manner requested condition (§ 171.301(a)) to clarify that the Manner Exception cannot be satisfied by contracts that are not at market rate, are contracts of adhesion, or contain unconscionable terms. Digital health application developers and third-party health IT vendors have consistently encountered certain health IT actors leveraging the Manner Exception to impose non-market-rate contracts, exorbitant fees, and adhesion contracts as a condition of data access. This dynamic directly undermines competition in the health IT marketplace and violates the spirit of the Cures Act's anti-information blocking provisions.

CHI further recommends that ASTP/ONC issue guidance, either in the preamble to the final rule or in a separate guidance document, providing examples of contract terms that would and would not satisfy the market-rate requirement. Such guidance will be valuable to both actors seeking to comply with the rule in good faith and to the OIG in its enforcement work.

e. Removal of the TEFCA Manner Exception (Subpart D)

CHI supports ASTP/ONC's proposal to remove Subpart D from 45 CFR Part 171, including the TEFCA Manner Exception (§ 171.403) and associated definitions. CHI has previously raised concerns that a reliance on TEFCA could create a two-tiered system in which healthcare actors who are subject to federal privacy and security laws but are not licensed healthcare professionals as defined in TEFCA Standard Operating Procedures may face barriers to accessing patient health information for treatment. Such a dynamic is counter to the Cures Act's requirement that "special effort" not be required to access EHI.

CHI recognizes the important role that TEFCA can play in advancing nationwide health information exchange, particularly through its FHIR-based exchange capabilities and its potential to support AI-driven interoperability applications. However, CHI agrees with ASTP/ONC's assessment, based on TEFCA's continued implementation and maturation and public comments received, that removing this dedicated exception from the information blocking regulations is appropriate at this stage. CHI views each of the information blocking exception clarifications in this Proposed Rule as important steps toward closing the loopholes that certain actors have exploited to withhold patient data. The Administration's goal of a connected care continuum requires that these exception-based escape hatches are not exploited.

f. Recommendations for Ongoing Information Blocking Enforcement

CHI notes the Proposed Rule's deregulatory reforms to the information blocking exceptions, and we take this opportunity to again urge robust enforcement of the information blocking rules by ASTP/ONC in collaboration with the OIG. CHI cannot overstate that the deregulatory changes proposed here will only deliver their intended benefits to patients and innovators if information blocking enforcement is simultaneously strengthened. The CHI community has directly observed information blocking being used by certain health IT actors to frustrate the access, exchange, and use of EHI by innovative third-party digital health developers. The regulatory reforms proposed here will be most meaningful if accompanied by active, visible enforcement actions against information blocking actors.

CHI also calls on ASTP/ONC to continue its efforts to provide pro-innovation guidance on the information blocking rules in a transparent and responsive manner, including by clarifying the application of the rules to novel data access scenarios involving AI, machine learning, and real-world data uses that have not yet been addressed in existing guidance.

IV. Additional Recommendations

a. Standard Essential Patent Licensing and Health IT Interoperability

CHI urges ASTP/ONC to remain attentive to the growing impact of standard essential patent (SEP) licensor abuses on the digital healthcare sector as the Certification Program transitions to an

increasingly FHIR-based framework. As standards adoption in health IT deepens, the risk of SEP holders seeking to extract above-FRAND licensing terms from health IT developers increases.[7] Such practices undermine the Administration's goal of creating a competitive and open healthcare technology ecosystem.

b. Digital Health in Value-Based Care and Medicare Programs

While this Proposed Rule is appropriately focused on certification and information blocking deregulation, CHI emphasizes that the full benefits of FHIR-based interoperability and reduced information blocking will only be realized if the broader healthcare payment and incentive environment rewards the use of digital health tools. CHI urges ASTP/ONC to continue its coordination with CMS to ensure that the interoperability improvements enabled by this Proposed Rule translate into concrete opportunities for digital health innovators to participate in and be reimbursed for their contributions to value-based care. In particular, CHI recommends that CMS revise its practice expense methodology to better support Software as a Medical Device (SaMD) and better integrate telehealth, remote monitoring, and AI into Medicare services.

c. Advancing Secure, Standardized APIs for Real-Time Data Sharing

As ASTP/ONC pursues its FHIR-forward future, CHI reiterates its recommendation that ASTP/ONC prioritize both payers and providers to adopt FHIR-based, standardized APIs for real-time data sharing, and CMS aligning its own API and interoperability requirements with those of ASTP/ONC. Certified technology used by providers must have a corresponding and standardized technical interface with payer API systems to function effectively, particularly for electronic prior authorization.

[7] Brian Scarpelli & Priya Nair, *Healthcare and Standard Essential Patents*, Connected Health Initiative Issue Paper (Feb. 2025), https://connectedhi.com/wp-content/uploads/2025/03/CHI-Issue-Paper-Healthcare-and-Standard-Essential-Patents-Feb-202568.pdf.

V. Conclusion

CHI appreciates the Administration's commitment to these shared goals, and looks forward to continued collaboration to advance a connected care continuum that benefits all Americans. Our community welcomes the opportunity to meet with you to discuss our shared views.

Sincerely,

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