February 27, 2026

The Honorable Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

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

RE: Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity (HTI-5) Proposed Rule; RIN 0955–AA09

Dear Assistant Secretary Keane:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments in response to the Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity (HTI-5) proposed rule. NAACOS is a member-led and member-governed nonprofit of nearly 500 accountable care organizations (ACOs) and value-based care entities in Medicare, Medicaid, and commercial insurance working on behalf of health care providers across the nation to improve the quality of care for patients and reduce health care costs. Collectively, our members are accountable for the care of more than 10 million beneficiaries through Medicare's population health-focused payment and delivery models, including the Medicare Shared Savings Program (MSSP) and the Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) Model.

We appreciate that ASTP/ONC aims to reduce administrative burden and costs to health care providers, offer flexibility to both health information technology (IT) developers and providers, and support innovation; however, we are concerned that deregulation may have unintended consequences and potential downstream financial impact on providers. Our comments below reflect the shared goal of an interoperable health data ecosystem that drives innovation and expands the digital health marketplace, while also ensuring that providers do not face undue burden.

Health Information Technology Standards, Implementation Specifications, And Certification Criteria and Certification Programs for Health Information Technology

ASTP is proposing to remove 34 and revise seven out of 60 current certification criteria, noting that these criteria are duplicative or overly burdensome, no longer necessary, or impede innovation. While we support streamlining and modernizing the criteria, we are concerned that rapid deregulation will have unintended consequences on providers. ACOs rely on certified products yet continue to face challenges with significant variability in systems and system version capabilities. These ongoing barriers make data aggregation difficult, require significant resources to overcome, and are an impediment to higher value care.

NAACOS strongly recommends that ASTP delay the removal or revision of any certification criteria associated with Merit-based Incentive Payment System (MIPS), Promoting Interoperability (PI), or any other CMS provider mandates (e.g., APMs) until 2028. PI requires providers to attest to how the certified electronic health record technology (CEHRT) is used, assessing functions like bi-directional reporting to health information exchanges (HIEs), registry reporting, and closing referral loops by receiving and reconciling information. Failure to meet the PI requirements results in significant payment penalties for providers, including physician payment penalties of up to nine percent, loss of shared savings eligibility, and inability to qualify for incentives for advanced alternative payment models (AAPMs). It is therefore critical that ASTP work with the Centers for Medicare and Medicaid Services (CMS) to ensure that vendor requirements equate to the same standards providers must meet. **A delay in retiring requirements will provide CMS with the opportunity to evaluate and adjust its own program requirements, with public input, to align with ASTP's modernized certification program.**

NAACOS urges ASTP to improve post-certification oversight mechanisms to ensure that CEHRT meets providers' needs without undue cost. ASTP notes that the capabilities captured by the criteria proposed for removal have been "widely adopted" or "widely implemented," suggesting that these capabilities will remain in health IT products even if the corresponding criterion is removed from the certification program. However, this assessment is often based on how long the certification criterion has been included in the base electronic health record (EHR) definition, or the CEHRT definitions established by CMS, and not by any analysis of IT developer behaviors or actions to date. We do not believe that market prevalence alone can predict whether these functionalities will remain a market baseline capability and be maintained by certified IT developers once they are removed as certification program requirements. ACOs have reported that vendors are not ready for widespread implementation of CMS-required quality measures and require ACOs to pay fees for the deployment of these measures and FHIR-Application Programming Interfaces (API). Accordingly, there is strong concern among ACOs and value-based care (VBC) providers that fewer mandates on IT developers will result in products that lack standardization and whose functionalities are insufficient to comply with CMS requirements, further compounding existing challenges with interoperability, regulatory compliance, and costs. By strengthening current post-certification oversight, end users will be better informed of any potential lags in reporting capabilities and can plan accordingly. At a minimum, ASTP should:

- Adopt mechanisms (e.g., random post-market surveillance, developer attestations) to carefully track whether certified products continue to effectively support providers required to comply with CMS mandates, without making provider compliance more challenging or costly.
- Monitor the extent to which cost savings accrued from this rule are passed on to provider end-users and not used exclusively for the benefit of IT developers.

NAACOS requests that ASTP enhances transparency. Along with enhanced oversight of certified products, ASTP should also adopt mechanisms that ensure providers have transparent information about the capabilities of certified technology. ASTP could partner with CMS to require that vendors use plain language explanations of how their products comply with specific CMS program requirements, including distinct functionalities and costs, and incorporate this information into the current Certified Health IT Product List (CHPL) website. Health systems, ambulatory clinics, and providers across VBC entities still face barriers complying with aspects of CMS quality reporting requirements tied to CEHRT. By providing these stakeholders with transparent and digestible information evaluating certified products' technical merit, including public vendor attestations, ASTP can enhance trust and efficiency among end-users, as well as support higher quality, safer patient care. Without proper oversight and guidelines on the capabilities of certified technology, many small and independent providers will

continue to experience hardships while navigating barriers to expand the use of new technologies in clinical care, including a lack of expertise and resources to build and assess their own tools.

NAACOS recommends that ASTP leverage ACOs to design future certification requirements. NAACOS appreciates that in some cases, ASTP is proposing to remove certification criteria to provide health IT developers with the flexibility to take more innovative approaches to specific functionalities than current criteria or standards allow. We also recognize the value of a marketplace that promotes customized solutions that are tailored to an end user's particular needs. As we have noted in the past, ACOs should serve as a test case for appropriate use of CEHRT, as they reflect networks of practices representing varying sizes, geography, and vendor systems; have advanced needs for leveraging data across the continuum of care; and can provide valuable, real-time information on how vendors are offering feasible and cost-appropriate functionalities. NAACOS would be pleased to support ASTP with leveraging ACOs to ensure that new requirements meet the needs of providers managing the health of populations.

Criteria to Consider for Delayed Removal or Retention

ASTP should consider delaying the removal of, or retaining, the following criteria:

- Delay removing criteria that pose a considerable risk to the ability of providers to meet certain requirements for the CMS Merit-based Incentive Payment System (MIPS) Promoting Interoperability (PI) Program. We believe further consideration from ASTP is needed ahead of the final rule to achieve cross-agency, harmonized standards for the following criteria: Clinical Decision Support; Family Health History; Implantable Device List; Transitions of Care; Clinical Information; Reconciliation and Incorporation; Security Tags; Care Plan; Patient Health Information Capture; Decision Support Interventions; Clinical Quality Measures (including automated numerator recording and measure calculation, Privacy and Security, Audit Reports, End-user Device Encryption, Integrity, and Multi-factor Authentication); Patient Engagement (View, Download, and Transmit to third party); Quality Management System; Application Access (patient selection and all data request); and Direct Project, Edge Protocol, and XDR/XDM. As noted earlier, we recommend that ASTP delay removal of these criteria until at least 2028 so that it can work with CMS to ensure alignment between its program requirements and evolving ASTP certification criteria. If ASTP ultimately adopts these proposals without delay, it is critical that it simultaneously adopt mechanisms to evaluate the impact of these changes on the ability of providers to comply with CMS programs without undue burden or cost and on interoperability, in general.
- Retain the AI "model card" transparency requirement. Currently, the AI "model card" transparency requirements for clinical decision support tools mandate that health IT developers seeking federal certification disclose certain information about AI algorithms in their software to clinicians. Removing all requirements related to source attribution would hinder a transparent procurement process and open providers to risk. AI is growing at a significant rate, making it challenging for providers to keep up with the ever-evolving landscape of AI-supported technology. In the absence of transparency, adoption is slowed as providers lack the ability to determine the clinical accuracy, and ultimately safety, of tools. Greater transparency is needed to build trust and speed adoption.
- Retain the "Insights" Condition and Maintenance of Certification. This requirement, stemming from the 21st Century Cures Act, mandates that developers of certified health IT report on specific metrics (e.g., in categories related to interoperability, usability, security, and

conformance to certification testing) to improve transparency in the health IT marketplace and assist end-users with selecting products. The very intent of this Congressionally authorized program was to enhance transparency and provide actionable, standardized data to address information gaps in the health IT marketplace regarding interoperability, usability, and user experience. ASTP purposely designed it so that metrics are phased in over three years, starting with calendar year (CY) 2026, and structured "so as not to unduly disadvantage small and startup developers of certified health."[1] We are concerned that ASTP has proposed to drastically narrow this program prior to implementation and prior to collecting any real-world results. We also question whether this proposal adheres to ASTP's obligations under the 21st Century Cures Act.

- Reconsider removal of criteria related to public health emergency preparedness. In light of the significant lessons learned from the global COVID-19 pandemic and any future viral threats, more consideration is needed for additional criteria under the public health certification umbrella for public health agencies, electronic case reporting, antimicrobial use and resistance reporting, and health care surveys. The following proposals will create unintended consequences for providers and increase their burden in tracking EHR functionalities they find most useful: revising certification criterion to be functional only and remove the reference to CDA-based standards for both electronic case reporting and antimicrobial use and resistance reporting; and removing health care surveys to "align with CDC priorities around data modernization and encourage the use of FHIR-based approaches." If ASTP plans to address these in future rulemaking, then it should not remove them until it has in place a carefully structured alternative in place.

Response to Proposals for Information Blocking

NAACOS supports tightening information blocking standards to reduce ongoing activities that interfere with interoperability, care coordination, patient empowerment, and improved patient outcomes. ASTP proposes revisions to the Infeasibility Exception to prevent EHR developers from unnecessarily inhibiting access, exchange, and use of Electronic Health Information (EHI) by third parties preferred by patients and providers. ASTP notes that this will help unleash innovation and competition for the improvement of health outcomes and lower health care costs. Additionally, ASTP proposes to:

- Modify the Manner Exception Exhausted Condition to ensure it does not cover any egregious contracts, agreements, or licenses and cannot be used to convince requestors to accept disagreeable terms considered an interference; and
- Remove the TEFCA Manner Exception, as it is no longer necessary as an incentive.

These efforts will support ACOs and providers in VBC arrangements with addressing the longstanding challenges of extracting data in a regular and timely manner.

NAACOS suggests additional consideration for the revised definitions for "access" and "use" regarding the exchange of EHI and the integration of automated technologies, such as robotic process automation and autonomous artificial intelligence systems. We are concerned that this proposed expansion of the definition could create confusion about which party is contributing to information blocking and potentially create a situation where providers are held liable for information blocking when their systems lack such capabilities. ASTP and CMS could launch a testing tool for APIs to support overall

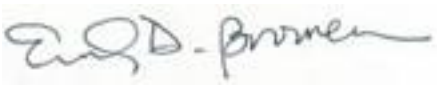
[1] https://healthit.gov/wp-content/uploads/2023/12/HTI-1_Insights_factsheet_508.pdf

program integrity and prevent unintentionally increasing regulatory burden or compliance costs for providers.

Conclusion

Thank you for the opportunity to provide feedback on the HTI-5 Proposed Rule. NAACOS and its members are committed to providing the highest quality care for patients while advancing population health goals for the communities they serve. We look forward to our continued engagement on improving patient and health care provider access to EHI. If you have any questions, please contact Aisha Pittman, senior vice president, government affairs at aisha_pittman@naacos.com.

Sincerely,



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