October 4, 2024

Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC)
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

RE: RIN 0955-AA06

Submitted electronically via regulations.gov

Dear Assistant Secretary Tripathi:

The Health Innovation Alliance (HIA) is pleased to submit comments to the 2024 proposed rule entitled *Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability*. HIA is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers working together to improve health care through the common sense use of data and technology.

HIA is supportive of many of the policies in this proposed rule, particularly advancing image sharing. However, we are concerned about the breadth and complexity of the proposed rule and whether or not it can be successful. Many of these subject areas are not traditionally certified under the Assistant Technology for Technology Policy (ASTP/ONC), so the included proposals represent a significant expansion of certification. It is unclear how ASTP/ONC will keep up with greatly expanded responsibilities with the same workforce and same budget, and we are concerned that resources may be allocated away from the office's core activities.

Comments to Specific Proposals

Burden and Implementation Concerns

ASTP/ONC required a significant amount of updates to health IT solutions when it finalized HTI-1 earlier this year. At that time, ASTP/ONC indicated that moving away from yearly updates and to these HTI-1 rules would lower burden for stakeholders and increase predictability of updates. No matter how well-intentioned the policies in this proposed rule are, they do not achieve that goal. To be clear, HIA supports a broad portion of the proposals in this regulation. However, these proposals do not happen in a vacuum – all of the provisions included will take time and resources to implement. As an example, there are numerous proposed requirements of public health agencies. These entities are already dealing with a lack of resources and an increasing need. State health information exchanges and immunization registries often have one person designated for health IT and data needs. We are concerned that these entities do not have the resources to implement the proposed API requirements in a timely manner. Further, requirements directed to public health agencies do not only impact those agencies, they also have significant overlap with the health IT sector broadly. We urge ASTP/ONC to reorient to a more sustainable path going forward. HIA and our members remain committed to improving health

IT solutions to meet the needs of the health sector and patients, and we look forward to working with ASTP/ONC to ensure these goals can be achieved.

USCDI Version 4

HIA fully supports the move to continue to update the United States Core Data for Interoperability (USCDI), and we are pleased to see ASTP/ONC propose to adopt a more recent version. However, we are concerned about sustainability in the long term. The requirement to adopt USCDI v4 is a significant leap in terms of the upgrades, implementations, and testing that will be required to bring existing software, systems, and processes up to date. The deadline is currently proposed for 2028. Meeting this timeline would require significant allocation of resources on the part of developers and providers.

We are concerned with the path forward with updating and requiring USCDI. The private sector cannot complete updates in less time, yet new versions of USCDI continue to be proposed more rapidly than they are adopted. USCDI v5 is already finalized – and by 2028 another three iterations may be finalized. HIA is in full support of requirements that are useful and additive to existing capabilities. Yet the implementation associated with these updates costs a significant amount of money and resources, costs that will be borne by technology vendors and downstream users. Overall, this will increase costs in the healthcare system at large, and we must make sure that such updates are actually necessary and productive rather than just a good idea.

Lastly, we believe industry needs more transparency from ASTP/ONC on what updates are coming down the line. Having a better readout from the agency about upcoming changes and policies under consideration as well as their cadence would better allow stakeholders to prepare for future requirements. In addition, more two-way communication would enable better proposals through stakeholder feedback.

Patient, Provider, and Payer APIs

We appreciate ASTP/ONC following CMS' lead in proposing implementation of API updates. However, as above, we are concerned about the cost burden this will impose on the health sector at large. While well-intentioned and in many cases necessary, these proposals require significant expenditures by stakeholders to develop, adopt, and implement. These resources must come from somewhere, and we are mindful that usually these costs are distributed and borne downstream. Specifically, we are concerned that the proposals will result in greater costs to consumers over the long term.

One consideration to mitigate this risk is to strike a balance with what is actually necessary and what is ready for use. We encourage ASTP/ONC to continue to build upon existing structures that work and are widely adopted while proposing updates and new functionalities to ensure updates achieve the intended outcomes. For example, we are concerned about the availability of some data that would be required under the proposals. A prime example is provider directories: providers can and do move around, enter and exit networks, and cease practicing entirely. The accuracy and availability of these data is very important for the proposals to work as intended.

Lastly, we want to encourage ASTP/ONC to ensure that these proposals align with existing and future requirements from CMS and other divisions of the Department of Health and Human Services (HHS). With the recent reorganization and promotion to the Assistant Secretary level, ASTP/ONC has the responsibility to ensure technology requirements align across HHS to ensure effectiveness and minimal burden on the healthcare sector. HHS funding touches a large swathe of the healthcare industry, whether directly in federal health programs, in state public health programs, or elsewhere. While the scope of the application of the proposals are not clear, they will have far-reaching impacts in the industry at large, and as such ASTP/ONC's burden of proof

is greater. We urge ASTP/ONC to be careful in how much it requires of the private sector, for what reasons, and when to set implementation deadlines.

Imaging Requirements for Health IT Modules

HIA appreciates and wholeheartedly supports ASTP/ONC's attention to imaging. This proposal should be finalized as proposed to encourage consistent and reliable sharing of imaging files. The availability of imaging across systems will improve patient care, outcomes, as well as reduce cost and unnecessary duplication of services. We thank ASTP/ONC for this proposal and look forward to helping members and others in the industry improve medical imaging interoperability.

Given the varying formats and size issues with imaging files, we appreciate the proposal to support linking to external sources. We have heard some security concerns from provider organizations regarding sending a patient or provider outside of controlled network. HIA does not believe these concerns should hinder the implementation of this proposal, but we do urge ASTP/ONC to continue working to provide assurances and technical guidance on secure connections. Full scale interoperability requires multiple systems to work together, so we encourage ASTP/ONC to consider the associated vulnerabilities and continue supporting appropriate safeguards, including encouraging common data agreements and architectures such as the Trusted Exchange Framework and Common Agreement.

As we have recommended in the past, we encourage the Office to consider adopting and supporting Digital Imaging and Communications in Medicine (DICOM) standards in a more direct way going forward. DICOM standards are proven and trusted by physicians and others in the healthcare sector, so there would be more certainty and minimal burden for practitioners with further supporting their use. Choosing DICOM will also force more consistency across the market, allowing for more robust and routine sharing of imaging files, regardless of the equipment manufacturer or associated software.

Revised Electronic Prescribing Certification Criterion

We appreciate ASTP/ONC's proposal to require NCPDP SCRIPT version 2023011. This is the version NCPDP and industry have deemed ready for formal adoption, and ASTP/ONC should move forward as proposed.

Real-Time Prescription Benefit Criterion

We are very pleased to see ASTP/ONC propose new certification criterion based on the NCPDP Real-Time Prescription Benefit (RTPB) standard. Real-time Benefit Tools (RTBTs) allow providers and patients to compare costs of drugs to their alternatives, compare prescription costs at different pharmacies, view out-of-pocket cost info, and check if prior authorization is needed for specific drug. This is critical information for patients and providers to make informed decisions to support effective care delivery and adherence to prescribed drug regimens. Therefore, we are supportive of the ASTP/ONC proposals for new certification criterion to require health modules to support transactions using the NCPDP RTPB version 13 standard and updating the base EHR definition to include RTBTs in alignment with the CMS final rule. We do note that full implementation of this section could and should have come earlier, as the direction from Congress has been law since late 2020.

We encourage ASTP/ONC to continue to monitor developments in the RTPB standard and explore requiring the most up-to-date and relevant features of current versions when available and ready to be adopted by industry. For example, NCPDP RTPB version 13 supports eligibility determinations, patient out of pocket cost information, and where the patient is regarding meeting their deductible. These are important facets of an

effective RTPT, and ASTP/ONC should work to encourage additional updates and capabilities that are included in future versions.

Health IT Modules Supporting Public Health Data Exchange

HIA supports the proposals to update certification of health IT modules that support public health data exchange. However, we are concerned that the proposal may be overly broad, applying to technology outside of the intended uses, and may be an additional burden on top of existing standards that does not improve functionality. For the first point, the proposed standard should only be required where applicable – i.e., not to use cases outside of the public health data exchange. Secondly, requiring the use of FHIR is acceptable in this case, but if there are existing standards or versions that accomplish the same goals, then additional standards should not be imposed for their own sake. Otherwise, it will merely impose more costs on the system with little or no improvement on functionality and interoperability. Again, we raise our concern that implementing new standards and functionalities requires resources from the industry. If a new standard or version does not increase or improve the target systems or technologies or is not widely used currently, the updates should be postponed until there is meaningful improvement and more consistently proven usability across systems. These proposals will cost developers, public health agencies, providers, and others resources to develop, deploy, implement, and test, and HIA is concerned that without dedicated funding, adoption of these proposals will be haphazard. Previous iterations of certification have been matched with clear funding incentives, and HIA encourages HHS to work with Congress to ensure appropriate support for improved interoperability across the healthcare system.

We are pleased to see ASTP/ONC put forth standards for public health data. HIA has called for this action in the past. As such, we applaud ASTP/ONC for moving forward in this regard to improve the experience, effectiveness, and responsiveness of public health agencies and providers and improving patient experience.

Finally, we encourage ASTP/ONC to align the standards for public health data exchange with other standards from federal agencies to ensure they work in concert with one another and minimize private sector burden. In particular, HIA urges HHS to ensure that standards statutorily required from CDC are aligned with the standards that ASTP/ONC has proposed in this rule. We encourage open communication between the agencies and aligning standards wherever possible and appropriate.

Public Health Data Exchange – State Requirements

HIA is concerned by a few requirements on technology vendors to support specific functionalities that may be limited or prohibited by state law. For example, ASTP/ONC proposes to add certification criteria requiring health IT modules to support the use of SMART health cards for patient immunization queries and other information. There are several jurisdictions in which SMART health cards are expressly prohibited. This creates a conflict for vendors and presents a difficult choice: is it preferable to run afoul of federal or state law? Another example is querying a prescription drug monitoring program (PDMP) – many states limit or prohibit information sharing with a PDMP, given the sensitivity of such information. Again, this creates unnecessary headaches for vendors attempting to comply with federal regulation while simultaneously navigating the ever-changing 50-state landscape. In light of these challenges, we recommend that ASTP/ONC avoid requiring functionalities that are not available in certain jurisdictions and working with jurisdictions to ensure appropriate public health data interoperability within local legal requirements.

Public Health Data Exchange – Standardized APIs

ASTP/ONC continues its past course of action in this proposed rule to require the use of standardized APIs in a range of settings. HIA is supportive of standardization in cases where it increases the interoperability and

capabilities of systems. However, we are concerned that requiring standardized APIs in situations where they may not add meaningful improvements or useful functionality is overly burdensome at best, and at worst risks upending successful existing systems. A prime example is in the area of immunizations: there are proven systems in place that meet the needs of exchanging patient information in interoperable and accessible formats. Requiring the use of new standardized APIs could risk modifying these systems to the detriment of their usefulness. As such, we believe more careful consideration should be undertaken as to the associated benefits and risks associated with these requirements, regardless of how well intentioned they are.

Bulk Data

HIA is concerned that the requirement to move to the HL7 Bulk Data Access v2 specifications may be premature. Associated implementation guides must be robust and available to allow for functionality of bulk data transfers. HIA has concerns that the implementation guide for the v2 specification is not yet ready for full implementation. Therefore, we believe requiring adoption of version 2 is misguided at this time, regardless of the roughly three-year runway for implementation. Bulk data transfer raises major security and privacy concerns, and there can be major issues with system functionality when they are overwhelmed with too many bulk data queries at once. If implementation guides are insufficient, these risks are amplified. We urge ASTP/ONC to be cautious and provide more support to ensure security and system capability/bandwidth concerns are addressed.

Information Blocking Requirements

While we recognize that ASTP/ONC is attempting to provide more flexibility and make useful updates to information blocking requirements, we are concerned with the overall implementation of these regulations. In particular, HIA is very disappointed by OIG's lack of engagement, interest, and enforcement of information blocking.

Regarding the application of information blocking requirements, we request more information from ASTP/ONC on their applicability to pharmacists and labs. Under the current enforcement rules, there are no mechanisms to enforce information blocking requirements against these actors. However, this proposed rule solidifies several definitions that underscore the inclusion of these providers in information blocking adjacent regulations. HIA would like to understand what ASTP/ONC intends to do by making sure these providers are included if there is no way to enforce these requirements.

We support the proposal to define "health information technology" and "health IT" in the same manner as one another pursuant to 42 U.S.C. 300jj(5). We believe that this is a common-sense move and will improve clarity.

HIA notes that in a post *Dobbs* environment, reproductive health is an increasingly important and yet divisive topic. Many of our members and associated organizations are navigating varying state and federal regulations on the use and disclosure of reproductive health information. HIA cautions ASTP/ONC as it considers policies that could lead to incomplete clinical information and raise the potential for patient harm. We see a parallel to past efforts on 42 CFR Part 2: stakeholders and Congress spent a great deal of time making sure patient substance use disorder treatment information is not segmented from other data. We caution ASTP/ONC to be cautious about segmenting patient data that could be necessary to provide patient care.

Trusted Exchange Framework and Common Agreement

HIA appreciates ASTP/ONC's continued attention to requirements related to the Trusted Exchange Framework and Common Agreement (TEFCA). We recommend that the Office ensure ownership requirements on qualified

health information networks align with existing Department of Homeland Security standards and recommendations. Again, aligning definitions across agencies reduces burden and promotes compliance clarity.

Conclusion

We thank ASTP/ONC for the opportunity to comment on this important proposed rule and look forward to continuing to work alongside HHS and other stakeholders to ensure the efficient application of health IT resources.

Sincerely,

Brett Meeks
Executive Director