October 4, 2024

Micky Tripathi, PhD, MPP
Assistant Secretary for Technology Policy
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street, SW, 7th Floor
Washington, DC 20024

Re: RIN 0955-AA06 HTI-2 NPRM

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

Dear Assistant Secretary Tripathi:

The Workgroup for Electronic Data Interchange (WEDI) writes today in response to the publication in the August 5, 2024, edition of the *Federal Register* entitled "Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability" (HTI-2) released by the Assistant Secretary for Technology Policy, Office of the National Coordinator for Health Information Technology (ASTP/ONC), Department of Health and Human Services (HHS).

WEDI was formed in 1991 by then HHS Secretary Dr. Louis Sullivan to identify opportunities to improve the efficiency of health data exchange. WEDI was named in the HIPAA legislation as an advisor to the Secretary of HHS. Recognized and trusted as a formal advisor to the Secretary, WEDI is the leading multi-stakeholder authority on the use of health information technology (Health IT) to efficiently improve health information exchange, enhance care quality, and reduce costs. With a focus on advancing standards for electronic administrative transactions, and promoting data privacy and security, WEDI has been instrumental in aligning the industry to harmonize administrative and clinical data.

WEDI supports and shares ASTP/ONC's goals of leveraging Health IT's advanced capabilities and functions to decrease burden and streamline processes to improve the quality of care while minimizing administrative costs. We applaud ASTP/ONC's decision to include electronic prior authorization (ePA) in the provider ONC Certification Program, facilitating provider implementation of the CMS Interoperability and Prior Authorization Final Rule. Encouraging providers to adopt and use a uniform set of

standards will be an important step toward enabling the automation of prior authorization workflows.

To aid us in developing our response to the ASTP/ONC proposed rule, WEDI conducted a Member Position Advisory (MPA) event on Sept. 12, 2024. The MPA process designed to solicit WEDI member input on topical issues, public and private sector proposals, or government regulations. More than 75 individuals participated in the MPA, representing health plans, providers, standards development organizations, clearinghouses, electronic health record (EHR) vendors, as well as consultants and other Health IT vendors.

General Comments and Recommendations

WEDI's mission and work are driven by easing administrative burden, putting patients at the center of their care, implementing consensus based, mature standards that support automation, and maintaining appropriate safeguards for privacy, security, and confidentiality. WEDI broadly supports the direction and purpose of this Notice of Proposed Rulemaking (NPRM) and we applaud the work of ASTP/ONC to improve health information exchange and reduce administrative burden for health care stakeholders.

WEDI's comments are based on key guiding principles that are integral and essential considerations of any regulatory action. Specifically, meeting the goals of this NPRM and the Centers for Medicare & Medicare (CMS) Interoperability and Prior Authorization Final Rule require that relevant stakeholders have ready access to several key capabilities and functions. Providers must know whether plans require prior authorization for a service, they must know what information is required by the plan to adjudicate the request, and they need the final answer regarding that authorization. It is important to design a transition to that level of automation that includes:

- Promotion of a seamless, automated data exchange through mature, clear, and unambiguous standards that have been thoroughly tested and demonstrate meaningful return on investment (ROI).

- Integration of the data exchange efficiently within the health plan, provider, and other end-users' workflows.

Certification as catalyst for nationwide ePA adoption

We are hopeful that the certification program inclusion of the ePA standards named in the CMS Interoperability and Prior Authorization Final Rule will facilitate provider adoption of the necessary technology. With providers investing in Certified Electronic Health Record Technology (CEHRT) that incudes ePA capabilities, we anticipate that health plans not impacted by the CMS Final Rule will consider supporting ePA using Fast Healthcare Interoperability Resources (FHIR®) APIs. We are concerned that providers may not invest resources in a technology solution to address only a small percentage of their prior authorization volume. A truly national ePA solution is necessary to reduce the use of proprietary approaches to prior authorization and serve to drive wide-spread adoption of ePA.

Develop an efficient user and developer feedback loop

ASTP/ONC should consider developing a process that could capture feedback from Health IT users and developers on the effectiveness of the functionality of Health IT. Most important, ASTP/ONC should validate that required data elements and functionality incorporated into the certification process are fully supported by the developer and effectively perform the role that they were intended. Also, end users should be queried regarding any excessive fees being charged by software developers. Capturing end user feedback could be accomplished, in part, by creating an anonymous survey that would encourage users and developers to share their perspectives on the certification process and certified software itself. The goal of this process would be to capture real-world input to advise ASTP/ONC on future programs and requirements.

Conduct real-world pilots

The ePA environment is constantly changing. Health Level Seven (HL7), National Council for Prescription Drug Programs (NCPDP), and X12 continue to develop new solutions and new implementation guides (IGs). While there is great promise with these new standards, there should be comprehensive pilot testing using real-world scenarios and conducted in multiple types of care settings. The value of piloting goes well beyond simply proving that a standard works outside a laboratory setting. Piloting a new standard or approach can identify workflow issues that will either need to be corrected by revising the standard itself or addressed by stakeholders during implementation. As well, successful piloting of a new standard and/or workflow approach can serve to increase support from plans and providers and that in turn can accelerate development of the supporting software. This momentum building within each stakeholder group is critical to avoid an overly protracted compliance glidepath.

Establish effective certification timing

The development of an ASTP/ONC certification program, in tandem with CMS efforts to assist the industry implement ePA, are important steps on the road to full industry adoption of this standard. However, we are concerned that if the appropriate timing for certification is not developed, it could result in needless costs, delays in benefits for health plans, providers, and patients, as well as unnecessary stakeholder burdens. We recommend ASTP/ONC work closely with CMS to ensure the appropriate implementation glidepath is established. We note that delays in implementing the ePA certification could create greater inertia, if not resistance, in the provider marketplace and create confusion for plans seeking to take advantage of automating prior authorization. WEDI also recommends the federal government explore phasing in the Da Vinci implementation guides, with Coverage Requirements Discovery (CRD) being considered for the initial implementation.

We believe the optimum glidepath would have the ONC provider Health IT Certification Program go live prior to the January 1, 2027, compliance date established in the CMS Interoperability and Prior Authorization Final Rule for the ePA API requirements. To advance provider implementation efforts, the compliance date for the Health IT Certification Program ePA certification requirements should occur optimally no less than

six months prior to the Jan. 1, 2027, date providers and plans will begin exchanging data using these new standards.

Ensure Health IT developer oversight

Providers will rely heavily on the ONC Health IT Certification Program to assist in determining which product or products will facilitate the transition to ePA. If certified products do not support ePA as promised, providers, plans and patients will not benefit from these automated processes. It is critical that ASTP/ONC conduct comprehensive oversight of certified products for the provider community and quickly identify and publicize those products that have had their certification revoked. Finally, it will be imperative that ASTP/ONC develop an easy-to-use process where providers can report any ePA or other software inconsistencies directly to the agency. We recommend ASTP/ONC work with professional associations to educate providers on this reporting process.

Develop a comprehensive regulatory roadmap

The transition to ePA is only one of the many Health IT requirements and implementations the industry is expected to face over the next few years. Uncertainty in terms of what requirements to meet and when to meet them can divert scare resources and harm the industry's ability to meet these government mandates. Also, the industry is experiencing a significant shortage in its Heath IT workforce, especially those with API expertise. Conversely, regulatory certainty will permit impacted stakeholders to free up appropriate monetary and personnel resources. We urge ASTP/ONC to work with its federal partners to coordinate mandates and compliance dates and develop a regulatory roadmap that ensures a smooth implementation glidepath for all impacted organizations.

Conduct provider ePA education

ASTP/ONC is in a unique perspective to assist providers understand the value of ePA as a component of CEHRT and encourage the deployment of supporting software. Leveraging the information contained in the Certified Health IT Product List (CHPL), ASTP/ONC can educate and support providers as they seek to better understand ePA and what products, or combination of products, will support their prior authorization workflow.

Establish an ongoing automation advisory process

We believe the deployment of FHIR®-based solutions to automate ePA will be followed by ASTP/ONC, CMS, and other federal partners identifying opportunities to leverage APIs to automate additional administrative transactions. In this ever-changing environment, it will be critical for HHS to have industry input from the entities directly impacted by these policies. We recommend that ASTP/ONC work with CMS and other appropriate HHS agencies to establish and support a public-private sector group convened under the Federal Advisory Committee Act (FACA). This FACA entity should be mandated to guide the Department as it furthers ePA efforts and recommend additional automation opportunities.

Consider a technology adoption assistance program

Due to a lack of resources and technical expertise, small provider organizations historically have challenges optimizing Health IT to improve the quality of patient care they provide. This same need for technical assistance was an issue when the provider community was seeking to adopt CEHRT and participate in the early days of the CMS Meaningful Use EHR Reporting Program.

HHS addressed this issue by deploying Regional Extension Centers (RECs) to offer technical assistance for solo and smaller provider practices and those who provide primary care services in public and critical access hospitals, community health centers, and other settings to implement and maintain EHRs. RECs established themselves as trusted advisors for these smaller care settings and facilitated the effective use of Health IT. The REC program was designed to leverage local expertise to provide practical, customized support to meet the needs of local healthcare providers. The REC core service areas included: (i) EHR implementation and project management; (ii) Health IT education and training; (iii) Vendor selection and financial consultation; (iv) Practice/workflow redesign; and (v) Privacy and security. Each one of these core service areas appear to mirror what small providers need to assist them implement CEHRT with ePA and generally for the transition to FHIR®-based administrative solutions.

The most effective way to encourage providers to adopt ePA solutions is to establish a clear ROI related time saved by administrative and clinical staff. Absent that ROI, especially in times of economic uncertainty, providers will be very unlikely to invest resources in untried and untested technologies.

Specific Comments on the NPRM

ASTP/ONC Proposal (P. 63506/63588)
As explained in section III.B.20, we propose a set of certification criteria in §170.315(g)(30) through (36) that aim to complement and advance the policies that CMS has developed to increase patient, provider, and payer access to information. Health IT developers, including those that support payers, would be able to ensure that Health IT Modules certified to these proposed criteria, when used to satisfy the CMS requirements, have been tested for conformance with widely available industry standards designed to support interoperability for each use case.

We propose to adopt a ''prior authorization API—provider'' certification criterion in §170.315(g)(34), which establishes requirements for Health IT Modules that can be used to facilitate a provider's request of coverage information and request for a prior authorization decision.

WEDI Comment
We are strongly supportive of ASTP/ONC including ePA into the provider ONC Health IT Certification Program. Publication of the landmark CMS Interoperability and Prior Authorization Final Rule earlier this year established an API-based communication protocol between the provider and the health plan that we believe has the potential to significantly streamline the prior authorization process. As software developers supporting

providers are not covered entities under HIPAA, CMS is requiring that providers participating in one of the Medicare EHR incentive programs attest to completing at least one electronic prior authorization utilizing an API.

By creating an ePA certification component, ASTP/ONC has the potential of streamlining the prior authorization process and decreasing administrative burden and cost for both health plans and providers by: (i) Reducing the volume of calls between providers and health plans simply to establish whether a prior authorization is required; (ii) Clarifying the clinical documentation required to support a prior authorization; (iii) Eliminating lost health plan requests for additional documentation and provider responses; (iv) Reducing the cost associated with staff manual collection of supporting documentation; (v) Decreasing plan documentation requests as there would be improved predictability of plan content needs (i.e., plans could be specific in what they required to render an authorization decision), thus eliminating the time consuming "back and forth" that currently exists in the system; and (vi) Reducing pended decisions, administrative appeals, and costly peer-to-peer discussions, resulting in increased adherence to health plan policy and faster treatment approvals.

WEDI makes the following recommendation in the interest of improving the ePA certification process:

- **Fully harmonize the certification criteria to the CMS Interoperability and Prior Authorization Final Rule requirements**. It is imperative that the API requirements of the ONC Health IT Certification Program be harmonized with the requirements mandated by the CMS Interoperability and Prior Authorization Final Rule. Deviation from these requirements will lead to industry confusion and the potential for less than optimum industry adoption of this new technology.

- **Address the continued use of the X12 278 transaction.** It is uncertain how providers and health plans will be able to continue leveraging the X12 Health Care Services Review and Response transaction (278). According to the 2023 CAQH Index Report, while industry adoption of the X12 278 is low at 31%, it has gone up from just 13% in 2019.[1] We note that adoption by CMS of a national standard for Electronic Attachments is expected to accelerate provider and health plan use of the X12 278.

  Further, while we appreciate the release on February 23, 2024, of the CMS X12 278 enforcement discretion[2] for all HIPAA covered entities, we remain concerned that this discretion could be sunsetted at any time. Requiring the inclusion of the X12 278 transaction as part of the API process would result in needless burden and cost for both providers and health plans.

  Should the ONC Health IT Certification Program only support FHIR®-based APIs, it is unsure how EHRs will effectively conduct prior authorizations with providers

[1] 2023 CAQH Index Report: https://www.caqh.org/hubfs/43908627/drupal/2024-01/2023_CAQH_Index_Report.pdf
[2] CMS X12 278 Enforcement Discretion (GL-2024-02): https://www.cms.gov/files/document/discretion-x12-278-enforcement-guidance-letter-remediated-2024-02-28.pdf

and health plans that continue to use the X12 278 standard. We anticipate there will be a significant length of time past the Jan. 1, 2027, ePA compliance date when providers will use the X12 278 to conduct prior authorization transactions with their health plan partners. We urge ASTP/ONC to work with CMS to address how the use of the FHIR® standard will interact with the long-term use of the HIPAA-mandated X12 278.

- **Develop an ePA module certification program to support all providers.** There are a significant number of provider types that traditionally do not participate in one of the CMS EHR incentive programs. These include pediatricians, dentists, physical therapists, and others. Many of these providers use EHR technology that is specifically designed to meet the needs of that specialty and does not require all the functionality that is included in the ONC certification criteria. Therefore, in many cases these "specialty" software products will not be certified under the ONC Health IT Certification Program. To allow these specialty vendors to offer products that conform to the ONC ePA requirements and take advantage of the API automation opportunities, we encourage ASTP/ONC to work with these specialties and design an ePA specific certification approach that meets their needs and facilitates support of the CMS Interoperability and Prior Authorization Final Rule API requirements.

  Similarly, we encourage ASTP/ONC to develop a module approach that conforms to the ONC ePA requirements to support self-developed EHR software. These self-developed EHRs often meet the needs of specific providers-some of whom may not require the complete functionality required from the full ONC certification. Allowing these products to certify to the ePA requirements in the CMS Interoperability and Prior Authorization Final Rule will allow these providers to take full advantage of the ePA API automation opportunities.

- **Integrate real-time solutions into the certification requirements when available.** The 2020 ONC report "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs[3]," includes recommendations for improving prior authorization processes. On page 18 of the report, ONC signaled its clear support for real-time ePA transactions when it makes the following recommendation: "Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers and plans."

  Real-time ePA transactions such as the Coverage Requirements Discovery (CRD) have the potential of reducing cost for health plans and providers by eliminating manual (e.g., fax, phone, and proprietary plan web portal) communications from the provider to the plan. These real-time CRD decisions on whether a medical service requires a prior authorization is an important step toward reducing administrative burden for both plans and providers.

[3] Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRSs: https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf

Requiring adherence to finalized HL7 Da Vinci Implementation Guide that include a real-time response from the health plan to the provider's use of the CRD API should be a goal of the certification program. It is important to note that in the CMS Interoperability and Prior Authorization Final Rule, the agency recommends adherence to the HL7 Da Vinci ePA Implementation Guides but does not require adherence. We are hopeful that once providers have the capability to initiate real-time CRD, impacted and non-impacted providers will be incentivized to purchase the technology and health plans incentivized to support this approach. We believe the eventual move to real-time CRD will decrease provider use of manual approaches to establish whether or not a service requires authorization from a health plan.

- **Work with CMS to incorporate drug PA APIs into the certification criteria.** We note that although prior authorizations for medications was not required in the CMS Interoperability and Prior Authorization Final Rule, it was included in the Spring 2024 Unified Agenda[4] under the title "Interoperability Standards and Prior Authorization for Drugs (CMS-0062)." The Unified Agenda states "*This rule CMS would propose new requirements for Medicare Advantage (MA) organizations and Qualified Health Plans (QHPs) offered on the Federally-facilitated Exchanges (FFEs) to streamline processes for the prior authorization for certain drugs. We are developing this rule, in part, based on the significant number of public commenters who responded to the CMS Interoperability and Prior Authorization proposed rule (87 FR 76238) urging CMS to expand the proposed prior authorization policies to include drugs. Increasing physician access to these high-value functionalities will address well-known transparency issues and administrative burdens related to drug prescribing and PA*." Including drugs covered under a patient's medical benefit plan as part of the prior authorization APIs would significantly improve the usability of the APIs, would decrease administrative costs for health plans and providers, incentivize those health plans and providers not impacted by the Final Rule to adopt the technology, and improve the care delivery process for patients.

  According to the Spring 2024 Unified Agenda, CMS plans to issue the NPRM in November 2024. This would be soon after the comment period closes for this HTI-2 NPRM. We urge ASTP/ONC to work with in tandem with CMS to incorporate, when appropriate, prior authorizations for drugs covered under a patient's medical benefit plan into criteria for the provider Health IT Certification Program.

- **Support for eRx and RTBT.** We strongly support the inclusion into the base EHR certification criteria of both NCPDP standards for electronic prescribing (eRx) and the real-time prescription benefit (RTPB). We urge ASPT/ONC to align with the CMS final rule requiring use of the NCPDP RTPB Standard Version 13. According to NCPDP, RTPB was developed to harmonize, as much as possible, with the

[4] Spring 2024 Unified Agenda: https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST&currentPub=true&agencyCode=&showStage=active&agencyCd=0900&csrf_token=03237CBE036426C601376D6654490D1ECD162EF617C31E3252BDF0B4D3667747563A498008A077A2F7F783B76665EBFF8DE9

NCPDP SCRIPT Standard and the NCPDP Telecommunication Standard. It supports information related to products and services covered under the pharmacy benefit and includes medications, vaccines, supplies/devices, and prescription digital therapeutics.

Both the updated eRx standard and RTPB standards will add significant value to the entire care delivery process. With eRx, there is decreased administrative burden for ordering clinicians and pharmacists, and improved medication adherence with patients. RTPB allows providers to receive accurate information regarding whether an ordered prescription is in the patient's health plan formulary, whether the prescription requires a prior authorization, what the patient out-of-pocket costs will be, and potentially any appropriate therapeutic alternatives. This benefits the health plan by reducing the number of prior authorization requests from the provider and having the RTPB system steer the provider toward an in-formulary, lower cost option. For the care professional, these automated approaches can significantly decrease administrative costs and improve patient medication adherence.

Patients finding out once they arrive at the pharmacy that their prescription is prohibitively expensive may not fill the prescription and therefore not receive the expected benefits. Many may be forced to contact the care professional for additional consultations, adding burden to themselves and their care professional. With the RTPB system in place, patients are more likely to receive the appropriate prescription, receive it faster, and at a lower cost.

Recognize the impact on software developers. Health IT developers are a critical component of any successful national transition to new or revised health care administrative standards. As they are not HIPAA covered entities, Health IT developers are not required by law to support the ePA standards. However, the ONC certification program has proven successful in the past for moving a significant number of provider-focused EHR software products toward a standardized set of functional capabilities.

We are hopeful Health IT developers will incorporate ePA capabilities not just because ASTP/ONC will include it in its certification criteria, but to facilitate their provider customers' long-awaited transition to a more automated and efficient prior authorization process. However, there are potential challenges facing Health IT developers on the path to ePA. It is important to recognize that developing and implementing new EHR functionality is time consuming, labor intensive, and expensive. Also, it will be important for ASTP/ONC to strike a balance between imposing an overly burdensome compliance timeline and meeting the needs of providers and health plans.

Finally, with the large number of health plans and health plan products in the marketplace, a critical element for API success will be the ability of providers to quickly and accurately identity a specific FHIR® endpoint. We urge ASTP/ONC to work with industry to stand up a FHIR® Endpoint Directory that is freely accessible by all health plans and providers.

ASTP/ONC Proposal (P. 63589)
In contrast to ''Light DTR EHR'' capabilities, ''full'' DTR capabilities are relevant to EHRs that manage the form filling functions of DTR internally. In §170.315(g)(34)(ii)(B), we propose that the Health IT Module must support the capabilities included in the ''Full DTR EHR'' Capability Statement according to at least one of the versions of the implementation specification adopted in §170.215(j)(2) (where we have proposed to adopt the DTR IG version 2.0.1—STU 2). Such EHRs need only support client capabilities for the Questionnaire Package, Value Set Expand, and Next Question operations.

WEDI Comment
WEDI fully supports including the DTR functionality for providers in the ONC Health IT Certification Program. Automating communication of the health plan's clinical requirements needed to support a requested medical service to the provider has the potential to significantly reduce administrative burden. However, we are concerned that allowing software developers the option of certifying to either the "light" or "full" version of DTR will not achieve the goals of standardization and full functionality of the DTR process. Requiring developers to support full DTR will ensure that providers have the complete suite of functions including the ability to automate the completing of clinical templates. Every improvement in ePA automation and enhancement of API functionality increases the likelihood of provider adoption of CEHRT.

ASTP/ONC Proposal (P. 63506, 63581)
We propose to adopt a set of HL7® FHIR® IGs in §170.215 to support these certification criteria, and to incorporate these specifications by reference in §170.299.

We believe that proposing to adopt the current versions of the IGs recommended by CMS in the rulemaking described above is appropriate for the proposed certification criteria at this time. Adopting and specifying use of these IGs is necessary to ensure that Health IT Modules certified to the criteria proposed in this section are implemented consistently and enable interoperable exchange of information. We also note that adoption of these IGs would support CMS policies established in their Interoperability and Prior Authorization Final Rule. Furthermore, if the adoption of these IGs is finalized, we would review and potentially approve future versions of these standards under the SVAP for voluntary use in the Program as they become available.

WEDI Comment
WEDI endorses standards for automatable and scalable prior authorization processes that eliminate burden and waste. WEDI supports FHIR® and the work of Da Vinci and incorporation into the ONC Health IT Certification Program the following Implementation Guides once they are finalized and ready for the industry to implement:

- HL7® FHIR® Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide.
- HL7® FHIR® Da Vinci Documentation Templates and Coverage Rules (DTR) Implementation Guide.
- HL7® FHIR® Da Vinci Prior Authorization Support (PAS) Implementation Guide.

When the timing is appropriate, required use of finalized implementation guides, will ensure that Health IT is implemented consistently and enables interoperable exchange of

information. WEDI believes the HL7 implementation guide development process has ensured that these IGs support both direct and clearinghouse connections, meeting the needs of providers with different levels of technology adoption. As well, with the February 23, 2024, publication of the CMS X12 278 enforcement discretion[5] for all HIPAA covered entities, it is important to note that the X12 278 transaction does not need to be incorporated in the FHIR® API.

ASTP/ONC Proposal (P. 63506)
As explained in section III.B.20, we propose a set of certification criteria in §170.315(g)(30) through (36) that aim to complement and advance the policies that CMS has developed to increase patient, provider, and payer access to information. Health IT developers, including those that support payers, would be able to ensure that Health IT Modules certified to these proposed criteria, when used to satisfy the CMS requirements, have been tested for conformance with widely available industry standards designed to support interoperability for each use case. We propose to adopt a set of HL7® FHIR® IGs in §170.215 to support these certification criteria, and to incorporate these specifications by reference in §170.299.

WEDI Comment
While we appreciate ASTP/ONC proposing to stand up a certification program for those Health IT developers that support health plan efforts to meet the API requirements in the CMS Interoperability and Prior Authorization Final Rule, we recommend an alternative approach.

HIPAA designated providers, health plans, and clearinghouses as “covered entities” under the law but excluded software developers. Thus, the certification program for Health IT software developers was developed to serve as a catalyst for providers to adopt EHR technology that met the requirements of the CMS inpatient and outpatient EHR incentive programs. Participation by providers in these CMS incentive programs continues to be voluntary, although there are significant financial incentives and disincentives associated with the program.

Under the CMS Interoperability and Prior Authorization Final Rule, providers are not required to comply with the prior authorization APIs, although incorporation of the APIs is included in the CY 2027 performance period/2029 MIPS payment year for the Medicare Promoting Interoperability Program. Incorporating prior authorization APIs in an EHR certification is appropriate as it, again, will serve as a catalyst for providers to take advantage of this administrative simplification opportunity.

The 2024 CMS Interoperability and Prior Authorization Final Rule applies only to Medicare Advantage plans, Medicaid and CHIP managed care plans, state Medicaid and CHIP Fee for Service (FFS) programs, and Qualified issuers on the federally facilitated exchanges (FFEs). The health plans impacted by the CMS Interoperability and Prior Authorization Final Rule are legally required to comply with the prior authorization APIs included in the regulation. Offering a voluntary prior authorization API certification would

[5] CMS X12 278 Enforcement Discretion (GL-2024-02): https://www.cms.gov/files/document/discretion-x12-278-enforcement-guidance-letter-remediated-2024-02-28.pdf

be redundant and we do not believe a significant number of impacted health plans or plans not mandated in the Final Rule to support the prior authorization APIs, would incur the expense of seeking certification. Further, those providers seeking to connect via APIs with impacted health plans after January 1, 2027, who found that the health plan was unable to support the prior authorization APIs, will have the ability lodge a formal complaint against the health plan directly to CMS.

An alternative approach to health plan certification

Deploying APIs in support of prior authorization is new to the health care industry. As an alternative to offering a voluntary Health IT Certification Program for developers serving the health plan market, we recommend an expansion of the HL7 Inferno testing platform that would allow both health plans and providers to test their individual ability to support the APIs. Inferno, as an open-source tool, creates, executes, and shares automated conformance tests for the FHIR® Standard. Inferno on HealthIT.gov hosts tests created with Inferno, but Inferno is also designed to allow the creation and hosting of individual tests. ASTP/ONC should also explore the option of expanding the platform to include testing end-to-end business processes.

With augmented support from ASTP/ONC, this expanded Inferno platform could offer all testing entities (health plans, providers, and their supporting vendors) both an opportunity to test systems and processes, and the ability to publicly report successful testing. We believe that public reporting of successful tests would incentivize other entities to conduct testing and report success.

ASTP/ONC Proposal (P. 63510-63511)
In section V of this proposed rule, we propose to implement certain provisions related to TEFCA in order to provide greater process transparency and further implement section 3001(c)(9) of the PHSA, as added by the Cures Act. We propose to add a new part, part 172, to subchapter D of title 45 of the Code of Federal Regulations to implement certain provisions related to the TEFCA. These proposed provisions would establish the processes associated with the qualifications necessary for an entity to receive and maintain Designation (as we propose to define that term in §172.102) as a QHIN capable of trusted exchange under the Common Agreement. The proposals would also establish the procedures governing Onboarding (as we propose to define that term in §172.102) of QHINs and Designation of QHINs, suspension, termination, and administrative appeals to ONC, as described in the sections below.

WEDI Comment
WEDI applauds ASTP/ONC for developing the Trusted Exchange and Common Agreement (TEFCA) framework and going live this year with the network. We also appreciate the agency proposing in this rule to improve the TEFCA infrastructure and add improved guardrails for Qualified Health Information Networks (QHINs). The current QHIN administrative process and onboarding methodology is focused very much on self-directed oversight and a less than optimally rigorous onboarding process. Needed improvements will shore up administrative processes and instill additional assurance for those seeking to leverage QHINs to exchange health data.

We strongly support ASTP/ONCs proposed modifications to QHIN administration. We urge the agency to finalize: (i) A more thorough verification process that includes background checks, validation of NPIs, and a rigorous review of organizational credentials; (ii) A more rapid decertification of QHINs found non-compliant or these engaged in fraudulent activity; and (iii) Enhanced monitoring of the use of QHIN and participant credentials. If fraudulent activity is detected, all parties must be contacted immediately, and appropriate actions taken to protect patent data and stop the continued use of those credentials.

ASTP/ONC is proposing to add a new part (172) to title 45 of the Code of Federal Regulations to implement certain provisions to establish the procedures governing QHIN Onboarding and Designation of QHINs, suspension, termination, and administrative appeals. We support these provisions as they will establish the qualifications necessary for an entity to receive and maintain designation as a QHIN capable of trusted exchange pursuant to TEFCA. We concur with the agency that these proposals, once adopted, will improve the reliability, privacy, security, and trust within the TEFCA environment. We believe that implementing these new requirements will instill additional public confidence in TEFCA and drive acceleration of TEFCA-led data exchange.

ASTP/ONC Proposal (P. 63503)
We propose to update the USCDI standard in §170.213 by adding USCDI v4 and by establishing an expiration date of January 1, 2028, for USCDI v3 for purposes of the Program. We propose to add USCDI v4 in §170.213(c) and incorporate it by reference in §170.299. We propose that up to and including December 31, 2027, a Health IT Module certified to certification criteria referencing §170.213 may use either version of the standard. We propose that by January 1, 2028, a Health IT developer of a Health IT Module certified to certification criteria referencing §170.213 must update its Health IT Module to USCDI v4 and provide the updated version to their customers in order to maintain certification of that Health IT Module. We propose that any Health IT Modules seeking certification to certification criteria referencing §170.213 on or after January 1, 2028, would need to be capable of exchanging the data elements that the USCDI v4 comprises.

WEDI Comment
The United States Core Data for Interoperability (USCDI) standard is a baseline set of data that can be commonly exchanged across care settings for a wide range of use cases. While v3 is currently required as part of the ASTP/ONC Health IT Certification Program criteria, v4 has been proposed. We support requiring USCDI v4 as part of the Health IT Certification Program.

While there was some support among WEDI members for adopting USCDI v5, as ASTP/ONC approved USCDI v5 earlier this year, the majority supported establishing USCDI v4 as the baseline standard for data elements to be collected under the Certification Program, a January 1, 2028, start date for v4, and supported establishing an expiration date of January 1, 2028, for USCDI v3 for purposes of the Certification Program.

ASTP/ONC Proposal (P. 63504)
We propose to incorporate the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard12 version 2023011 in an updated version of the electronic prescribing certification criterion in §170.315(b)(3)(ii). Under this proposal, as described in section III.B.8 of this proposed rule, Health IT developers may maintain Health IT certification conformance with the current version of the criterion using NCPDP SCRIPT standard version 2017071 for the time period up to and including December 31, 2027. We propose that by January 1, 2028, a Health IT developer of a Health IT Module certified to the criterion in §170.315(b)(3) must update the Health IT Module to use the NCPDP SCRIPT standard version 2023011 and provide that update to their customers in order to maintain certification of the Health IT Module.

WEDI Comment
We support the inclusion of the NCPDP SCRIPT standard version 2023011 as an updated version of the electronic prescribing certification criterion. We also support permitting Health IT developers to maintain Health IT certification conformance with the current version of the criterion using NCPDP SCRIPT standard version 2017071 until December 31, 2027. We concur with the agency's proposal to then by January 1, 2028, require a Health IT developer of a Health IT Module to update the Health IT Module to use the NCPDP SCRIPT standard version 2023011 and provide that update to their customers to maintain certification of the Health IT Module.

ASTP/ONC Proposal (P. 63506)
As explained in section III.B.17, we propose to revise the ''multi-factor authentication'' (MFA) certification criterion in §170.315(d)(13) and accordingly update the privacy and security (P&S) certification framework in §170.550(h). The proposed update would revise our MFA certification criterion by replacing our current ''yes'' or ''no'' attestation requirement with a specific requirement to support multi- factor authentication and configuration for three certification criteria on and after January 1, 2028.

WEDI Comment
Cyberattacks and data breaches are an all too familiar issue in today's health care environment. The recent cyberattacks on large organizations reveal just how serious the vulnerabilities are throughout the U.S. health care system. These attacks have alerted industry leaders and policymakers to the urgent need for enhanced cybersecurity and improved business continuity planning to support redundancies when unplanned outages impact the delivery of health care services.

Health care organizations today are greater targets for theft than organizations in other sectors for a few important reasons. The personal health and research information organizations collect, hold, and transmit are high value commodities to cyber criminals, including nation state actors. Decentralized information systems, where a vendor may use the services of one or more subcontractors, provide for a greater number of potential access points for incursion, putting patient care and privacy at risk.

Regardless of their size, health care organizations make attractive cyberattack targets. First, they are financially lucrative targets because of the value of protected health information. Since attackers adjust ransom amounts to the perceived ability of the target

to pay, attackers often will hold health information systems hostage until they have extracted maximum ransom payments, utilizing sophisticated tactics to transfer breach threats across criminal enterprises.

We are supportive of the ASTP/ONC proposal to revise the existing MFA certification criterion by replacing the current ‘‘yes’’ or ‘‘no’’ attestation requirement with a specific requirement to support multi- factor authentication and configuration for three certification criteria on and after January 1, 2028. We recommend that the agency encourage Health IT developers to work with their provider customers to ensure that effective security controls are not only available but are effectively deployed.

ASTP/ONC Proposal (P. 63504)
As discussed in section III.B.11, we propose to revise §170.315(d)(7) to include a new requirement that Health IT Modules certified to this criterion encrypt EHI stored server-side on and after January 1, 2026.

WEDI Comment
We applaud ASTP/ONC for recognizing the importance of improving the security hygiene of Health IT software through use of encryption software. Encryption is an excellent method of protecting patient information and we strongly support the proposal to include a new requirement that Health IT Modules certified to this criterion encrypt electronic health information (EHI) stored server-side on and after Jan. 1, 2026.

ASTP/ONC Proposal (P. 63540)
We propose to create a new certification criterion in §170.315(f)(9) Prescription Drug Monitoring Program (PDMP) Data—Query, receive, validate, parse and filter to enable the bidirectional interaction and electronic data exchange between Health IT and PDMPs.

WEDI Comment
WEDI recommends the agency consider using the NCPDP SCRIPT standard’s RxHistoryRequest and RxHistoryResponse transactions in the ONC Health IT Certification Program. The NCPDP SCRIPT Standard is currently used in the industry for the exchange of prescription drug information. This is acknowledged in the ASTP/ONC PDMP-EHR Integration Toolkit Quick Start Guide and is referenced in the Interoperability Standards Advisory. With ASTP/ONC previously requiring certification for RxHistoryRequest and RxHistoryResponse transactions, we believe systems should already support these transactions.

ASTP/ONC Proposal (p. 63630)
We propose the Protecting Care Access Exception to address actors’ concerns about potentially implicating the information blocking definition if they choose not to share EHI in an EHI sharing scenario that an actor believes in good faith could risk exposing a patient, provider, or facilitator of lawful reproductive health care to potential legal action based on what care was sought, obtained, provided, facilitated, or (specific to the patient protection condition) is often sought, obtained, or medically indicated for the patient’s health condition(s) or history.

WEDI Comment
We are supportive of the proposed Protecting Care Access exception from the information blocking definition for providers. This exception would be implemented based on the actor's "good faith belief" that sharing EHI indicating that any person(s) sought, received, provided, or facilitated the provision or receipt of reproductive health care that was lawful under the circumstances in which it was provided and could result in a risk of potential exposure to legal action for those persons and that the risk could be reduced by practices likely to interfere with particular access, exchange, or use of specific EHI.

This new Protecting Care Access exception is an important addition in response to the *Dobbs v. Jackson Women's Health Organization* decision by the U.S. Supreme Court (597 U.S. 215 (2022)). A straightforward and flexible information blocking exception is critical to protect both patients and their care providers in cases where the exchange of reproductive health information could be harmful to one or both. At the same time, we are anticipating significant complexity associated with applying this exception. For a provider organization seeking to apply this exception, we expect that they would need to engage with multiple internal and external partners and entities. It is likely that in addition to the care provider team, the organization's legal staff, EHR vendor, external data exchange organizations such as Health Information Exchanges, and possibly others would need to be consulted.

With this complexity as a backdrop, we urge ASTP/ONC and the Office of the Inspector General to be flexible when reviewing these exception applications and deploy an enforcement glidepath that focuses on corrective action plans as opposed to the imposition of civil monetary penalties. This complexity also signals the clear need for comprehensive education and guidance for impacted actors on how this exception applies and examples of when it applies.

ASTP/ONC Proposal (P. 63621)
Privacy Sub-exception — Individual's Request Not to Share EHI-We propose to broaden the applicability of the sub-exception so that it is available to any actor responding to a request for EHI where the circumstances set out in 45 CFR 164.524(a)(2)(i) through (v) apply, and not just for actors who are also HIPAA covered entities or business associates.

WEDI Comment
ASTP/ONC is proposing to revise the sub-exception to remove the existing limitation that applies the exception only to individual requested restrictions on EHI sharing that are permitted by other applicable law. We support the proposal to broaden the sub-exception's availability by removing its existing limitation to individual-requested restrictions on EHI sharing. We concur with the agency that this proposal would lead to improved assurance for any actor who elects to honor an individual's request for restrictions on sharing of the individual's EHI that applying those restrictions will not be considered information blocking if the requirements of this sub-exception are satisfied. It is also expected to provide enhanced assurance for individuals that information blocking regulations support actors' choices to honor the individual's request and not share EHI when the individual asks that it not be shared.

WEDI supports the proposal to revise the sub-exception. We urge the agency to develop comprehensive guidance to ensure actors understand when and how the Privacy Sub-exception applies.

ASTP/ONC Proposal (P. 63510)
We propose in section IV.B.4, a new information blocking exception: "Requestor Preferences" in 45 CFR 171.304. This exception would stand separate from and independent of other exceptions and would apply where an actor honors or adheres to a requestor's preference(s) expressed or confirmed in writing for: (1) limitations on the amount of EHI made available to the requestor; (2) the conditions under which EHI is made available to the requestor; and (3) when EHI is made available to the requestor for access, exchange, or use. The exception would offer an actor certainty that, so long as the actor's practices meet the conditions of the exception, the actor can honor or adhere to a requestor's preferences related to these specific preferences without concern that the actor may be engaging in "information blocking" as defined in 45 CFR 171.103.

WEDI Comment
We support the addition of the "Requestor Preference" exception and urge the agency to finalize this new exception with one important modification. This exception would offer providers certainty that it would not be considered information blocking to adhere to a requestor's preferences for: limitations on the scope of EHI, the conditions under which EHI is made available to the requestor, and the timing of when EHI is made available to the requestor for access, exchange, or use.

We recognize the challenge of ensuring that while the patient still has full access to their health information when they need it, and in the format they request, there may be a desire on the part of the requestor to have information be first sent to and reviewed by their care professional. Actors should have the ability to discuss with their patients how they would prefer to receive health information such as laboratory or radiology results. Patients should have the right to dictate that these and other types of test results be sent directly to the care professional, who then can inform the patient, discuss the results, and plan the course of treatment.

We do recommend a change to the proposed exception. The proposal requires the patient to express their preference in writing, which we believe would be inappropriate. Patients trust their care professionals and should have the ability to communicate their preferences verbally during the consultation process. Adding yet another form for patients to fill out and for providers to collect and store increases administrative burden on both sides. As an alternative, we urge the agency to consider adding a field in the certification criteria that would permit the care professional to record patient preferences.

Conclusion

WEDI thanks ASTP/ONC for the opportunity to comment on the HTI-2 proposed rule. This represents an important step forward in realizing the vision outlined by policymakers in the bipartisan 21st Century Cures Act of 2016. As ASTP/ONC further develops its approach to ePA and certification, we encourage the agency to collaborate closely with CMS regarding the content of regulations and the timing of compliance dates. Also, we

encourage you to work with organizations like WEDI should additional industry input on these regulatory provisions be needed and to identify opportunities to educate impacted entities. As an advisor to the HHS Secretary and a multi-stakeholder organization comprised of health plans, providers, vendors, standards development organizations, federal and state government, and patient advocacy groups, WEDI offers a unique structure for cross-industry collaboration. WEDI has proven leadership engaging the industry to address the most impactful health care administrative transitions of our time, including the HIPAA versions 4010 and 5010, National Provider Identifier, and the International Classification of Diseases, 10th Revision.

We appreciate the opportunity to share our perspective regarding the proposals included in the HTI-2 proposed rule. We hope our perspectives and recommendations will serve to assist ASTP/ONC as it finalizes this important regulation. Please contact Charles Stellar, WEDI President & CEO, at cstellar@WEDI.org with any questions on these comments and recommendations.

Sincerely,
/s/
Ed Hafner
Chair, WEDI

cc: WEDI Board of Directors