601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004

T 202.778.3200
F 202.331.7487
ahip.org

June 20, 2023

Micky Tripathi, PhD MPP
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services

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

RE: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing — AHIP Comments

Dear Dr. Tripathi:

AHIP appreciates the opportunity to provide comments on the Office of the National Coordinator for Health Information Technology's (ONC) Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) proposed rule. AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to making health care better and coverage more affordable and accessible for everyone. Thank you for the opportunity to provide comments and feedback.

AHIP and its members wholeheartedly agree with the underlying goal of achieving a health care system in which data flow seamlessly among appropriate stakeholders to the benefit of Americans. Patients deserve high-quality, equitable care delivered by clinicians, facilities and health insurance providers working together and sharing reliable health information. Thus, we support ONC's work to promote interoperable data exchange, ensure safe and transparent use of artificial intelligence (AI), and reduce burden and costs. However, we are mindful of policies that have the potenital to negatively impact patient privacy and market dynamics. We believe ONC could strengthen the proposed policies by:

- **Requiring certified electronic health record technologies (CEHRT) to build and providers to use electronic prior authorization (ePA)—**Prior authorization is an essential tool for health insurance providers to ensure members receive safe and effective care while maintaining affordability. Despite its many benefits, the prior authorization process could benefit from streamlining and automation. However, successful implementation of ePA will require collaboration and action by all stakeholders in concert. For the Centers for Medicare and Medicaid Services (CMS) requirement that health insurance providers to build and maintain the Prior Authorization Requirements, Documentation and Decision (PARDD) API to be successful, ONC must also act to avoid disjointed and ineffective policies by requiring CEHRT vendors to build connections to the PARDD API and health care providers to use the technology.

- **Updating the United States Core Data for Interoperability (USCDI) with caution.** ONC should not add data elements that cannot be feasibly implemented because the underlying standards are not sufficiently mature or that reflect personally identifiable information without a concrete tie to patient care. For example, ONC should revise the Health Insurance Information data class to protect patient privacy, ensure feasibility, and avoid the disclosure of competitively sensitive information.

- **Adopting a process to review the use of artificial intelligence (AI) and machine learning (ML) that balances technology innovations with consumer protections.** We agree that as the use of AI grows, there is a need to protect consumers and guard against bias through techniques like transparency and explainability. However, ONC should focus on the use of AI that directly impacts clinical care and solutions that are proportional to risk to avoid hampering advancements such as those that streamline administrative functions.

- **Developing a roadmap, in partnership with CMS and the private sector.** ONC should consider this rule within the broader landscape of HIT regulations. Stakeholders, including health insurance providers, face numerous new requirements to meet CMS and ONC policies. ONC, in partnership with CMS and the private sector, should develop a roadmap of all upcoming changes including exchange requirements and updates to required standards, to ensure there is a sequential, coordinated process and timeline for adoption.

Thank you for the opportunity to provide feedback. We include detailed comments on of the provisions of proposed rule in the attached recommendations. We look forward to the opportunity to work with ONC on policies to advance interoperability to improve patient care and harness technologies, such as ePA, to meaningfully reduce burden for all stakeholders. If you have any questions, please reach out to me at either dlloyd@ahip.org or 202-778-3246.

Sincerely,

Danielle A. Lloyd
Senior Vice President, Private Market Innovations & Quality Initatives

AHIP Attachment

AHIP respectfully submits these detailed comments to the Office of the National Coordinator for Health Information Technology on the following provisions of the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule (HTI-1)

- Adoption of the USCDI Version 3
- Proposed Requirements for Decision Support Interventions (DSI) Certification Criterion
- Revisions to the Patient Demographics and Observations Certification Criterion
- Revisions to the Patient Requested Restrictions Certification Criterion
- Request for Information on Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities
- Updates to the Information Blocking Defined Terms and Exceptions

III. C. 1. The United States Core Data for Interoperability Standard (USCDI) v3

The Office of the National Coordinator for Health Information Technology (ONC) proposes to adopt the USCDI Version 3 as a standard within the Certification Program and establish an expiration date for USCDI Version 1 as an adopted standard within the Certification Program. Specifically, ONC proposes that the USCDI v1 (July 2020 Errata) in the USCDI standard will expire on January 1, 2025.

Relationship between USCDI and CMS Interoperability Rules

AHIP appreciates ONC's ongoing work to advance the interoperability of health information through the United States Core Data for Interoperability (USCDI). We agree that a common set of data classes and elements is essential to achieving interoperability and advancing towards a system in which data flows seamlessly between stakeholders. However, as noted in our comments on the draft USCDI v3 and draft USCDI v4, as ONC adds additional data elements to the USCDI, the risk to patient privacy and data security grows not only because of the magnitude of data shared but also because of its tie to other downstream policies. Through a combination of ONC and Centers for Medicare & Medicaid Services (CMS) requirements, both health care and health insurance providers must share USCDI data through application programing interfaces (APIs) with third-party applications (apps) on behalf of consumers.

The apps with which the providers and payers must share data at the request of consumers were not contemplated, let alone included, as covered entities within the traditional Health Insurance Portability and Accountability Act (HIPAA), Health Information Technology for Economic and Clinical Health (HITECH), and 42 CFR Part 2 rules. This gap in the federal privacy and security framework leaves consumers' healthcare data vulnerable. While the Federal Trade Commission is considering significant changes to enhance the Health Breach Notification Proposed Rule, it is unclear what policies will be included in the final rule.

Current information sharing and interoperability policies are structured around an all or nothing approach— stakeholders are required to share all requested data elements in the currently required version of the USCDI. This reflects what is currently technologically feasible and expeditious but is not patient-centered as it does not provide consumer choice in data sharing. Thus, data elements in the USCDI should have a clear clinical value and purpose to ensure information is relevant to care. Furthermore, each element must be supported by mature standards so that organizations can ingest and understand the information. **Until technology sufficiently matures to permit easy data segmentation, ONC must be judicious about which data is added to the USCDI and thus shared with actors not covered by HIPAA. Otherwise, ONC and CMS should designate a subset of data that will be shared through the APIs to protect consumers.**

Health Insurance Data Class

As noted in our previous comments, we are concerned that the USCDI v3 Health Insurance Information data class contains a number of data elements that are not germane to the provision and coordination of patient care and could create conflicting or inaccurate records. While we agree certain information about a person's coverage status is important for care coordination, quality measurement, and assessing disparities, ONC should revise certain data elements to protect patient privacy, avoid the disclosure of confidential pricing information, and ensure feasibility.

Clinical Purpose and Patient Privacy

ONC should remove data elements that provide personally identifiable information that does not support the provision of patient care. For example, the "Relationship to the Subscriber" and "Group Identifier" data elements do not have unique value or clinical significance. Information about a person's social supports and employment would be better captured by the SDOH-related data elements. Including specific and unnecessary information about a person's familial relationships and employer could be used by third parties to identify someone in a different data set or even re-identify a de-identified data set.

We also urge ONC to clarify the submission level and purpose of the "Coverage Status" use case. ONC should not add data elements to the USCDI that duplicate processes housed in practice management systems. Currently payers use the X12 Eligibility & Benefits 270/271 transaction set and associated Committee on Operating Rules for Information Exchange (CORE) to transmit coverage eligibility information to providers.

Plans also share claims and encounter information directly with consumers via their own on-line platforms and via the Patient Access API. This method ensures consumers get such data from the source (their payer). Requiring this information to be captured in the electronic health records (EHRs) is duplicative and risks patients and providers relying on outdated information. Moreover, it would unnecessarily add costs to the system.

For example, while there may be value in capturing if a patient is uninsured or on Medicaid as a proxy for social needs, there is not a clinical need for detailed insurance information. In fact, it may be off putting to patients and raise concern if a clinician asks for such information during the course of care rather than by office staff at check in or check out.

Coverage Status

ONC should structure the "Coverage Status" data element to indicate whether and which type of health insurance a patient has, rather than if specific services are covered. The submission[1] implies the data for the "Coverage Status" data element would be at the claims level. However, the CARIN IG for Blue Button Standard defines the allowable entries for "Coverage Status" as active, cancelled, draft, or entered-in-error. We ask ONC to clarify how this data element should be characterized. We urge ONC to not require claims-level data and clarify it should be coded more broadly (e.g., active, pending, etc.)

We are concerned that as currently written, the Coverage Status data element requires sharing of claim-level payment information through the USCDI. Consumers already have access to the information they need via plan transparency tools—the most up-to-date and accurate source for claims, pricing, and coverage information. Furthermore, we remain concerned that the forced disclosure of confidentially negotiated rates could have unintended consequences if shared beyond consumers. CMS has carefully crafted policies that ensure the paid amounts are only released through the Patient Access API and not through the Provider Access and Payer-to-Payer APIs. Incorporating claims level data with the paid amounts in the required version of the USCDI could cause conflicting policies across agencies and lead to the sharing of data with parties whom CMS did not intend.

We recognize that a best practice would be to make available at the point of care whether a service is covered, whether a provider is in-network, and/or the relative costliness of a provider to assist consumers in making decisions in concern with their provider. However, the technology and standards to support such real-time benefit checks and calculation of a consumer's potential cost sharing for medical services remains limited. The health insurance industry is busy working with CMS to develop advanced explanation of benefits (AEOB), but they will not be in real time. Moreover, many policy recommendations remain unresolved both for the AEOB and how to surface pricing information on other providers to the referring provider without creating anti-competitive dynamics. **ONC should not include any financial data in the USCDI, particularly confidentially negotiated rates or any other information that could harm consumers by making public competitively sensitive information.**

In addition, it is unclear how the Coverage Status data element would be operationalized. As noted above, such data is not currently in the EHR and would need to either come from payer directly (which they are not currently required to provide) or be ported over from the providers practice management system on a pre-adjudicated basis or after the fact. We are not clear what purpose this either inaccurate or lagged data would serve and at the same time could have adverse unintended consequences for affordability if data on confidentially negotiated rates can

[1] https://www.healthit.gov/isa/taxonomy/term/3601/uscdi-v3#uscdi-proposal-mode-uscdi-data-element-page-display

be bought and sold if released through the API requirements (providers or plans). Additionally, we note that data elements such as Member Identifier, Payer Identifier, and Subscriber Identifier do not have universally accepted standards. Without associated standards, such as national payer identification numbers, these data elements will not generate useful and usable information.

ONC should revise the Health Insurance Information data class to focus on sharing information that can be feasibly collected based on national standards and can facilitate patient care, help consumers and health care providers assess quality and understand the impacts of social determinants of health. A more streamlined approach could protect patient privacy, prevent the sharing of inaccurate information, and avoid market disruption. We suggest the Health Insurance Information data class focus on data elements that allow understanding of whether a person has insurance coverage, the type of coverage, and what payer(s) are covering the person. These data elements would allow health care providers to understand if a person has insurance coverage and the potential implications for care and care transitions, support quality and equity efforts, and help consumers and providers connect with health insurance provider tools for up-to-date information on the coverage of specific services. ONC should work with health insurance providers to educate consumers about the Patient Access API and other tools available to encourage data access. Leveraging these tools would ensure consumers have access to their data while protecting their identities and ensuring the information they receive is accurate and up to date.

Until the Health Insurance Data Class is revised, ONC should not adopt a policy requiring a wholesale adoption of USCDI v3. As an alternative, we suggest ONC adopt selected Data Classes from USCDI or advance the requirements to USCDI v2. As ONC and CMS consider advancing the required version of the USCDI, we recommend that rather than adopting versions of the USCDI wholesale, CMS and ONC should consider the contribution of each data element and whether it is necessary to share through the Patient Access API and expose to the risk of passing to a third-party app that is not a covered entity subject to HIPAA. CMS and ONC should consider removing personally identifiable data elements that do not provide unique value to avoid re-identification and the potential exposure of a person's health information or alternatively, revise policies that require automatic inclusion of all data elements in the named version of the USCDI through the APIs required in CMS's interoperability regulations.
If ONC does not believe it is feasible to parse versions of the USCDI for adoption, the agency should adopt USCDI v2 instead of USCDI v3. Advancing to USCDI v2 would facilitate the sharing of valuable information, such as on a person's social determinants of health (SDOH) without the risks that could incur from the inclusion of the Health Insurance Information Data Class. ONC should not advance to requiring sharing of USCDI v3 until the Health Insurance Data class has been revised.

Implementation Timeline

We also recommend ONC work with CMS to ensure adequate time for stakeholders to share additional data elements. Updating the version of USCDI adopted as a standard would also change the information impacted payers are required to share through the APIs mandated by CMS. ONC and CMS should work with stakeholders, including impacted payers to determine a feasible date to update the version of USCDI adopted for the CMS APIs. We recommend that

ONC consider the proposal to require an implementation date of January 1, 2025, for updates to the required version of USCDI. Instead ONC should work with CMS to coordinate a reasonable implementation deadline that aligns with and allows successful implementation of the regulations currently proposed in the CMS Interoperability and Prior Authorization rule. ONC should advance to USCDI v2 or a selected group of USCDI v3 data classes in coordination with the timelines established by the Interoperability and Prior Authorization final rule. **ONC should also not mandate sharing of the data elements in the Health Insurance Information Data Class until there are defined standards and CMS clarifies through rulemaking on which data elements do not have to be shared through the Payer-to-Payer API to avoid the exchange of competitively sensitive information.**

III. C. 5. c. Proposed Requirements for Decision Support Interventions (DSI) Certification Criterion

ONC proposes a certification criterion for predictive "decision support interventions (DSI)." This is a revision of the CDS criterion and would reflect an array of contemporary functionalities, data elements, and software applications, including the use of predictive models or algorithms, that certified Health IT Module(s) enable or interface with to aid decision-making in healthcare.

We share ONC's Department's commitment to ensuring the highest levels of consumer protection when it comes to HIT. We agree that as the use of advanced analytics, machine learning (ML), and artificial intelligence (AI) grows, there is a need address potential risks while working to optimize the use of these technologies.

AI has great potential. As examples, AI has proven effective at detecting lung cancer and has been used in breast cancer screening methods.[2] It has also been used in developing medicines, particularly for rare diseases and personalized treatments.[3] However, we must balance innovation with patient protections and transparency. We agree with ONC that biases in the data and algorithms underlying AI and ML could negatively impact certain subpopulations. For example, AI developed using total cost of care data could leave out individuals who experience challenges accessing care and who could benefit from additional care management and services.[4]

However, we are concerned that ONC's proposed policies could stifle innovation and lead to overly restrictive reviews. The private sector needs flexibility to realize the potential of AI for individual consumers. To balance innovation and consumer protections, ONC should implement a risk-based framework to evaluate AI and determine what disclosures are necessary. For example, AI that supports clinical decision making involves greater risks to the patient than AI that helps with routine administrative functions such as appointment scheduling and reminders.

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[2] A. Brooks, "The Benefits of AI: 6 Societal Advantages of Automation" Rasumessen University (Nov. 4, 2019) available at: https://www.rasmussen.edu/degrees/technology/blog/benefits-of-ai/. See also, S. Bansal, "10 Advantages and Disadvantages of Artificial Intelligence" available at: https://www.analytixlabs.co.in/blog/advantages-disadvantages-of-artificial-intelligence/.

[3] S. Daley, 32 Examples Of Ai In Healthcare That Will Make You Feel Better About The Future (updated July 29, 2020) available at: https://builtin.com/artificial-intelligence/artificial-intelligence-healthcare.

[4] Oberymeyer, et al. Dissecting racial bias in an algorithm used to manage the health of populations. *Science*. 2019; 366(6464): 447 – 453.

AI has many advantages that include operational efficiencies, cost reduction, technical innovation, and error reduction. Health insurance providers can use AI in a number of ways.[5] Many of these functions are not directly related to clinical care such as prospecting clients, predictive analytics, actuarial analyses, and performance measurement. AI and decision support technologies can help streamline these processes and have little or no risk to consumers.

This rulemaking represents an initial approach by the federal government into overseeing AI. We are concerned about the downstream implications for decision support technologies that health insurance providers depend on to perform routine administrative functions, not clinical care. While we appreciate that this rule does not require an external review of decision support technologies, we are concerned that such a review could be required in the future. Currently there are no standards to review AI and decision support technologies against, there's no current entity that could perform such a review, and such reviews could be cost prohibitive.

As written, this criterion is overly broad and could prevent the innovation and automation of administrative functions. We are concerned that as proposed the definition of "predictive decision support intervention" as meaning "technology intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation, or analysis" is overly broad and risks including technologies health insurance providers depend on to modernize administrative functions to increase efficiencies and control costs rather than deliver patient care. **We recommend ONC revise this definition to clarify that this criterion applies to clinical predictive decision support interventions, and does not include utilization management, case management, care coordination and other activities conducted by insurers**. Moreover, the language stating "interface with to aid decision-making in healthcare" could affect other payer technologies such as the proposed Provider Access API and Prior Authorization Requirements, Documentation and Decision (PARDD) API that are designed to accessed through a provider's EHR to meet this criterion. **ONC should clarify that such technologies are excluded from this criterion.**

We are also concerned that the criterion as currently written could pose challenges for health insurance providers who depend on vendors whose algorithms are proprietary for some of these functions. Vendors may be unwilling to risk their intellectual property to seek certification. ONC should clarify how developers could meet the requirement to allow a user to review predictive DSI "source attribute" information through the Health IT Module without being required to disclose proprietary information or risk their intellectual property.

We urge ONC not to implement this criterion hastily and to work with the private sector to revise the criterion in a way that focuses on patient risk. The private sector has been a leader in terms of deploying and using AI, as well as conveying ethical considerations and standards for AI uses and effects. ONC should work with private sector stakeholders, including health insurance

[5] Humana and IBM Watson Health Humana and IBM Watson Health are joining forces on a new collaboration, one that will use IBM's conversational artificial intelligence platform to achieve greater clarity and transparency on benefits and other related matters for Humana Employer Group members.

providers, to develop a risk-based framework that could be used in the Certification program. ONC should work with public and private sector partners to develop a revised, risk-based criterion that leverages the work of the National Institute of Standards and Technology (NIST), American National Standards Institute (ANSI), the Consumer Technology Association (CTA) and other organizations who have been leaders in this field. Vendors and developers of AI and algorithms should be brought into public forums to discuss their models and provide insight for how to detect, investigate, and resolve unintended bias.

Public and private partners should work together to create standards that can be leveraged by AI using NIST, ANSI, the CTA and other organizations who have been leaders in this field to determine the best approach to fostering innovation while ensuring transparency and protecting consumers. We note that in addition to ONC's proposal for certified health IT developers seeking certification to this criterion, numerous states have proposed or implemented AI-related reporting or attestations. Such requirements involve significant staff resources, and there is concern that the administrative burden of duplicative and non-aligned reporting may detract from AI innovation. Additionally, due to the lack of standardized reporting across healthcare AI, users, including providers and patients, may face further burden when interpreting differing transparency reports. Thus, we ask ONC to support alignment efforts with standards development organizations (SDOs).

III. C. 7. d. Access Token Revocation

ONC proposes to specify that a Health IT Module's authorization server must be able to revoke and must revoke an authorized application's access at a patient's direction within one hour of the request.

We appreciate ONC's efforts to permit patients to further direct the use of their EHI. However, one hour is not enough time to process such a request and terminate data from the application. Presently, patients can revoke access to data through both the third-party app and through their patient portal. Providers also need time to contact their HIT developers to make the revisions if a patient asks them in person, via e-mail, or over the phone. We are also concerned that if this policy requirement were to be applied to health plans in federal programs by CMS for its mandated Patient Access API, enrollees would likely make the request of the plan and not the third-party app. Plans would have similar problems making a change in this time-frame for requests that are not within the technology, and perhaps even within the technology. ONC should provide clarification on how the one-hour revocation requirement would be applied when there are numerous ways a patient could make such a request. **ONC should also coordinate with CMS to ensure the timeframes and processes for revocation are feasible for impacted payers to meet to comply with the requirements for the Patient Access API.**

III. C. 8. Patient Demographics and Observations Certification Criterion in § 170.315(a)(5)

ONC proposes to change several data elements in USCDI, namely Sex (Assigned at Birth), Sexual Orientation, and Gender Identity to reflect public feedback that these standards and terms are outdated. ONC proposes to recharacterize Sex (Assigned at Birth) to Sex. ONC proposes to

update the specific codes referenced in Sexual Orientation and Gender Identity with the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT ®) code set.
We appreciate ONC's efforts to ensure the data elements in the USCDI reflect current terms and standards and support the proposed changes. We encourage ONC to work with the International Health Terminology Standards Development Organization to continue to refine the SNOMED code set to reflect up-to-date and inclusive terminology.

Standardizing and improving demographic data has been a priority of the health insurance industry. Between 2020 and 2022, AHIP sought to develop improved demographic data standards that are more aligned, patient-centered, and actionable than the various standards that exist today. AHIP employed an evidence-based and stakeholder-driven process to conduct this work by convening diverse groups of health insurance providers and other stakeholders (e.g., patients representing different communities, providers, community-based organizations, others). In addition to race and ethnicity, our workgroup also developed recommended data standards[6] for language, sexual orientation, gender, pronouns, relationship status, disability status, military experience, and spirituality. While largely aligned, our recommended data standards for sexual orientation and gender identity allow a person to provide more nuanced information about themselves to best inform care. We would encourage other organizations to look to these standards to allow a consistent and patient-centered approach to the collection and codification of SOGI data.

We hope this work will lead to high-level data standardization and alignment across the health care ecosystem while allowing for local granular customization. This will ensure organizations can collect a reasonable amount of data that is actionable and relevant for their local communities while still aggregating and exchanging data seamlessly with appropriate entities. ONC also proposes to add three new data elements: "Sex For Clinical Use" (SFCU), "Name to Use" and "Pronouns" to facilitate data capture that supports providers' ability to provide culturally competent care for their patients.

We support ONC's proposal to add these additional data elements to support providers' ability to render culturally competent and person-centered care. However, ONC should work with stakeholders to provide education on the differences between related data elements like Sex and Sex for Clinical Use to ensure patients' identities are respected while important information for clinical care is captured correctly. We also urge ONC to work with stakeholders to provide guidance on how Sex for Clinical Use should be characterized in data that is provided to the patient. For example, this information could be shared with a patient through the Patient Access API required by CMS but could be distressing or confusing to a patient if the data on their sex for clinical use does not align with their identity. Moreover, this data element could provide extremely granular information about a person's sex and gender identity, at an individually identifiable level, that under current CMS required policies can be freely sold or disclosed by the app developer as long as it is noted in the consumer terms and agreement provided by the app (which can be changed at any time). We also note that the SFCU data element may impact health plan medical policies, clinical appropriateness screening criteria, and existing utilization

[6] https://www.ahip.org/documents/AHIP-Letter-on-Demographic-Data-Standards-with-Appendix.pdf

management and coverage determination programs. Specifically, the use of these codes may require substantial administrative efforts to update impacted policies and operations.

III. C. 10. Patient Requested Restrictions Certification Criterion

ONC proposes to adopt a new certification criterion, revise a certification criterion, and propose modifications for Health IT Modules certified to specific criteria under the Privacy and Security Certification Framework. ONC proposes this criterion should enable a user to implement a process to restrict uses or disclosures of data in response to a patient request when such restriction is agreed to by the covered entity. ONC proposes that users should be able to flag data that should not be used or disclosed and prevent such data being included in a subsequent use or disclosure.

We agree that changes in health and health care technology, interoperability, and increasing awareness of social determinants of health present both opportunities to improve patient care and risks to patient privacy and support the goals of this proposal. While we are open to evaluating "privacy tagging" in a variety of electronic environments, we remain uncertain how using a variety of "tagging" functions will support greater interoperability and make patient information more readily available at the point-of-care.

We are very concerned with any proposed adoption of a standard that moves the level of tagging for segmentation purposes from the document level to the level of individual data element. Any such requirement will not only create risks of detrimental system performance, as every data element captured will need to be individually tagged with metadata, but will also create significant burden on health care organizations to develop systems and processes that support segmentation at the data element level. Such a requirement will also create the risk of having incomplete health records filled with data element holes (so-called "swiss-cheese effect"), which could increase the risk for medical errors and other patient safety issues, undermining care management efforts and clinical determinations. For example, tagging information can be suppressed or removed from an electronic record resulting in incomplete information being made available to individuals and their treating providers.

Getting legal and operational designations to mesh to the degree of precision necessary to enable patients to choose which data to share will be contentious, laborious, and run counter to member expectations. For example, 42 CFR Part 2 attaches to records based on the provider, but other state laws may require health plans to filter substance use conditions at the diagnostic level, regardless of the source of the diagnosis. In addition, there is no standardized delineation of "mental health diagnoses," which the Mental Health Parity and Addiction Equity Act (MHPAEA) leaves up to state law or to health plans. Mapping such a distinction on to diagnostic or service codes would require a clinical standards development process, would probably fail to align with certain state laws and will create needless conflict across professional organizations. Inevitably, the distinction drawn whether for mental health or other conditions and services, will not line up with the specific expectation of the consumer.

Based on today's technology, consumers should have the choice to share all or none of their data via APIs. If consumers are concerned that some of their PHI is too sensitive to share, they

should rely on other existing HIPAA-compliant mechanisms (e.g., CD-ROM) that can be segmented based on their preferences.

Considering the implementation challenges and the risk of creating and sharing incomplete records, if ONC chooses to adopt this criterion it should be optional and limited to specific use cases at first. Such a progressive transition approach will allow for better testing and demonstration of these technologies before they are widely required. ONC should also provide full guidance on what different types of information should be flagged and how such flags would be addressed in FHIR resources.

ONC seeks comments on whether patients should be able to terminate the restriction upon request. If ONC chooses to finalize a policy allowing patients to restrict access to parts of their health data, we believe the functionality to stop that restriction in the future is necessary to ensure patients remain in control of their health data and should be required. However, ONC should clarify a process for how patients can terminate the restriction and work with stakeholders to ensure the process and timelines for allowing access to the unrestricted data are feasible.

III. G. 2. Request for Information on Pharmacy Interoperability Functionality within the ONC Health IT Certification Program including Real-Time Prescription Benefit Capabilities

ONC seeks comments about specific issues related to establishing a certification criterion using National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit (RTPB) standard version 12 and other potential actions that could support complementary and interoperable workflows.

We support ONC's vision of a holistic solution that incorporates a series of capabilities that are part of a comprehensive workflow for evaluating and prescribing medications. We agree that building these functions into a comprehensive solution would minimize the burden on prescribers while allowing them to share more complete information with patients. However, we believe the ONC Certification tied to NCPDP RTPB standards alone does not fully address requirements that need to be fulfilled by EHRs that offer RTPB. Although we support NCPDP and the effort toward standardization of data, we believe ONC should consider the role EHRs play in displaying RTPB and offering accurate data from payers and third-party vendors.

<u>Require Certified EHRs to Offer RTPB Alongside Electronic Prescribing</u>

First, we are concerned that that EMRs are not currently required to implement RTPB and believe that **ONC should issue a rule to require certified EHRs to offer RTPB alongside an electronic prescribing capability**. This will help RTBP to better fit into a prescriber's workflow and along with standardization, would reduce burden and incentivize use.

<u>Ensure the Accuracy of Information Displayed</u>

We believe ONC should take steps to ensure the accuracy of information displayed in the EHR. **EHR connections to RTPB should be data from the payer and not representative data**

created by third parties. EHRs should connect to payers or data vendors with real-time, payer information to ensure patients are provided accurate information about their benefits via RTPB. EHRs should not connect to third-party actors offering RTPB services (e.g., claim adjudicators or switch companies) that are not connected to payer data and could provide conflicting information with the patient's plan benefit. For example, third-party actors may use averaged claims data that could misrepresent utilization management tools such as prior authorization or coverage status leading to data that is not real-time or based on a patient's benefits.

Provide Display Guidance

ONC should provide guidance to ensure EHR displays include standard data elements. For example, many EHRs do not present or display medication alternatives, pharmacy information or coverage alerts in a way that helps the prescriber understand options. Moreover, some EHRs blend benefit information with cash discount cards that can result in abrasion for members that need their medication to impact their deductible. To address this ONC could require disclosures to ensure the prescriber adequately displays warnings for using cash cards. **We recommend ONC work with CMS and NCPDP to create a set of required and standardized data elements to ensure meaningful data provided by the payer in RTPB is displayed to the prescriber.**

Implement Protections to Prevent Abuse

ONC should implement protections to prevent the use of data and potential abuse of RTPB transactions. **To protect the integrity of the information shared, EHRs should only use RTBP data for electronic prescribing purposes and should not be permitted to use it for other functions.**

Require Connections to ePA Tools

Finally, ONC should require connections to electronic prior authorization tools alongside RTPB. Evidence-based medical management programs and services, including tools such as prior authorization, are key to promoting the delivery of clinically appropriate high-quality care, reducing waste, and improving affordability for all Americans. The implementation of electronic prior authorization has the potential to streamline the prior authorization process for patients and providers while maintaining a critical safety and quality check. However, successful implementation of ePA will require collaboration and coordination across many stakeholders in a complex ecosystem. One-sided requirements that require impacted payers to build APIs will not result in the broad adoption necessary to achieve the benefits. While health insurance providers can build APIs to facilitate ePA, these tools will have minimal value if EHR vendors do not build the necessary connections to allow clinicians to access them as part of their workflow.

To advance adoption of ePA by providers, health information technology developers will need to play a leading role. Integration of ePA technology into EHRs could reduce the burden on providers and increase the likelihood of adoption. Moreover, by incorporating the ability to retrieve critical information at the point of care via EHRs or other interfaces, ePA solutions can

facilitate transparency of information and decision making, resolving another key reported burden of the prior authorization process.

We urge ONC to issue a new rule with a criterion for certified HIT vendors to build connections to the Prior Authorization Requirements, Documentation and Decision (PARDD) API that CMS has proposed to requite impacted payers to build. Without commensurate requirements on certified HIT vendors to build connections to the PARDD it will be difficult for providers to access the API as part of their workflow, minimizing the likelihood of widespread adoption.

III. G. 3. FHIR Standard

The FHIR Standard RFI focuses on the FHIR standard for APIs (including FHIR Subscriptions, CDS Hooks, FHIR standards for scheduling, and SMART Health Links). ONC notes this RFI aligns with the agency's aims of advancing interoperability using APIs for treatment, payment and operations use cases. ONC seeks comments as the agency considers the applicability of these standards and specifications for potential future rulemaking.

FHIR Subscriptions RFI

ONC seeks input on the maturity of these resources in the FHIR Release 4 standard that is incorporated in 45 CFR 170.315(g)(10). Additionally, ONC seeks comment on whether the FHIR Subscriptions capability aligns with the adoption of the FHIR Release 5 standard.

We believe the FHIR subscriptions could be a great tool with the automatic capabilities to query and update information. However, we do not believe the FHIR subscriptions are mature enough or have been sufficiently tested to be adopted at this point. **We recommend defining a minimum set of Subscription Topics that can be consistently implemented by all health IT developers.** Otherwise, this would only add to the complexity. Moreover, given potential data concerns, ONC should explore the use of TEFCA and how the participating QHINs could serve in this clearinghouse type role. **Finally, we recommend backport of subscriptions from Release 5 into Release 4.**

Clinical Decision Support Hooks RFI

ONC seeks input from the public on whether to require certified health IT systems to adopt the CDS Hooks FHIR Implementation Guide v1.0 as part of the requirements in the Program.

We support the use of CDS hooks. CDS Hooks allow payers and other stakeholders to integrate with Certified Health IT in a standard way that is scalable and applied across multiple EHR systems. Some upcoming regulations, such as CMS's Interoperability and Prior Authorization rule, depend on CDS Hooks. **We believe the CDS hooks functionality is sufficiently developed and mature and should be considered for adoption.**

FHIR Standard for Scheduling Request for Information

ONC seeks input on the maturity and scope of the SMART Scheduling Links Implementation Guide that is aligned with FHIR Release 4, to be considered for future certification as part of the Program.

From a patient perspective, scheduling standards could be valuable. For example, a Provider could send both medical information to a patient and assist with scheduling their follow-up visit to a specialist. We agree this capability would be beneficial and recommend ONC continue to collaborate with standards development organizations and stakeholders to mature the appropriate standards for adoption.

IV. A. Defined Terms

ONC proposes to modify how it defines "offer health information technology" for purposes of the information blocking regulations. ONC proposes to carve out by explicit exclusion the provision of funding for obtaining or maintaining certified health IT. ONC also proposes to explicitly codify that the agency does not interpret health care providers or other health IT users to offer health IT when they engage in certain activities customary and common amongst both health care providers that purchase certified health IT from a commercial developer or reseller and health care providers that self-develop certified health IT.

We support ONC's modification of the definition of "offer health information technology." However, **we ask ONC to clarify that the exclusion from the "offer health IT" definition to include "subsidy arrangements"** (funding or cost subsidies) that are provided by external sources, such as health plans to providers, in some circumstances. **We also ask that ONC provide additional guidance and examples of how the agency will define "beneficial" and "necessary" in this context.**

ONC should continue to refine the definitions in the information blocking provisions to ensure feasibility and clarity. As noted in our comments in the response to the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule, **we strongly recommend ONC narrow the definition of "Health Information Networks" and clearly state in the regulatory text payers are not included in this definition and thus are not subject to the information blocking provision.**

IV. B. Exceptions

Infeasibility Exception

ONC proposes to revise the Infeasibility Exception by adding two new conditions and by revising one existing condition to further clarify when an actor's practice of not fulfilling a request for access, exchange, or use of EHI meets the condition.

Overall, AHIP supports the proposed changes to the Infeasibility exception. However, ONC should make several modifications to the agency's proposal to ensure successful implementation.

While we support the addition of the Third-Party Seeking Modification Use condition, **ONC should provide example use cases of where this condition could apply**. This will ensure clarity on when a situation covered by this condition might occur. ONC requests comments on whether this condition should be for a limited duration or potentially eliminated in the future if technology advances. AHIP believes that ONC should not place such restrictions on this condition at this time.

Manner Exception Exhausted Condition

Next, we strongly support the manner exception exhausted condition as it will promote interoperability based on standards rather than the creation of unique, non-scalable solutions. Allowing actors to focus resources on standards and certified health IT solutions rather than requiring one-off solutions will incentivize both actors and requestors to adopt certified health IT. However, **ONC should modify the condition to require actors to offer a minimum of 2 (instead of all) alternative manners if at least one of those manners uses either certified technology or content and transport standards**. Providing greater clarity and specificity will reduce the burden on large organizations that have to handle a large volume and variety of requests.

We also recommend clarifying "substantial number" to a fixed number for the same reasons outlined in the proposed rule. We also do not support more textual specificity or clarity on "similarly situated to the requestor" verbiage since, as noted, the same verbiage is used under the Fees and Licensing Exceptions.

We also ask ONC to clarify whether this includes former methods or just includes current method of sharing data. For example, if TEFCA or FHIR replaces some other point to point methods used in the past, actors would not be required to fall back on old methods or continue to maintain outdated technology because it was used successfully in the past.

Manner Exception – TEFCA Reasonable and Necessary Activities

ONC also proposes to add a Trusted Exchange Framework and Common Agreement (TEFCA) condition to the proposed revised and renamed Manner Exception. The new condition would state "If an actor who is a QHIN, Participant, or Subparticipant offers to fulfill a request for EHI access, exchange, or use for any permitted purpose under the Common Agreement and Framework Agreement(s) from any other QHIN, Participant, or Subparticipant using Connectivity Services, QHIN Services, or the specified technical services in the applicable Framework Agreement, then: (i) The actor is not required to offer the EHI in any alternative manner; (ii) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and (iii) Any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303."

AHIP generally supports the addition of the Manner Exception—TEFCA Reasonable and Necessary Activities. We believe that it could incentivize organizations to participate in TEFCA. However, while we believe the goal of advancing TEFCA adoption through this

exception is desirable, the exception may rarely be used in practice given some limitations, namely, the responder must be able to provide EHI through TEFCA to invoke this exception.

TEFCA currently only requires that USCDIv1 be exchanged and most (if not all) responders likely will be unable to send all EHI through this method. In turn, alternate manners of exchange may still be required to comply with a request for complete EHI.

However, ONC should clarify the interactions with state exchanges and data sharing initiatives. Some states, such as California's Data Exchange Framework (DxF), are establishing requirements to exchange data within a specified network and referencing federal rules. This complicates and confuses what is required and by which entity. It could also result in payers having to participate in multiple networks which may conflict with timelines and resources to engage with TEFCA. **ONC should work with the states and the TEFCA Recognized Coordinating Entity (RCE) to address potentially conflicting requirements.**