June 16, 2023

Mr. Micky Tripathi
Office of the National Coordinator
Department of Health and Human Services,
Attention: RIN 0955-AA03
Mail Stop 7033A, 330C Street Southwest, Washington, D.C. 20201

Re: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

Dear Mr. Tripathi,

On behalf of the CARIN Alliance, we want to thank you for providing the opportunity to comment on the Office of the National Coordinator's proposed rule on Health Data, Technology, and interoperability. We are excited about the efforts you have made to advance interoperability, reduce administrative burden, and accelerate consumers' access to health information.

As you are aware, the CARIN Alliance is a multi-sector group of stakeholders representing numerous hospitals, health plans, technology vendors, application developers, thousands of physicians, and millions of consumers and caregivers. We are committed to providing consumers and their authorized caregivers access to health information. Specifically, we are promoting the ability for consumers and their authorized caregivers to gain digital access to their health information via the open APIs and the ability to use that information in any third-party application they choose and to promote consumer-centered privacy and data practices across the health data ecosystem.

We are very supportive of many of the proposals included in ONC's rule to promote and encourage patients to get and use a digital copy of their own health information. We appreciate the ONC's reaffirmation of the primacy of the patient access and API-based interoperability as driving themes for implementing the Cures Act. We also appreciate the ONC's request for information regarding scheduling, real time benefit tools and SMART HealthLinks. Our coalition recognizes patient access as a starting point in interoperability and encourage the ONC to build on a broader conception of patient access that improves the patient experience, reduces administrative burdens, and enables the shift to value. We look forward to continuing the work of advancing data exchange and empowering consumers.

Again, we appreciate your consideration of our comments. Please do not hesitate in contacting me if you have any further questions.

RR Ryan Howells

Ryan Howells
Leavitt Partners
On behalf of the CARIN Alliance
Email: Ryan.Howells@leavittpartners.com

ONC Proposed Rule text is in **BLACK** text and CARIN's comments are in **BLUE** text.

In the interest of clarity and cohesion among HHS components, we have proposed to align some of our compliance dates to the calendar year for consistency with calendar-year based performance periods in CMS programs when participants may be required to use updated certified health IT. We believe this approach reduces confusion for participants in these programs and better serves the public interest.

CARIN supports the clarity established here by ONC. We support this clarity because, as ONC notes, it reduces the confusion for participants across various programs and provides needed consistency across programs for those seeking to use tools made available by HIT developers, providers, and other actors. This will be a critical consumer benefit as more individual patients, consumers, caregivers, and care-partners seek to access additional data across systems.

Specifically, we heard that a consistent, transparent, incremental update cycle that includes the following features would be preferred by some: 1) regular updates to recognize standards advancement and an allowance for voluntary standards advancement between updates, 2) incremental updates rather than wholesale certified Health IT Module certification criteria overhauls, 3) a predictable timeline for updates based on standards development cycles with reasonable development timelines, and 4) a reasonable development timeline for any new criterion based on the specific development needs.

CARIN supports the clarity offered by ONC. We also recognize that managing criterion on their own timeline requires a continuous understanding of the total effort in progress at any point in time. That is not only a challenge for HIT developers, but also for providers to have to manage a continuous stream of enhancements, many of which are not only software upgrades that are invisible, but have a substantial impact on process and workflows, requiring education, roll-out, etc. However, notwithstanding these challenges, we believe this proposal is the best way to rapidly advance updates in technology, including those that will advance consumer access and the consumer experience, and we support this harmonization.

To advance interoperability, in section III.C.1, ONC proposes to add the newly released USCDI v3 in § 170.213(b). We propose that USCDI v1 would remain in regulation and now be codified in § 170.213(a) and we propose to add USCDI v3 to § 170.213 (to be codified as § 170.213(b)). We also propose to incorporate by reference USCDI v3 in § 170.299 as of the effective date of the final rule. In addition, we propose that the USCDI v1 (July 2020 Errata) in the USCDI standard in § 170.213(a) will expire on January 1, 2025. Under this proposal, both versions would be referenced as applicable in the USCDI standard in § 170.213 for the time period up to and including December 31, 2024.

We support the sunsetting of USCDI v1 (July 2020 Errata) by January 1, 2025. Alternatively, ONC could consider aligning date to other regulatory requirements, consistent with other sections of this NPRM. The consensus-driven standards advancement process for USCDI has been operating on a defined

annual basis and is transparent and open to all participants. USCDI v3, released in final form in October 2022, was first published in draft form in July 2022, and was preceded by review by HITAC and public comment. USCDI went through a similar timeline and process in 2020. The reason for running a standard advancement process outside of formal notice-and-rulemaking is to promote interoperability. Allowing USCDI v1 to sunset 5 years after it was finalized is an appropriate step, so that the v3 standard can become the de facto interoperability standard.

We propose in section III.C.7 to revise the "standardized API for patient and population services" certification criterion in § 170.315(g)(10) in several ways. We propose to require a certified Health IT Module's authorization server to issue a refresh token according to the implementation specification adopted in § 170.215(c). The token should be valid for a period of no less than three months and will apply to all applications using the "confidential app" profile for both first time and subsequent connections.

CARIN supports this requirement. CARIN third-party, consumer-facing application members have noted the challenges with refresh tokens over the last several years. While much work has been done in this space, and several data holders and HIT developers have addressed challenges with both refresh and access tokens, standardization in the certification process will be appreciated. CARIN supports a consistent baseline and experience and believes that consistency should be encouraged and supported.

We also propose to adopt the FHIR US Core Implementation Guide STU version 5.0.1 in § 170.215(b)(1)(ii). Based on the annual US Core release cycle, we believe US Core IG v6.0.0 will be published before ONC issues a final rule.13 Therefore, it is our intent to consider adopting 13 http://hl7.org/fhir/us/core/history.html. the updated US Core IG v6.0.0 that supports the data elements and data classes in USCDI v3 since we propose to adopt USCDI v3 in this rule. Health IT systems that adopt this version of the US Core IG can provide the latest consensus-based capabilities for providing access to USCDI data classes and elements using a FHIR API.

CARIN has long supported the advancement of US Core IGs to help expand consumer access to more data while experience less friction. We believe that as V6 has now been published, it should be the version that ONC adopts and prioritizes both in terms of the data content (HL7® FHIR®) and the actual mechanism (RESTful APIs) in which the content is delivered. We join other commenters in noting that ONC, CMS, health care providers, patients and other industry stakeholders will be better served if ONC adopts a predictable framework to incorporate updates as standards, technology, and clinical care evolves; and that ONC work closely with CMS and other agencies and standards bodies involved in developing these standards across programs and with appropriate references to ensure that the agencies, developers, and users are on the same page about what requirements are in place and that all stakeholders are working off and toward the same standards.

This could be in the form of a cyclical review, such as once every 36 months; or be tied to requirements to implement new standards within a certain time period after the standards are published by the appropriate government or private standards body. Such an approach should make

it easier for ONC and the industry to improve care delivery by providing a more predictable and stable environment that will efficiently and reliably accommodate important but incremental clinical and technological advances.

Alignment of regulatory requirements, including standards advancement is critical for all actors impacted by ONC certification programs, CMS incentive and payment programs, and other regulatory programs. We encourage ONC, and HHS generally, to work to better align regulatory requirements, standards development updates, and other program obligations.

Additionally, we propose to amend the API Condition and Maintenance of Certification requirements by adding the requirement that Certified API Developers with patient-facing apps must publish their service base URLs for all customers, regardless of whether the certified Health IT Modules are centrally managed by the Certified API Developer or locally deployed by an API Information Source, according to a specified format.

CARIN commends ONC for addressing the issue of endpoint discovery in this NPRM and for adding the requirement to publish service base URLs. Many CARIN members have discussed the various challenges that this presents, and CMS has worked through their Interoperability and Patient Access Rule to address some of the challenges that exist in operationalizing connections to both authorization servers and FHIR servers. In addition to publication of service base URLs, we encourage ONC to consider the creation and recommendation of standard ways to validate endpoints as well as displaying to the user the data holder from which they seek data. Additionally, if updating to US CORE v6, we ask ONC to provide further clarity on the endpoint resource, and where the service base URL points to the organization resource. Work done by CARIN on an Application Registration Guide set of best-practices could be used for a number of application-registration purposes.[1] Additionally, current work done by several CARIN members and the Argonaut project on Patient-Access Brands and Endpoints could serve as a useful starting point.[2]

We also propose to revise the requirement in § 170.315(g)(10)(vi) to specify that Health IT Modules presented for certification that allow short-lived access tokens to expire, in lieu of immediate access token revocation, must have such access tokens expire within one hour of the request. This revised requirement would align with industry standard practice for short-lived access tokens, would provide clarity and consistent expectations that developers revoke access or expire access privileges within one hour of a request, and would offer patients an assurance that an application's access to their data would be revoked or expired within one hour of a request.

As noted above, both access and refresh tokens have been a source of friction in consumer-directed health information exchange. CARIN re-states our belief that for both access tokens and refresh tokens, a consistent baseline and experience should be supported and encouraged. Generally, we support short access tokens and long refresh tokens.

[1] https://www.carinalliance.com/wp-content/uploads/2021/07/CARIN-Alliance_App-Registration-IG_07222021.pdf
[2] https://build.fhir.org/ig/HL7/smart-app-launch/branches/pab/brands.html

As part of this proposal, we propose to adopt several sections specified as "optional" in the SMART v2 Guide as "required" for purposes of the Program for certification criteria that reference § 170.215(c)

There has been ongoing confusion about consumer ability to connect browser-based apps persistently, without the need to re-authenticate. Previous ONC regulations guaranteed this ability for some apps but not others, drawing distinctions by client type (confidential vs public, or native vs browser-based). Previous ONC regulations also do not require support for Cross-Origin Resource Sharing, leading to a situation where some server configurations prevent browser-based apps from receiving an access token. SMART 2 introduced support for PKCE to reliably bind token issuance to a client's authorization request, mitigating previous concerns. However, the HTI-1 proposal still does not ensure long-term access for "public clients," even though "public clients" can offer better data segregation than "confidential clients" by avoiding the need for consumer data to transit through a developer's backend server. Such restrictions impose unnecessary risk by encouraging app developers to use a backend server and limit patient choice by artificially limiting the capabilities of browser-based local apps.

CARIN joins with the SMART team and others in the following recommendations:

1. Adopt the current release -- i.e., SMART 2.1 (not 2.0), which includes:
    - Improved FHIR Context management
    - App State capability
2. Mandate support for client-side browser-based apps:
    - Mandate that consumers can approve "offline access" scope for any registered app, not just confidential or native clients
    - Mandate that servers "support purely browser-based apps" per https://hl7.org/fhir/smart-app-launch/app-launch.html#considerations-for-cross-origin-resource-sharing-cors-support

We encourage CMS and ONC to work together to align their requirements in this area as you have in other areas of the interoperability space.

Patient Requested Restrictions Certification Criterion We believe that individuals should be provided a reasonable opportunity and technical capability to make informed decisions about the collection, use, and disclosure of their electronic health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provides individuals with several legal, enforceable rights intended to empower them to be more active participants in managing their health information. We make several proposals in support of the HIPAA Privacy Rule's individuals' "right to request a restriction" on certain uses and disclosures of their PHI (see also 45 CFR 154.522(a)). We propose 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. We propose a new certification criterion in § 170.315(d)(14), an addition to ONC's Privacy and Security Certification Framework under the Program in § 170.550(h),

and a revision to an existing criterion in § 170.315(e)(1) to support additional tools for implementing patient requested information privacy restrictions.

As previously noted, CARIN strongly supports an individual's right to access their information when and where they want it. We also strongly support the right of an individual to restrict the use of their information. We support ONC's intent to support the restriction of PHI disclosure. We recognize that under the HIPAA Privacy Rule, covered entities are not required to honor a patient's right to request a restriction, except in the case of an individual who pays out-of-pocket in full for their health care and requests that information related to that care not be disclosed to their health plan. However, there are also existing state and federal laws that do require entities to obtain patient consent prior to disclosing certain types of data. Today we do not have widespread implementation of technologies that would support granular consent in compliance with existing laws or the right to request a restriction.

Regarding data segmentation, there is a practical reality that implementing data segmentation right now is not realistic. The rule as written is vague on exactly what needs to be restricted. Is it entire categories of data (e.g. lab data, individual tests/procedures/note types/etc.)? Is it at the encounter level or patient level? Does it affect internal use as well as health information exchange? The inability for the organization's internal physicians or billers to understand what data is restricted and the practical realities of restricting that data using open standards, could be crippling and dangerous to either the physician or the patient as well as the ability to code encounters correctly for both claims and population health purposes. Secondly, the granularity of patient-managed restrictions is not supported by existing systems either at the database level or at the HIE level. The work associated with this requirement for the entire health care ecosystem *far exceeds* the last 8 years of work and cost in trying to get FHIR APIs in place which is still in its very early stages. Even if the implementation was partially feasible in some longer timeframe, our provider community has stressed the unintended impact on both providers and patients in terms of safety for either or both and in making appropriate treatment decisions. Finally, due to the widespread use of unstructured notes for office and inpatient visits, there is no technology today that can prevent each and every item of patient-restricted data from "leaking" through in an otherwise unrestricted note. Again, while we very much value and support data consent standards and approaches to protect a patient's privacy, in its current form this policy approach isn't realistic in today's health care technology ecosystem.

The HIPAA right to request restrictions, because it is largely discretionary, may provide entities with an opportunity to counsel patients about the potential impact of the restriction on patient care and to set patient expectations on the extent to which the restriction can be honored - both longstanding obstacles to the adoption of technological approaches to granular patient choice. \

In the spirit of solutioning and what can be done now to protect patient's data no matter what regulatory authority (HIPAA or FTC) governs the health data, we *strongly* believe attestation and certification to the CARIN Code of Conduct[3] will provide a robust mechanism for third-party applications to protect consumer's health data using the most robust privacy standards in the world

[3] https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/
See also: https://myhealthapplication.com/ and https://www.ehnac.org/carin-code-of-conduct-accreditation-program/

including GDPR, CCPA, HIPAA, and others. The CARIN Code of Conduct was named by CMS twice in Federal Regulations as 'an industry best practice'[4], used by the Veteran's Health Administration[5] prior to an application connecting with the health data in production, cited multiple times by the Federal Trade Commission[6] in its most recent Health Breach Notification NPRM, and used extensively by hundreds of providers and health plan data holders across the country. Nearly all consumer-facing third-party applications who have connected to an HL7® FHIR® API in production have attested to the CARIN Code of Conduct[7]. We know that applications who adopt the privacy-preserving data handling practices associated with the CARIN Code of Conduct will *exceed* the protections an individual's health care data receive today under HIPAA. Within the TEFCA ecosystem, Individual Access Service (IAS) providers who follow the guidelines of TEFCA (which includes HIPAA data privacy and security standards) and the CARIN code of conduct will guarantee individuals will have better privacy protections, consent-based data sharing options, and increased security of their data than is afforded to them today under HIPAA alone.

As such, we would strongly encourage the ONC to follow the lead of CMS, the VHA, and the FTC and reference the need for Individual Access Services (IAS) providers who voluntarily join TEFCA to not only follow the guidelines outlined in TEFCA for HIPAA privacy and security but also require those IAS provides to attest to the CARIN Code of Conduct which has become an industry best practice.

In the 5 years since the CARIN Code of Conduct was released, not a single third party, consumer-facing application who has attested to the CARIN Code of Conduct was ever reported as having breached the terms of the CARIN Code of Conduct. This validates the Code's success in protecting consumer's health care data in the FTC regulated space and testifies to the seriousness of which third-party applications who have attested to the code treat PHI data outside the regulatory jurisdiction of HIPAA.

We again urge the ONC to work with the RCE to ensure IAS providers also attest to the CARIN Code of Conduct as part of TEFCA.

We also agree with other commenters in recommending ONC also consider the following approaches to providing patients with greater rights and transparency regarding data about them:

- Adopt two pragmatic approaches that empower patients with controls over and insights into the use of their data:
- *Controls at the source*: Let patients ensure data accuracy at the source, to prevent sharing of inaccurate information. Introduce a functional requirement aligning with the HIPAA right to request corrections and amendments to erroneous information. This would:

[4] https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf
https://www.govinfo.gov/content/pkg/FR-2022-12-13/pdf/2022-26479.pdf
[5] https://developer.va.gov/onboarding/request-prod-access
[6] https://www.regulations.gov/document/FTC-2023-0037-0001
[7] https://myhealthapplication.com/

    - Ensure that patient portals and patient APIs provide patients an easy path to requesting corrections to their medical records, or to amending records in the case that providers decline to apply corrections.
    - Provide a clear market signal to drive participation in standardization efforts through HL7's patient empowerment workgroup.
- *Insights and controls for exchange:* Let patients see who's querying their data in TEFCA and provide opt-out controls. Since most uses of TEFCA would fall under "treatment, payments, and operations," and to the extent the Individual Access use case could also extend to patient-directed exchange (i.e., the disclosure of data to a third party that is not the patient's personal health app for that third party's use), ONC should ensure that data exchange via TEFCA could provide patients with a mechanism for patients to review:
    - Who made a query for my records?
    - When?
    - For what purpose of use?
    - Who responded to the query?

B. Standards and Implementation Specifications 1. National Technology Transfer and Advancement Act The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 et. seq.) and the Office of Management and Budget (OMB) Circular A-11925 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A-119 provide exceptions to electing only standards developed or adopted by voluntary consensus bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. Agencies have the discretion to decline the use of existing voluntary consensus standards if it is determined that such standards are inconsistent with applicable law or otherwise impractical, and instead use a government-unique standard or other standard. In addition to the consideration of voluntary consensus standards, the OMB Circular A-119 recognizes the contributions of standardization activities that take place outside of the voluntary consensus standards process. Therefore, in instances where use of voluntary consensus standards would be inconsistent with applicable law or otherwise impracticable, other 25 https://www.whitehouse.gov/wp-content/uploads/2020/07/revised_circular_a-119_as_of_1_22.pdf. standards should be considered that meet the agency's regulatory, procurement or program needs, deliver favorable technical and economic outcomes, and are widely utilized in the marketplace. In this proposed rule, we use voluntary consensus standards except for: · The United States Core Data for Interoperability (USCDI), October 2022 Errata, Version 3 (v3) standard. We propose to adopt USCDI v3 (October 2022 Errata) in § 170.213. This standard is a hybrid of government policy (i.e., determining which data to include in the USCDI) and voluntary consensus standards (i.e., the vocabulary and code set standards attributed to USCDI data elements); and · The standard we propose to adopt in § 170.207(f)(3) for race and ethnicity. We are not aware of any voluntary consensus standards that could serve as an alternative for the purposes we describe in further detail throughout this proposed rule including establishing a baseline set of data that can be commonly exchanged across care settings for a wide range of uses. We refer readers to section III.C.1 of this preamble for a discussion of the USCDI.

CARIN is a voluntary consensus body of interested stakeholders who are focused on advancing a consumer's ability to aggregate all of their health information from any provider or payer in the country. CARIN is also an HL7® FHIR® accelerator program which consists of interested stakeholders looking to drive new open standards and frameworks. CARIN believes ONC should be looking at the work of the FHIR accelerators as meeting the requirements of 'voluntary consensus bodies' outlined in the OMB Circular A-119 for standards and frameworks that fall outside of the HL7 process. For example, CARIN has worked with FAST to develop a framework for how digital identity is federated across health care stakeholders with our CARIN / HHS Healthcare Digital Identity Federation Proof of Concept report in which the ONC participated. The concept of digital identity federation is critical to how a FHIR-based ecosystem works, but doesn't fit well within the HL7 workgroups.

We strongly encourage ONC to leverage the open-source work we have done to advance digital identity federation in future rulemaking. We also encourage the ONC to examine the CARIN Alliance Application Registration Guide for a set of best practices on how applications register with FHIR endpoints.

This information will be critical to advancing how the health care ecosystem supports HL7® FHIR® in the years ahead. Both reports followed the process outlined in the OMB circular. Other work, including the CARIN IG for Blue Button and the CARIN IG for Real-time Pharmacy Benefit check should also be considered.

Health Insurance Information USCDI v3 includes the Health Insurance Information data class, which provides an opportunity for health IT to capture and exchange key elements of healthcare insurance coverage. This information can be useful for patient matching and record linkage, coverage determination, prior authorization, price transparency, claims and reimbursement efficiencies, and identifying disparities related to insurance coverage. This is a new data class as compared to USCDI v1. This data class includes seven data elements: Coverage Status, Coverage Type, Relationship to Subscriber, Member Identifier, Subscriber Identifier, Group Identifier, and Payer Identifier.

We support the opportunities and benefits from the sharing of the other classes an element in USCDI v3, such as SDoH data elements. However, more work is needed to clarify and improve data exchange related to the health information class. For example, Payer IDs are used differently by vendors and are then cross walked to the Health Insurance Payer ID. It must be assured that there is a true Payer/Plan ID or NAIC IDs and that these are discoverable. Thus, we recommend adopting USCDI v3 except for the health information class at this time, and for ONC to champion further standards development and work to improve the health information class.

We also would strongly encourage ONC to adopt the data elements in USCDI and USCDI+ that are included in the CARIN IG for Blue Button and has become the standard for how payers send claims

and administrative data to consumer, payers, and providers[8].

We would also strongly encourage additional guidance from ONC on the differences between USCDI, USCDI+, and US Core. There is widespread confusion in the market about who can recommend data elements for each program, how those data elements are chosen, where those data elements must be used and where they may be used, and how the standards process can be leveraged to advance data elements in each of these areas.

We also propose in section III.F to implement the Insights Condition and Maintenance of Certification requirements in § 170.407 in two phases, where some of the measures will be required to be reported earlier than others. For each proposed measure, we have included information on the rationale for proposing the measure, the proposed numerators and denominators, and other key topics. Overall, the intent of the Insights Condition is to provide transparent reporting, address information gaps in the health IT marketplace, and provide insights on the use of health IT.

CARIN supports the concept and level of detail in the ONC's proposed "Insights Condition of Certification", especially ONC's decision to define measures that reveal insights about patient's seeking access to their EHI. This proposal accurately portrays the available avenues for patients to access their EHI, including patient portal and networks, provider-provisioned applications and "true" third party applications. We also support the requirement that the underlying data measures be reported, and refreshed on a recurring six-month frequency. We agree that the Insights proposal should not present a significant regulatory burden, since the data is and can be collected automatically in real time, and reported using well-established internet technologies without special effort. For these reasons as well, we support the applicability date attached to this proposal, particularly in light of regulatory delays with releasing final enforcement rules for Information Blocking. Enabling policymaking to be informed by data-driven insights is a top-most priority to meet Cures Act mandates and ONC's expressed centering of interoperability imperatives on patient access, in addition to treatment, use cases. We believe public reporting about the number of apps actively connected to patient access APIs, consumer usage of these apps, the types of pathways utilized by patients and the types of FHIR resources being consumed are extremely relevant considerations for guiding policy and enforcement activities. We also endorse the level of detail regarding intended users and purposes of the apps, the correlations that may be revealed when a given pathway for EHI access is accompanied by a feature or capability that also delivers convenience or other forms of value exchange for patients. Over time, we believe these correlations will support a broader conception of interoperability, by ensuring the use cases that drive patient digital interactions are not concentrated in one type of pathway. For example, if patients want to communicate with their care team, schedule care, or utilize real time benefit tools – all of which require interactions with an EHR, data from the Insights proposal would suggest that these capabilities be made available to provider-provisioned applications, in addition to patient portals provisioned by the developer of

[8] See the first CMS final Interoperability rule (9115-F) and the CMS proposed rule (9123-P):
https://www.federalregister.gov/documents/2022/12/13/2022-26479/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability
https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and

certified HIT.

In this RFI, we seek 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. Furthermore, we request comment on the guidance specified in the SMART Scheduling Links Implementation Guide for publishers to advertise the API endpoints and whether there are other approaches that ONC could take to ensure that the APIs are easily discoverable by users of the API.

A number of CARIN members have integrated with APIs that EHR vendors have implemented based on these specifications. Based on these experiences, CARIN believes these specifications are sufficiently mature to be included in future certification standards. We also believe it is important to prioritize FHIR standards for scheduling as a priority certification enhancement, as it will reduce administrative burdens for providers and patients, and the care-providers that help patients with scheduling and managing their health care appointments, in addition to providing a remedy for health disparities and promoting public health. Scheduling became a de facto priority during the COVID-19 PHE, as providers added scheduling to their patient facing application for vaccine administration. In the process, providers learned they could also implement scheduling to reduce their call center staff, and help patients locate nearby urgent care centers, hold their place in line. The Cures Act mandate broadly conceptualizes interoperability beyond data access to use cases that enable broad system transformation. Establishing a FHIR standard for scheduling is a high-value use case to bring this broader conception of interoperability into widespread use.

In this RFI, we seek input on the value and feasibility of the SMART Health Links Protocol, as well as concerns regarding its implementation. Furthermore, we invite comment from the public on approaches ONC could take, within our authorities, to encourage rapid advancement of the technology.

The SMART Health Cards (SHC) specification has been used to provide COVID-19 immunization and lab results to individuals at scale including deployments in at least 15 countries. Implementers include major EHRs, and pharmacy chains, as well as public health programs from over 24 US states. Immunization records are available as SMART Health Cards for over 225M people in the USA. By leveraging FHIR and W3C Verifiable Credentials, SMART Health Cards allows sharing of static data sets, with a focus on data that are small enough to fit in a single QR code.

Building on SHC's format, signature scheme, and trust infrastructure, the SMART Health Links specification allows for more advanced usage including larger data sets (e.g., a full immunization history or patient summary) as well as dynamic data sets (e.g., an immunization history that can be augmented when a patient receives vaccine doses). The SHL specification underwent an initial round of design, prototyping, and feedback through the Argonaut standards accelerator in 2022. Early industry adoption of SHL in 2023 has focused on immunizations and health insurance coverage details, with additional prototypes demonstrating a workflow for sharing International Patient Summary documents.

In the CARIN Alliance, we hosted a virtual Digital Insurance Card working session in February 2023 and a follow-up session in June 2023 with payers, providers, and application companies focused on educating and discussing the details surrounding SMART Health Cards, SMART Health Links, and the payload for the insurance card which is included as part of the CARIN IG for Digital Insurance Card API. Along with these videos, a summary of the presentation is included. You can find all of our work on Digital Insurance Card on the HL7 Confluence site under CARIN IG for Digital Insurance Card. We also have included the draft technical specifications for using SHCs and SHLs with the CARIN IG for Digital Insurance Card on a subpage on the Confluence site. We will be testing the draft approach at the upcoming CMS Connectathon in July.

We would strongly encourage both ONC and CMS to support the CARIN IG for Digital Insurance Card and SMART Health Card / SMART Health Link framework to advance the ability for individuals to digitally and securely access their insurance/coverage information using these standards.

We believe ONC can foster broader adoption of SHC and SHL by sponsoring programs to identify and address unmet needs in consumer mediated data exchange. In particular, SHCs demonstrate how reducing friction to health data access makes a tangible difference for patients, and SHLs enable this access pattern to be scaled to nearly any data type or use case. In the near-term, SHC and SHL provide a common pattern for sharing use-case-specific data bundles, expanding the reach of FHIR implementation guides for sharing with minimal coordination across organizations. Over time, we see a path for this technology to support more interactive sharing paradigms that could address some of the high-frequency, high-friction touch points that people have with healthcare. This could include prompted sharing (e.g., before a clinical visit, patients might receive an information sharing request that they can review and respond to using a personal health app or wallet) as well as assisted form-filling (e.g., when presented with a blank clipboard asking for clinical information, a personal health app could pre-fill many items and, when desired, could attach verifiable provenance to the submission).

We intend to propose in future rulemaking the establishment of a real-time prescription benefit health IT certification criterion within the Program and include this criterion in the base EHR definition in § 170.102. We intend to propose a criterion that would certify health IT to enable a provider to view within the electronic prescribing workflow at the point of care patient-specific benefit, estimated cost information, and viable alternatives. We are also considering a proposal to adopt and reference the National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit (RTPB) standard version 12 as part of the potential certification criterion.363 This standard would enable the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identify coverage restrictions and alternatives when they exist.

CARIN supports the advancement of certification standards for real time prescription benefit tooling for certified Health IT Modules. Enabling these tools will move toward fulfilling Congressional mandates under the No Surprises Act and Transparency provisions of the Consolidated Appropriations Act of 2020, the Patient Right to Know Act and efforts by CMS to implement consumer-centered real time benefit tools. As a recognized HL7 FAST Accelerator, the CARIN community has developed, tested, balloted, and published an HL7® FHIR® API standard for a

consumer-facing real time pharmacy benefit tool (https://hl7.org/fhir/us/carin-rtpbc/index.html). We believe the quality of the patient-provider relationship and shared decision making are enhanced by putting real time pharmacy benefit information in the workflows of patients and providers *at the same time*. We also know from discussing this topic with PBMs that without naming the actual standard in Federal regulations, the PBMs will not implement a HL7® FHIR® API to allow consumers to access their real-time benefit information on an application of their choice.

CARIN strongly encourages the ONC to work with CMS so that both agencies actually name the CARIN IG for Real-time Pharmacy Benefit Check[9] as a required standard for providing consumers information on how their prescribed drug affects their out-of-pocket costs and what therapeutic alternatives are available to them. Without ONC and CMS naming the actual standard in Federal regulation, consumers will never be able to see this information themselves which will prevent their ability to join with their provider in shared decision-making related to managing their own health care.

Even as API access to clinical data has become more robust, API access to imaging data has remained a challenge. This year the Argonaut Project has organized development and testing of a specification for application access to Imaging data, building on the SMART on FHIR API capabilities of Certified EHR Technology. The Argonaut design leverages existing EHR app-registration and app-approval workflows, augmenting the available data from an EHR's "clinical server" with an additional set of imaging data from an imaging endpoint. The imaging endpoint hosts a narrow subset of FHIR and DICOMweb functionality, authorized using SMART on FHIR token introspection to allow SMART apps to list the studies available for a patient and retrieve user-selected studies. We believe this architecture offers a promising and scalable approach to enhance patient and provider access to imaging studies alongside clinical data. Such access would facilitate diverse use cases for providers and patients including:

- For Providers
  - Support analysis w/ preferred tools, such as specialty-specific viewers, image-driven severity scoring, or image-driven risk calculations.
  - Streamline consultation workflows.
- For Patients
  - Enable access, compilation of full data.
  - Ensure data are available to specialists.
  - Facilitate second opinions, and
  - Streamline data donations for research.

We join with Argonaut and the SMART team to encourage ONC to identify opportunities to support Argonaut Imaging and functionality that expands on the API capabilities of Certified EHR Technology. Over time, projects like Argonaut Imaging Access can serve as a model for widespread application access to a growing swath of Electronic Health Information.

[9] https://hl7.org/fhir/us/carin-rtpbc/index.html

We seek input on the maturity of (Subscription, Subscription Topic, and Subscription Status) resources in the FHIR Release 4 standard that is incorporated in 45 CFR 170.315(g)(10)… Additionally, we seek comment on whether the FHIR Subscriptions capability aligns with the adoption of the FHIR Release 5 standard, and whether alignment with FHIR Release 5 would avoid any costly refactoring of the resources and give more time for industry to test the various features and capabilities under development.

Furthermore, we request comment on whether there is a need to define a minimum set of Subscription Topics that can be consistently implemented by all health IT developers of certified health IT to provide a base level expectation for clients using the services. We also invite comments on appropriate industry led activities to maintain and keep the artifacts up to date.

Additionally, we welcome comments on security, channels, payloads, and any other areas that would need to be further specified to achieve our goal of providing subscription capabilities across certified Health IT Modules in a consistent and standardized manner using an already adopted standard.

HL7® FHIR® has included preliminary support for subscriptions since R3 and has recently introduced support for "topic-based subscriptions" incorporating industry feedback to enable scalable deployment. Topic-based subscriptions are available starting with FHIR R4 based on the "Backport IG" at https://hl7.org/fhir/uv/subscriptions-backport, and are natively supported in FHIR R5.

Given ONC's current investment in HL7® FHIR® R4, we suggest that introducing topic-based subscriptions via the Backport IG is the most pragmatic and incremental way to expand capabilities of the current deployed base of FHIR implementations. Using this Backport approach, the certification program could require implementers to support a limited starter set of subscription topics, functionally defined to align with core regulatory priorities. A suggestion for initial use cases would be:

1. "Patient data updates." Allow notifications when new/updated patient data are available in association with a specific patient ID. This could be used to allow monitoring by patient-facing apps that currently have to poll at regular intervals. It could also help enable public health applications that are monitoring patient encounters in the context of a reportable condition.
2. "Encounter data update." Allow notifications when a new encounter is created or when an encounter is updated within the health system. This could be used to enable integration of public health triggering and reporting logic into a clinical system without requiring each clinical system vendor to independently implement support for detailed temporal triggering and reporting logic. This might also be the starting point for a FHIR-based encounter notifications alternative to ADT, but in our experience, it is easiest to drive adoption around new capabilities rather than reworking the mechanisms for already available capabilities.

Both use cases could be supported by a single "*US Core Event Feed*" topic, which would enable subscriptions to the resources defined in FHIR US Core with filtering available by:

- Resource Type
- Category (as applicable)
- Code (as applicable)
- Patient ID (for subscriptions at the single-patient level)

In Section 171.301(c), ONC proposes to create a new exception that would allow an actor that is participating in the Trusted Exchange Framework and Common Agreement (TEFCA) to require exchange via the TEFCA for any permitted purpose, as long as the requestor is also a TEFCA participant. Specifically, the proposal is:

(c) TEFCA manner. If an actor who is a QHIN, Participant, or Subparticipant offers to fulfill a request for EHI access, exchange, or use for any purpose permitted 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 available to both parties, 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.

Although we acknowledge the value of creating incentives for entities to join TEFCA, and the CARIN Alliance is actively in conversations with TEFCA stakeholders to help assure that TEFCA can be leveraged for the Individual Access use case, we have significant concerns about this approach and believe it could create disincentives for participation in TEFCA. Today, the charging of fees for individual access (either by the individual or by an app acting on the individual's behalf) is prohibited under the fee exception in the information blocking rules, if the mechanism of access does not involve manual effort, and even if that prohibition is not applicable, data requestors have option to seek mechanisms of exchange that would be subject to the fee exception. If a data requestor such as a patient app participates in the TEFCA, they would be required to exchange under TEFCA terms and conditions and would not be protected by the fee exception. The lack of protection against high fees (or fee increases) could detract from the value of TEFCA participation.

We strongly support the Individual Access use case in TEFCA and urge ONC to consider ways to incentivize TEFCA participation that do not have the unintended effect of undermining critical protections of the information blocking rules or charge any fees to IAS providers who are looking to access health care data on behalf of individuals which would violate previous ONC and CMS final rules.

We also strongly support the ONC and the RCE rapidly advancing support for HL7® FHIR® within TEFCA as quickly as possible to allow for third-party applications to more easily access data on behalf of consumers.

General feedback on USCDI Updates and their impact on Consumer Access

CARIN supports the advancement of USCDI and advance towards EHI/ePHI scope, plus other critical data for interoperability. As a key goal is to not only address large EHRs, but also specialty EHRs and other HIT holding EHI and ePHI that should be directly accessible to patients and their caregivers, it is important that USCDI, in combination with the supporting interoperability standards, implementation guides, and certification criteria enable the largest variety of HIT to be certified to the data they manage.

For example, a geriatric focused EHR need not manage pediatric data, while an LIS managing lab tests and result need not support non-lab specific data, and an imaging service only needs to be able to provide the imaging linked to in a radiology report. It is critical that relevant HIT that is the source of EHI/ePHI can be consistently accessed for the data they manage. However, the certification criteria, and in particular §170.315(g)(10) certification criterion requires HIT to support all USCDI to be certified. The current proposed USCDI+ data sets would not support such targeted certification either and creating the wide range of USCDI+ for the variety of HIT seems unmanageable.

We suggest that certification criteria such as §170.315 (g)(10) are based on the data that the HIT seeking certification actually manages. In other words, we suggest that criteria require the HIT seeking certification focuses on the data they discretely manage through their user interface and data feeds in support of their target user community, not data part of documents that at most need to be displayed in that context. Such an approach promotes consistent access for consumer apps to EHI/ePHI from any relevant HIT.

We recognize that ONC does not have the levers to incent HIT to be certified, as that authority and those incentives reside with other programs. However, providing a flexible and dynamic certification program in support of USCDI would enable other programs, including market forces, for other HIT to also seek certification in support of their users' patients.

Again, we thank you for the opportunity to provide feedback and appreciate all of the work the ONC has done to advance data exchange and interoperability in the US. If you have any questions about our comments, please contact Ryan Howells using the contact information listed above.