June 3, 2019

Dr. Don Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Dear Dr. Rucker:

On behalf of the CARIN Alliance, we want to thank you for providing the opportunity to comment on the Office of National Coordinator's (ONC's) work to develop rulemaking in conjunction with the 21st Century Cures Act. We are excited about the efforts you have made to advance interoperability, reduce information blocking, and accelerate consumers' access to health information.

As you are aware, the CARIN Alliance is a multi-sector group of stakeholders representing numerous hospitals, 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 mandated under MIPS/Stage 3 Meaningful Use (MU) ACI objectives and the use of 2015 Edition CEHRT to use that information in any third-party application they choose.

We are very supportive regarding the recommendations in the ONC proposed rule to promote and encourage patients to get and use a digital copy of their own health information. We are especially encouraged to see that ONC is requiring providers to provide patients with a copy of their health information for free using any application of their choice. This is something the CARIN Alliance has been promoting for the last few years.

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

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Section IV – Updates to the 2015 Edition Certification Criteria

§ 170.213 United States Core Data for Interoperability (USCDI)

We propose to adopt the USCDI at new § 170.213: "Standard. United States Core Data for Interoperability (USCDI), Version 1 (v1) (incorporated by reference in § 170.299)."
We propose to revise the following 2015 Edition certification criteria to incorporate the USCDI standard in place of the "Common Clinical Data Set" (currently defined at § 170.102 and proposed for removal in this rule):

- ''Transitions of care'' (§ 170.315(b)(1));
- ''view, download, and transmit to 3rd party'' (§ 170.315(e)(1));
- ''consolidated CDA creation performance'' (§ 170.315(g)(6));
- ''transmission to public health agencies—electronic case reporting'' (§ 170.315(f)(5)); and
- ''application access—all data request'' (§ 170.315(g)(9)).]

Preamble FR Citation: 84 FR 7441 **Specific questions in preamble?** *Yes*

Regulatory Impact Analysis: Please see 84 FR 7567-68 for estimates related to this proposal.

Public Comment Field:

The CARIN Alliance supports the ONC's efforts to create the USCDI including the recommended updates in the proposed rules. We believe the USCDI provides a unique opportunity to document an industry roadmap for the data elements that will be required to transmit between organizations both now and in the future. The USCDI roadmap will help organizations prioritize development resources, develop innovative functionality through the use of third-party applications, and enable the industry to incrementally increase the number of available standardized data elements.

While we remain supportive of the ONC's USCDI approach, we believe the ONC is taking a narrow view of what would need to be included in the final USCDI. In addition to clinical data, we believe the USCDI can provide a roadmap for standardizing numerous other data sets that are important to advancing value-based care. This should include at a minimum data related to claims and encounters, social determinants of health (i.e., Project Gravity), real-time pharmacy benefit check, and other person-specific data that would improve a person's well-being. USCDI should, as rapidly as possible, be expanded to encompass all digital information that would be considered to be part of the designated record set.

Determining which data gets added to the USCDI requires a joint effort between both the public and private sector. As such, the CARIN Alliance would recommend a public / private sector committee be established under the recognized coordinating entity (RCE) to identify and prioritize the data set that will be included in the USCDI roadmap based on the work being done by various industry collaborations who are working to gain consensus as they develop various FHIR implementation guides for specific use cases.

§ 170.205(a) Patient summary record

We propose to adopt the HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 1 C-CDA Companion Guide to support best practice implementation of USCDI v1 data classes and enhance the implementation of other 2015 Edition certification criteria that also reference Consolidated Clinical Document Architecture (C-CDA) Release 2.1 (§ 170.205(a)(4)). Those criteria include:

- "transitions of care" (§ 170.315(b)(1));
- "clinical information reconciliation and incorporation" (§ 170.315(b)(2));
- "care plan" (§ 170.315(b)(9));
- "view, download, and transmit to 3rd party" (§ 170.315(e)(1));
- "consolidated CDA creation performance" (§ 170.315(g)(6)); and
- "application access – all data request" (§ 170.315(g)(9)).

Preamble FR Citation: 84 FR 7443 **Specific questions in preamble?** *No*

Regulatory Impact Analysis: Not applicable

Public Comment Field:
ONC asks for information related to the expansiveness of data provided to the consumer/patient through an API. The CARIN Alliance supports an expansive release of information to individuals, including the entirety of the notes kept in electronic format, images, and expanded laboratory information.

1. **Notes:** Given that clinical notes contain critical observations and information relevant to patients and their care team, ONC should adopt a requirement that all notes be made available via API. In so doing, we agree with our members' individual comments that the notes release should be in accordance with refined implementation guides (e.g. the eight note types identified through the Argonaut Project).
2. **Clinical Imaging:** We are concerned that sharing of images, an essential data type for patient care, may slip through the cracks. EHR systems often contain metadata around the available imaging studies, however, the imaging studies themselves are frequently stored in separate systems known as picture archiving and communication system (PACS). Providers should be responsible for sharing this imaging data, regardless of the technology supplier they choose. We recommend making PACS vendors subject to EHR certification rules, specifically for API access requirements.
3. **Laboratory Data:** While some clinical laboratory result data are accessible to patients through EHR APIs, historical data may not be comprehensive. Recently, national laboratory companies have begun to make these data available through API access for select apps. To promote a robust ecosystem of clinical applications, guidance should be provided on how this access should be expanded to an open ecosystem of apps to comply with the information blocking restrictions in the Rule.

The CARIN Alliance is committed to ensuring broad access to health care information for all consumers. Helping people understand how their information may be collected, shared and used

will be foundational to securing and bolstering consumer trust and confidence in the Administration's efforts to improve patient access and information sharing. Outreach and education efforts are a collective responsibility; all stakeholders have role to play, including governmental entities, health care providers, health plans, technology developers, and consumer advocacy organizations. This is true in the context of information exposed through EHI technologies subject to the CEHRT program and claims information exposed in accordance with the CMS Patient Access and Interoperability rule. It's why we believe the ONC should promote and encourage the use of the CARIN Alliance Code of Conduct which was agreed to by over 60 organizations and provides a set of principles entities that are not covered by HIPAA should follow in order to protect, use, and manage PHI.

§ 170.205(b) Electronic prescribing

* * *
(1) Standard. National Council for Prescription Drug Programs (NCPDP), Script Standard Implementation Guide, Version 2017071 (incorporated by reference in § 170.299).

Preamble FR Citation: 84 FR 7444 **Specific questions in preamble?** *No*

Regulatory Impact Analysis: Not applicable

Public Comment Field:
In addition to electronic prescribing, we would encourage the ONC to also adopt additional industry-led consensus implementation guides that will promote the transparency of drug pricing to consumers. As an HL7 FHIR Accelerator program, the CARIN Alliance is developing a consumer-facing real-time pharmacy benefit check FHIR implementation guide that will be balloted in January 2020. It will provide the consumer with formulary and benefit information, therapeutic alternatives, out of pocket costs, and cash price. This information will be in a FHIR API format and allow the consumer to use any application of their choice to access this data.

§ 170.315(b)(10) Electronic health information export
Included in 2015 Edition Base EHR Definition? *Yes*
Electronic health information export. (i) Single patient electronic health information export. (A) Enable a user to timely create an export file(s) with all of a single patient's electronic health information the health IT produces and electronically manages on that patient. (B) A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate. (C) Limit the ability of users who can create such export file(s) in at least one of these two ways: (1) To a specific set of identified users. (2) As a system administrative function. (D) The export file(s) created must be electronic and in a computable format. (E) The export file(s) format, including its structure and syntax, must be included with the exported file(s). (ii) Database export. Create an export of all the electronic health information the health IT produces and electronically manages. (A) The export created must be electronic and in a computable format. (B) The export's format, including its structure and syntax must be included with the export. (iii) Documentation. The export format(s) used to support single patient electronic health information export as specified in paragraph (b)(10)(i) of this section and database export as specified in paragraph (b)(10)(ii) of this section must be made available via a publicly accessible hyperlink.
Preamble FR Citation: 84 FR 7446-49 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Please see 84 FR 7568-70 for estimates related to this proposal.
Public Comment Field: On the subject of full EHI access, we are concerned about the gap between the proposed rule for EHI Export and the regulatory intent of the 21st Century Cures Act to achieve interoperability with APIs that provide "access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws." In ONC's proposal for certified API access, "all data elements" has been interpreted to mean "a limited set of data elements." While not all data have been standardized, ONC should still include a functional requirement that the EHI Export capabilities must be available through a documented (if potentially vendor-specific) API, and accessible to patients.

Specifically, to provide a usable consumer experience, the EHI Export capability must be:

1. *Accessible directly to a patient* (or authorized representative), rather than (or in addition to) being built as a feature for clinic staff. This is to ensure that patients don't need to make a request by, e.g., phoning the medical records department, and waiting while the departmental staff hits the "export" button in response to a request — a friction-laden process.
2. *Exposed end-to-end through an API*, rather than being implemented exclusively as a button hidden deep within a patient portal experience, or being crippled by the exchange of physical media like CD-ROMs. This is critical because:
    - Portal experiences vary, making features difficult to find and correctly describe (e.g., if a third party is trying to guide patients toward the export functionality in a variety of portals). This was a clear challenge for anyone trying to identify the "Transmit to a third party" features of a patient portal in the MU2 timeframe.
    - Managing physical media, e.g., CDs, would take access outside the realm of modern, convenient consumer experiences, and would violate the without special effort requirement.
    - Managing files may be challenging on many patient devices (e.g., mobile phones), and some files may be best suited for off-device storage (e.g., in the cloud). API connectivity ensures that patients can have a seamless experience for accessing all of their health data, not just a core data set.

Our key recommendation on EHI Export is that ONC should require certified EHRs to support full EHI export via patient-accessible API, even without standardizing the API or the data payloads. This will meet the Cures intent for API access.

§ 170.315(d)(12) Encrypt authentication credentials
Included in 2015 Edition Base EHR Definition? *No*
Encrypt authentication credentials. Health IT developers must assess their Health IT Modules' capabilities and make one of the following attestations: (i) "Yes." Health IT Module encrypts stored authentication credentials in accordance with standards adopted in § 170.210(a)(2). (ii) "No." Health IT Module does not encrypt stored authentication credentials.
Preamble FR Citation: 84 FR 7450 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Please see 84 FR 7575 for estimates related to this proposal.
Public Comment Field: Two-factor authentication is an opportunity to better identify individuals across systems. The CARIN Alliance believes the health care industry would benefit from a universal two-factor authentication open standard called FIDO2. The FIDO Alliance recently announced it will become a ubiquitous standard across multiple internet browsers for both desktop and mobile at no cost to the consumer or developer. The CARIN Alliance believes this open standard can be adopted by the health care industry to better secure individuals who authenticate across systems using industry-leading universal two-factor authentication. The open standard will dramatically increase security across systems and lower the operational burden associated with identifying individuals within and across systems. We urge CMS to work with ONC to encourage the use of two-factor authentication for use of apps associated with the open APIs.

§ 170.315(b)(12) Data segmentation for privacy – send
Included in 2015 Edition Base EHR Definition? *No*
Data segmentation for privacy – send. Enable a user to create a summary record formatted in accordance with the standard adopted in § 170.205(a)(4) and (a)(4)(i) that is tagged as restricted at the document, section, and entry (data element) level and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).
Preamble FR Citation: 84 FR 7452 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Please see 84 FR 7575-77 for estimates related to this proposal.
Public Comment Field: We appreciate ONC's intention to make progress in in technical capabilities regarding data segmentation. This is particularly important to consumers and patients who support technology that enables individuals to flag certain parts of their record as not to be shared without explicit permission. However, multiple CARIN members are concerned about the requirements related to DS4P. While noting that these standards are not mandatory at this time, we encourage ONC to fully account for the implementation costs associated with compliance in the proposed rule's regulatory impact analysis. This accounting, we believe, will should significant upfront costs and ongoing costs for maintenance of the systems necessary to comply with this provision (even while voluntary). While we recognize privacy maintenance and consenting as essential functions in health care, we are very concerned that a premature push for adoption of these immature standards would have unintended negative effects. In addition, it's not clear that these standards sync up well with what state privacy laws require, which means this standard – largely designed for Part 2 compliance – could result in an "overfit" and end up placing downstream restrictions on sharing of data that are not required by law. We encourage ONC to provide additional guidance on the adoption of the DS4P standards and certification criteria and forgo the inclusion of this requirement until additional real-world testing is available.

§ 170.315(b)(13) Data segmentation for privacy – receive
Included in 2015 Edition Base EHR Definition? *No*
Data segmentation for privacy – receive. Enable a user to: (i) Receive a summary record that is formatted in accordance with the standard adopted in § 170.205(a)(4) and (a)(4)(i) that is tagged as restricted at the document, section, and entry (data element) level and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1); and (ii) Preserve privacy markings to ensure fidelity to the tagging based on consent and with respect to sharing and re-disclosure restrictions.
Preamble FR Citation: 84 FR 7452 **Specific questions in preamble?** *Yes*

Regulatory Impact Analysis: Please see 84 FR 7575-77 for estimates related to this proposal.
Public Comment Field: We appreciate ONC's intention to make progress in in technical capabilities regarding data segmentation. This is particularly important to consumers and patients who support technology that enables individuals to flag certain parts of their record as not to be shared without explicit permission. However, multiple CARIN members are concerned about the requirements related to DS4P. While noting that these standards are not mandatory at this time, we encourage ONC to fully account for the implementation costs associated with compliance in the proposed rule's regulatory impact analysis. This accounting, we believe, will should significant upfront costs and ongoing costs for maintenance of the systems necessary to comply with this provision (even while voluntary). While we recognize privacy maintenance and consenting as essential functions in health care, we are very concerned that a premature push for adoption of these immature standards would have unintended negative effects. We encourage ONC to provide additional guidance on the adoption of the DS4P standards and certification criteria and forgo the inclusion of this requirement until additional real-world testing is available.

§ 170.315(g)(11) Consent management for APIs
Included in 2015 Edition Base EHR Definition? *No*
Consent management for APIs. (i) Respond to requests for data in accordance with: (A) The standard adopted in § 170.215(c)(1); and (B) The implementation specification adopted in § 170.215(c)(2). (ii) Documentation. (A) The API(s) must include complete accompanying documentation that contains, at a minimum: (1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns. (2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s). (3) All applicable technical requirements and attributes necessary for an application to be registered with an authorization server. (B) The documentation used to meet paragraph (g)(11)(ii)(A) of this section must be available via a publicly accessible hyperlink.
Preamble FR Citation: 84 FR 7453 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Please see 84 FR 7575 for estimates related to this proposal.
Public Comment Field: The CARIN Alliance would recommend the ONC point to existing industry-led FHIR implementation guides including the form and format that were agreed to as part of the development of these implementation guides.

Note: Because this template presents comment tables in the order in which the new and revised provisions of 45 CFR parts 170 and 171 are discussed in the preamble of the proposed rule, comment tables for other new and revised certification criteria, standards, and definitions can be found in Section VII, below.

Section VII – Conditions and Maintenance of Certification

Note: Because this template presents comment tables in the order in which their subject proposed provisions are discussed in the preamble of the proposed rule, this section includes tables for certain new and revised provisions in 45 CFR subparts A, B, C, and E, in complement to the proposed new subpart D.

Trusted Exchange Framework and the Common Agreement – Request for Information
We request comment as to whether certain health IT developers should be required to participate in the Trusted Exchange Framework and Common Agreement (TEFCA) as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI. We also welcome comment on the certification criteria we have identified as the basis for health IT developer participation in the Trusted Exchange Framework and adherence to the Common Agreement, other certification criteria that would serve as a basis for health IT developer participation in the Trusted Exchange Framework and adherence to the Common Agreement, and whether the current structure of the Trusted Exchange Framework and Common Agreement are conducive to health IT developer participation and in what manner.
Preamble FR Citation: 84 FR 7466-67 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Not applicable
Public Comment Field: We appreciate ONC's work to advance a Trusted Exchange Framework and a Common Agreement (TEFCA) and the proposed rule's inclusion of a Request for Information on the subject. The CARIN Alliance has developed a Voluntary Code of Conduct that we would recommend serve as the basis for how data holders register entities not covered by HIPAA. This model has been developed by a group of multi-sector stakeholders that include leading providers, payers, health IT companies, EHR companies, consumer platform companies, consumers, caregivers and others focused on advancing consumer-directed exchange across the United States. The model is based on internationally recognized standards including the Code of Fair Information Practices (FIP) and numerous other consumer information sharing accepted principles and practices. ONC could rely on consensus-based initiatives such as the CARIN Voluntary Code of Conduct to signal to consumers where processes are in place to appropriately manage data, including operating like TEFCA where there is a designated entity that validates actors. The CARIN Alliance does not believe there is a need currently to make the TEFCA mandatory. We believe there are a number of opportunities for the industry to weigh in on ways to improve the TEFCA and the RCE process both during the comment period and once the RCE is chosen.

VII.B.4 Application Programming Interfaces

§ 170.315(g)(10) Standardized API for patient and population services (Certification Criterion)
Included in 2015 Edition Base EHR Definition? *Yes*
Standardized API for patient and population services. The following technical outcomes and conditions must be met through the demonstration of application programming interface technology. (i) Data response. Respond to requests for data (based on an ID or other token) for each of the resources referenced by the standard adopted in § 170.215(a)(1) and implementation specifications adopted in § 170.215(a)(2) and (3). (ii) Search support. Respond to search requests for data consistent with the search criteria included in the implementation specification adopted in § 170.215(a)(4). (iii) App registration. Enable an application to register with the technology's "authorization server." (iv) Secure connection. Establish a secure and trusted connection with an application that requests data in accordance with the standard adopted in § 170.215(a)(5). (v) Authentication and app authorization – 1st time connection. The first time an application connects to request data the technology: (A) Authentication. Demonstrates that user authentication occurs during the process of authorizing the application to access FHIR resources in accordance with the standard adopted in § 170.215(b). (B) App authorization. Demonstrates that a user can authorize applications to access a single patient's data as well as multiple patients data in accordance with the implementation specification adopted in § 170.215(a)(5) and issue a refresh token that is valid for a period of at least 3 months. (vi) Authentication and app authorization – Subsequent connections. Demonstrates that an application can access a single patient's data as well as multiple patients data in accordance with the implementation specification adopted in § 170.215(a)(5) without requiring re-authorization and re-authentication when a valid refresh token is supplied and issue a new refresh token for new period no shorter than 3 months. (vii) Documentation. (A) The API(s) must include complete accompanying documentation that contains, at a minimum: (1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns. (2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s). (3) All applicable technical requirements and attributes necessary for an application to be registered with an authorization server. (B) The documentation used to meet paragraph (g)(10)(vii)(A) of this section must be available via a publicly accessible hyperlink.
Preamble FR Citation: 84 FR 7481-84 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Please see 84 FR 7570-75 for estimates related to our proposals regarding APIs.

§ 170.315(g)(10) Standardized API for patient and population services (Certification Criterion)

Public Comment Field:

The CARIN Alliance supports this approach to registering applications. Centrally managed, one-time application enablement which then includes the ability to provide access to all client sites is our preference. This approach is ***critically*** important to ensure the application does not have to go through separate, manual, and often undefined processes with each client site after they have centrally registered with the vendor. This is extremely important because in order to have a robust application ecosystem we cannot allow a system where individual providers and practices are the ones who control when the application is enabled. In some instances, it has taken months for a provider to agree to 'turn on' access to an application. Most small to medium-sized providers do not have a process in place for turning on access for third-party applications. This is true for all data holders across both proposed rules (i.e., health plans, providers, state Medicaid agencies, etc.). We also agree with the 5-day window for registering and turning on the API end point. We have also heard from our EHR vendors that they have an interest in reducing the friction here, especially given the new requirements.

We also believe there should be an option for all data holders (i.e., health plans, providers, EHR vendors, state Medicaid agencies, etc.) to support dynamic client app registration (RFC7591) if the data holder prefers to use that approach. For example, we believe if a consumer-facing application registers with a trusted network then it would be appropriate for that application to dynamically register with the data holder/API supplier if they are also a member of that same trusted network. We believe ONC should more closely examine the opportunities that exist when an application and a data holder/API supplier registers with the same trusted network to expedite the use of dynamic client app registration.

We have heard concern that dynamic client app registration may not be able to differentiate between a B2B vs. B2C application because there may not be an ability for the user to enter their credentials. We have found this not to be true. CARIN members are using OAuth 2.0 today in production to present a page to the user so they can enter their credentials while still using dynamic client app registration.

In time, we believe there will be a series of ways that applications will be endorsed by trusted third-party sources. Some of the ideas we are actively working on include:

- Independent third-party certifying organizations who validate compliance with the CARIN Code of Conduct
- A vendor and technology platform agnostic website that lists the consumer-facing applications, whether they have voluntarily agreed to the CARIN Code of Conduct, and a listing of the API data holders they are connected with including any third-party certifications they have received
- Open technology like POET, UDAP, and other technology to federate and validate trust across the ecosystem. To clarify, POET does not identify who would perform vetting. It would be completely possible and appropriate for a vendor, for example ACME EHR, to have an internal process for vetting applications and issue their own JWS to approved applications. This JWS could be used in Dynamic Registration but the existing web UI would also remain as another route to application registration. ACME EHR could also choose to trust other vetting bodies at their discretion. For example, ACME EHR may trust applications (to register dynamically) that have been vetted (and issued a JWS) by CMS, a state Medicaid, BCBSNC, NIH, Consortium X, ACME EHR(internal), etc. POET relies on

DNS and public keys to ensure provenance of the vetting body.

Although these ideas are not ready to be included in final regulations, we would encourage ONC to continue to engage with the CARIN Alliance as we build out these trust mechanisms to help inform future policy.

The CARIN Alliance supports the use of a 3-month renewable refresh token for consumer-facing apps. We believe if the consumer or the client app is continuing to pull data on behalf of the patients, the token should automatically renew for another 3 months. Revocation of the token or disconnecting the app from the API at any time needs to be the user's choice.

§ 170.404 Application programming interfaces (Condition and Maintenance of Certification)

The following Condition of Certification applies to developers of Health IT Modules certified to any of the certification criteria adopted in § 170.315(g)(7) through (11).
(a) Condition of Certification.
(1) General. An API Technology Supplier must publish APIs and must allow health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws.
(2) Transparency conditions.
(i) General. The business and technical documentation published by an API Technology Supplier must be complete. All documentation published pursuant to paragraph (a)(2)(ii) of this section must be published via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.
(ii) Terms and conditions.
(A) Material information. The API Technology Supplier must publish all terms and conditions for its API technology, including any fees, restrictions, limitations, obligations, registration process requirements, or other similar requirements that would be needed to:
(1) Develop software applications to interact with the API technology;
(2) Distribute, deploy, and enable the use of software applications in production environments that use the API technology;
(3) Use software applications, including to access, exchange, and use electronic health information by means of the API technology;
~~(4)~~ Use any electronic health information obtained by means of the API technology; and
(5) Register software applications.
(B) API fees. Any and all fees charged by an API Technology Supplier for the use of its API technology must be described in detailed, plain language. The description of the fees must include all material information, including but not limited to:
~~(1)~~ The persons or classes of persons to whom the fee applies;
(2) The circumstances in which the fee applies; and

§ 170.404 Application programming interfaces (Condition and Maintenance of Certification)

(3) The amount of the fee, which for variable fees must include the specific variable(s) and methodology(ies) that will be used to calculate the fee.
(C) Application developer verification. An API Technology Supplier is permitted to institute a process to verify the authenticity of application developers so long as such process is objective and the same for all application developers and completed within 5 business days of receipt of an application developer's request to register their software application for use with the API Technology Supplier's API technology.
(3) Permitted fees conditions.
(i) General conditions.
(A) All fees related to API technology not otherwise permitted by this section are prohibited from being imposed by an API Technology Supplier.
(B) For all permitted fees, an API Technology Supplier must:
(1) Ensure that fees are based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests.
(2) Ensure that fees imposed on API Data Providers are reasonably related to the API Technology Supplier's costs of supplying and, if applicable, supporting API technology to, or at the request of, the API Data Provider to whom the fee is charged.
(3) Ensure that the costs of supplying and, if applicable, supporting the API technology upon which the fee is based are reasonably allocated among all customers to whom the API technology is supplied, or for whom the API technology is supported.
(4) Ensure that fees are not based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the API technology in a way that facilitates competition with the API Technology Supplier.
(ii) Permitted fee – Development, deployment, and upgrades. An API Technology Supplier is permitted to charge fees to an API Data Provider to recover the costs reasonably incurred by the API Technology Supplier to develop, deploy, and upgrade API technology for the API Data Provider.
(iii) Permitted fee – Supporting API uses for purposes other than patient access. An API Technology Supplier is permitted to charge fees to an API Data Provider to recover the incremental costs reasonably incurred by the API Technology Supplier to support the use of API technology deployed by or on behalf of the API Data Provider. This permitted fee does not include:
(A) Any costs incurred by the API Technology Supplier to support uses of the API technology that facilitate a patient's ability to access, exchange, or use their electronic health information;
(B) Costs associated with intangible assets (including depreciation or loss of value), except the actual development or acquisition costs of such assets; or
(C) Opportunity costs, except for the reasonable forward-looking cost of capital.
(iv) Permitted fee – Value-added services. An API Technology Supplier is permitted to charge fees to an API User for value-added services supplied in connection with software that can interact with the API technology, provided that such services are not necessary to efficiently and effectively develop and deploy such software.

§ 170.404 Application programming interfaces (Condition and Maintenance of Certification)

(v) Record-keeping requirements. An API Technology Supplier must keep for inspection detailed records of any fees charged with respect to the API technology, the methodology(ies) used to calculate such fees, and the specific costs to which such fees are attributed.
(4) Openness and pro-competitive conditions. General condition. An API Technology Supplier must grant an API Data Provider the sole authority and autonomy to permit API Users to interact with the API technology deployed by the API Data Provider.
(i) Non-discrimination.
(A) An API Technology Suppler must provide API technology to API Data Providers on terms that are no less favorable than it provides to itself and its own customers, suppliers, partners, and other persons with whom it has a business relationship.
(B) The terms on which an API Technology Supplier provides API technology must be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests.
(C) An API Technology Supplier must not offer different terms or service on the basis of:
(1) Whether the API User with whom an API Data Provider has a relationship is a competitor, potential competitor, or will be using electronic health information obtained via the API technology in a way that facilitates competition with the API Technology Supplier.
~~(2)~~ The revenue or other value the API User with whom an API Data Provider has a relationship may derive from access, exchange, or use of electronic health information obtained by means of API technology.
(ii) Rights to access and use API technology.
~~(A)~~ An API Technology Supplier must have and, upon request, must grant to API Data Providers and their API Users all rights that may be reasonably necessary to access and use API technology in a production environment, including:
(1) For the purposes of developing products or services that are designed to be interoperable with the API Technology Supplier's health information technology or with health information technology under the API Technology Supplier's control;
(2) Any marketing, offering, and distribution of interoperable products and services to potential customers and users that would be needed for the API technology to be used in a production environment; and
~~(3)~~ Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information.
(B) An API Technology Supplier must not condition any of the rights described in paragraph (a)(4)(ii)(A) of this section on the requirement that the recipient of the rights do, or agree to do, any of the following:
~~(1)~~ Pay a fee to license such rights, including but not limited to a license fee, royalty, or revenue-sharing arrangement.
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§ 170.404 Application programming interfaces (Condition and Maintenance of Certification)

(2) Not compete with the API Technology Supplier in any product, service, or market.
(3) Deal exclusively with the API Technology Supplier in any product, service, or market.
(4) Obtain additional licenses, products, or services that are not related to or can be unbundled from the API technology.
(5) License, grant, assign, or transfer any intellectual property to the API Technology Supplier.

(6) Meet additional developer or product certification requirements.
(7) Provide the API Technology Supplier or its technology with reciprocal access to application data.

(iii) Service and support obligations. An API Technology Supplier must provide all support and other services reasonably necessary to enable the effective development, deployment, and use of API technology by API Data Providers and their API Users in production environments.
(A) Changes and updates to API technology. An API Technology Supplier must make reasonable efforts to maintain the compatibility of its API technology and to otherwise avoid disrupting the use of API technology in production environments.
(B) Changes to terms and conditions. Except as exigent circumstances require, prior to making changes or updates to its API technology or to the terms and conditions thereof, an API Technology Supplier must provide notice and a reasonable opportunity for its API Data Provider customers and registered application developers to update their applications to preserve compatibility with API technology and to comply with applicable terms and conditions.
(b) Maintenance of Certification.
(1) Registration for production use. An API Technology Supplier with health IT certified to the certification criterion adopted in § 170.315(g)(10) must register and enable all applications for production use within 1 business day of completing its verification of an application developer's authenticity, pursuant to paragraph (a)(2)(ii)(C) of this section.
(2) Service Base URL publication. API Technology Supplier must support the publication of Service Base URLs for all of its customers, regardless of those that are centrally managed by the API Technology Supplier or locally deployed by an API Data Provider, and make such information publicly available (in a computable format) at no charge.
(3) Rollout of (g)(10)-Certified APIs. An API Technology Supplier with API technology previously certified to the certification criterion in § 170.315(g)(8) must provide all API Data Providers with such API technology deployed with API technology certified to the certification criterion in § 170.315(g)(10) within 24 months of this final rule's effective date.

Preamble FR Citation: 84 FR 7485-95 **Specific questions in preamble?** *Yes*

Regulatory Impact Analysis: Please see 84 FR 7570-75 for estimates related to this proposal.

Public Comment Field:
The CARIN Alliance believes **strongly** that API end point discovery in a publicly available, machine-readable location is vitally important to enabling a robust application ecosystem. We are supportive the ONC and CMS is requiring providers and plans to publish their API end points but we believe more can be done. We believe the ONC and CMS can partner with the

CARIN Alliance and other private-sector groups to ensure the API end points for across the health care ecosystem are collected, published, and maintained on a publicly available site. We believe that instead of providing the FHIR end point as an example of what *could* be provided in the provider's digital contact information, ONC and CMS should make it a *requirement* that both providers and plans published their FHIR end points and all other necessary elements in the NPPES to make it active (OAuth URL, provider URL address, etc.). In the beginning, these end points change significantly but over time that change tapers off. As such, dedicated public/private resources are needed to ensure the API end points are updated over time otherwise the data will be quickly out of date much like the issues the industry is seeing with maintaining a provider directory.

We would encourage the ONC to examine the use of "OAuth 2.0 Authorization Server Metadata (RFC 8414) and OpenID Connect Discovery as examples of how to leverage open standards to publish these end points for the application ecosystem to consume. With respect to discovery of the endpoint for the Dynamic Client Registration Protocol RFC 7591 there already exists the recommended item "registration_endpoint". See section 3 of https://openid.net/specs/openid-connect-discovery-1_0-17.html

There already exists a broader concern over the fact there are still many providers who do not have a portal and therefore the SMART API cannot work as designed. Where there is a portal available to the patient, we strongly believe it should be clearly communicated to the patient on the provider's website to where to go in order to get a portal username and password. That information is often not visible even with some of largest providers in the country. Requiring patients to call up a practice, send in a letter, or go in person creates a substantial barrier to the patient without providing much of a security benefit.

The CARIN Alliance is also working the public and private sectors to develop a way to connect directly to the API with increased mobile biometric security and privacy but *without the need for a portal account.* We believe this is the next opportunity to streamline the ability for a consumer to access their provider and plan information remotely from any third-party application. We are developing an open standard framework to solve for 5 key issues: identity proofing, universal two-factor authentication, matching patients to their health information, trust and federation, and federating a consumer's health data sharing preferences. The public can follow our work on our website. We are grateful for the support of CMS and the ONC as we mutually work together to solve these issues.

VII.B.5 Real World Testing

§ 170.555 Certification to newer versions of certain standards
(b) * * * (1) ONC-ACBs are not required to certify Complete EHRs and/or Health IT Module(s) according to newer versions of standards adopted and named in subpart B of this part, unless: (i) The National Coordinator identifies a new version through the Standards Version Advancement Process and a health IT developer voluntarily elects to update its certified health IT to the new version in accordance with § 170.405(b)(5); or (ii) The new version is incorporated by reference in § 170.299.
Preamble FR Citation: 84 FR 7497-501 **Specific questions in preamble?** *No*
Regulatory Impact Analysis: Not applicable
Public Comment Field: The CARIN Alliance recommends the use of FHIR Release 4(Option 4) + US CORE. We believe EHR vendors should be able to move up in versions without getting recertified. Previousl versions of FHIR R2 would still need to be supported. We also support the standards version advancement process outlined by the ONC.

Section VIII – Information Blocking

§ 171.103 Information blocking
Information blocking means a practice that— (a) Except as required by law or covered by an exception set forth in subpart B of this part, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and (b) If conducted by a health information technology developer, health information exchange, or health information network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or (c) If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.
Preamble FR Citation: 84 FR 7508 **Specific questions in preamble?** *No*
Regulatory Impact Analysis: Please see 84 FR 7584-86 for estimates related to this proposal.
Public Comment Field: In general, we would support the definition of information blocking. We have significant concerns over ONC's definition of a health information network that we outline in our § 171.102

comments. We also are unclear as to whether or not the information blocking provisions listed in the ONC rule also apply to health plans in the CMS rule. Further, we would encourage both CMS and the ONC to clarify which additional entities besides those specifically called out in the ONC rule (health care or otherwise), the information blocking provisions would apply.

§ 171.102 Definitions

For purposes of this part:
Access means the ability or means necessary to make electronic health information available for use, ~~including~~ the ability to securely and efficiently locate and retrieve information from any and all source systems in which the information may be recorded or maintained.
Actor means a health care provider, health IT developer of certified health IT, health information exchange, or health information network.
API Data Provider is defined as it is in § 170.102.
API Technology Supplier is defined as it is in § 170.102.
~~Electronic Health~~ Information (EHI) means—
(1) Electronic protected health information; and
(2) Any other information that identifies the individual, or with respect to which there is a reasonable ~~basis to believe the information can~~ be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.
Electronic media is defined as it is in 45 CFR 160.103. Electronic protected health information (ePHI) is defined as it is in 45 CFR 160.103.

§ 171.102 Definitions

Exchange means the ability for electronic health information to be transmitted securely and efficiently between and among different technologies, systems, platforms, or networks in a manner that allows the information to be accessed and used.Fee means any present or future obligation to pay money or provide any other thing of value.

Health care provider has the same meaning as ''health care provider'' at 42 U.S.C. 300jj.

~~Health Information~~ Exchange or HIE means an individual or entity that enables access, exchange, or use of electronic health information primarily between or among a particular class of individuals or entities or for a limited set of purposes.

Health Information Network or HIN means an individual or entity that satisfies one or both of the following—

~~(1) Determines, oversees, administers~~, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

(2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

Health IT developer of certified health IT means an individual or entity that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which had, at the time it engaged in a practice that is the subject of an information blocking claim, health information technology (one or more) certified under the ONC Health IT Certification Program.

Information blocking is defined as it is in § 171.103 and 42 U.S.C. 300jj-52(a).

Interfere with means to prevent, materially discourage, or otherwise inhibit access, exchange, or use of electronic health information.

Interoperability element means—

~~(1) Any functional~~ element of a health information technology, whether hardware or software, that could be used to access, exchange, or use electronic health information for any purpose, including information transmitted by or maintained in disparate media, information systems, health information exchanges, or health information networks.

~~(2) Any technical information~~ that describes the functional elements of technology (such as a standard, specification, protocol, data model, or schema) and that a person of ordinary skill in the art may require to use the functional elements of the technology, including for the purpose of developing compatible technologies that incorporate or use the functional elements.

(3) Any technology or service that may be required to enable the use of a compatible technology in production environments, including but not limited to any system resource, technical infrastructure, or health information exchange or health information network element.

(4) Any license, right, or privilege that may be required to commercially offer and distribute compatible technologies and make them available for use in production environments.

§ 171.102 Definitions
(5) Any other means by which electronic health information may be accessed, exchanged, or used. Permissible purpose means a purpose for which a person is authorized, permitted, or required to access, exchange, or use electronic health information under applicable law. Person is defined as it is in 45 CFR 160.103. Protected health information is defined as it is in 45 CFR 160.103. Practice means one or more related acts or omissions by an actor. Use means the ability of health IT or a user of health IT to access relevant electronic health information; to comprehend the structure, content, and meaning of the information; and to read, write, modify, manipulate, or apply the information to accomplish a desired outcome or to achieve a desired purpose.
Preamble FR Citation: 84 FR 7509-15 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Not applicable
Public Comment Field: Like many of our members, we believe that the proposed definition of a "Health Information Network" is overly broad. The definition currently includes an actor who determines, oversees, administers, controls, or substantially includes policies or agreements that define the business, operation, technical or other conditions or requirements that enable or facilitate the access, exchange or use of EHI between or among two or more unaffiliated individuals or entities. As some of our members have noted, current business practices, including standards-development or policy alliances (like the CARIN Alliance), may inadvertently be defined as a Health Information Network under this definition. We believe that removing language from the HIN definition regarding "substantially includes policies or agreements" would properly exclude alliances or collaboratives, like the CARIN Alliance, from this definition. We also believe the definition should include that an HIN needs to have a technical infrastructure that exchanges data between 2 or more individuals in order to be considered a HIN. For example, there are entities that could be considered an HIN under the current language which we believe the ONC did not intend to include within their definition. These entities could include school nurses who are electronically exchanging information on behalf of a student with one or more than one providers. Standard-development organizations administer the technical conditions to facilitate access between two unaffiliated entities. We do not believe SDOs would need to be considered an HIN. Patient-facing applications may also fall under the HIN definition which we believe would defeat the administration's primary intent to share health information with any application of the patient's choice. We believe finalization of this definition should be part of a broader public/private discussion that would include the RCE and industry-led consortiums like the CARIN Alliance and others.

Request for comment regarding price information (Department of Health and Human Services)	
The overall Department seeks comment on the technical, operational, legal, cultural, environmental and other challenges to creating price transparency within health care.	
Preamble FR Citation: 84 FR 7513-14	**Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Not applicable	

Public Comment Field:

Along with our members, we see price transparency as one aspect of value transparency, which we consider the ideal goal that should be reached for consumers. Value transparency incorporates directly comparable data regarding at least price, safety, effectiveness, and convenience/access. Consumer reviews, which could provide information to enhance a consumer's ability to find a provider who is a good personality match, is likely not valuable for the consumer to determine a provider's effectiveness. Further, when looking beyond providers to prescription drugs, consumer reviews have less value than scientific data regarding effectiveness because individual experience with a particular drug varies based upon individual physiology and medical need. For these reasons, we recommend that any requirement regarding price transparency go further than regulating price disclosure, with the possibility of public reviews of providers and/or medications. Rather, we encourage legislation or rulemaking that will require data sharing to address full value transparency for consumers. Below are a series of recommendations based on the questions outlined in the RFI:

ONC language

- *Should prices that are included in EHI:*
  - *Reflect the amount to be charged to and paid for by the patient's health plan (if the patient is insured) and the amount to be charged to and collected from the patient (as permitted by the provider's agreement with the patient's health plan), including for drugs or medical devices;*
  - *Include various pricing information such as charge master price, negotiated prices, pricing based on CPT codes or DRGs, bundled prices, and price to payer;*
  - *Be reasonably available in advance and at the point of sale;*
  - *Reflect all out-of-pocket costs such as deductibles, copayments and coinsurance (for insured patients); and/or*
  - *Include a reference price as a comparison tool such as the Medicare rate and, if so, what is the most meaningful reference?*

CARIN response

CARIN believes that all of this data should be made available to consumers and authorized caregivers. Much of this data should also be made available by providers. We note, though, that certain prices are more impactful than others. Chargemaster prices, by themselves, might not be useful for the patient in the patient's decision making. However, providing additional contextual

information, as the CMS Administrator has encouraged, including reference or projected pricing for a specific provider location, can go far in advancing transparency.

ONC language

- *For the purpose of informing referrals for additional care and prescriptions, should future rulemaking by the Department require health IT developers to include in their platforms a mechanism for patients to see price information, and for health care providers to have access to price information, tailored to an individual patient, integrated into the practice or clinical workflow through APIs ?*

CARIN response

The CARIN Alliance supports full public access to de-identified aggregate price transparency data. Further, under direct bulk data sharing from health plan to providers, as discussed elsewhere in this rule and the CMS Patient Access and Interoperability Rule, where there is a shared population, we support pricing individual members' claim/encounter data sharing from health plan to provider. This sharing would support a provider in the understanding of all care a member has received. In addition, if the provider is in a risk-based relationship with the health plan, we support supplying financial information on that claim/encounter.

ONC language

- *To the extent that patients have a right to price information within a reasonable time in advance of care, how would such reasonableness be defined for:*
  - *Scheduled care, including how far in advance should such pricing be available for patients still shopping for care, in addition to those who have already scheduled care;*
  - *Emergency care, including how and when transparent prices should be disclosed to patients and what sort of exceptions might be appropriate, such as for patients in need of immediate stabilization;*
  - *Ambulance services, including air ambulance services; and*
  - *Unscheduled inpatient care, such as admissions subsequent to an emergency visit?*

CARIN response

The CARIN Alliance notes that health plans are already required to provide this pricing data to members and that in the Patient Access Rule, expanded access through machine-readable formats will be required. As discussed above, we believe that providers should also be required to publicly publish this data both by line item (billing code) and by bundled services.

Individualized cost estimates should be made available to patients who are able to plan for procedures in advance. However, it's important for price transparency regulations to differentiate between a price estimate and a binding quote. An estimate is based on the likely price for a medical service from a provider and can be used to shop between providers and understand the difference between different health plans and provider networks. An estimate would be based on average prices for that provider, but the price could vary based on the specific services performed on a specific patient. A binding quote, though, would be a more specific price based on knowing exactly what will be included in the service. In some cases, within the fee for service space, an exact quote wouldn't be possible before the service since the provider won't know the exactly what will happen during the procedure until it happens. If price transparency requires binding quotes before a

service is performed, it would require structural changes to the fee for service model of healthcare to generate a quote.

The standards should also require allowances for prices of alternative treatments. Prices are particularly helpful when they are able to be compared to other treatment options. In other words, pricing for therapeutic alternatives or various treatment options should all be available. For this to happen, diagnosis data is needed. Ideally, outcome data would also be made available.

We strongly support a federal law or rule that addresses surprise billing universally across the country. State by state solutions are difficult to administer. A national standard regarding surprise billing would make price estimates more reliable for patients.

- How would price information vary based on the type of health insurance and/or payment structure being utilized, and what, if any, challenges would such variation create to identifying the price information that should be made available for access, exchange, or use?

Reference prices are very difficult to establish, and anything selected will require some form of trade-off. This is because of contracting considerations between providers, networks, etc. The standards should allow for estimated reference prices that may be derived from proprietary methods and should be expected to be close to the true price, if not exact.

Price estimates for a value-based care plan may vary significantly from a fee for service model. Fee for service healthcare has significant variation. It can vary based on the type of insurance, the contract structure, the services performed, etc.

Various proprietary technologies have been built to compile estimate costs based on a variety of factors. It may be reasonable to provide a reference price that's expected to be within some range of a true price.

ONC language

- *Should price information be made available on public web sites so that patients can shop for care without having to contact individual providers, and if so, who should be responsible for posting such information? Additionally, how would the public posting of pricing information through API technology help advance market competition and the ability of patients to shop for care?*

CARIN response

Public information will be most valuable if (1) there are legislative/regulatory standards that providers must meet so that data is directly comparable; and (2) broader data is also provided so that patients can compare value, not just price.

ONC language

- *If price information that includes a provider's negotiated rates for all plans and the rates for the uninsured were to be required to be posted on a public web site, is there technology currently available or that could be easily developed to translate that data into a useful format for individuals? Are there existing standards and code sets that would*

facilitate such transmission and translation? To the extent that some data standards are lacking in this regard, could developers make use of unstandardized data?

CARIN response

The CARIN Alliance, and our members, are working on making price and value transparent to patients and consumers. Meaningful medical price transparency is complex because the health care industry is a more complex economy than other consumer-driving economies. Scientific data, interplay between diagnoses, recommended procedures, outcomes, effectiveness of procedures in treating diagnoses, etc. are among relevant factors to make a meaningful price comparison.

On area where the Alliance is working on price transparency is the CARIN consumer facing real-time pharmacy benefit check API implementation guide. Through this work, we hope to provide consumers with information related to their drug benefit, pharmacy prices for on-formulary purchases as well as cash pricing. We are also working on the CARIN Blue Button implementation guide for commercial health plans. **We would encourage CMS and the ONC to adopt the open standard API implementation guide once they are completed later this year.** As others have experienced, this is a complex activity that requires multiple actors to coordinate data disclosures, technology infrastructure, and information exchange. Again, we encourage regulators and law makers to value incremental progress toward complete value transparency, while ensuring that each step provides meaningful data rather than piecemeal data that should not be used in isolation to draw value comparisons.

ONC language

- *What technical standards currently exist or may be needed to represent price information electronically for purposes of access, exchange, and use?*

CARIN response

A FHIR-based approached to enable payer pricing transparency to be presented prior to the delivery of services will enable patients with their clinician's guidance to make informed decisions on their course of treatment and the cost to the patient.

In addition to the work CARIN has done, other conveners and FHIR accelerators, such as DaVinci, could support the development and adoption of common standards.

ONC language

- *Are there technical impediments experienced by stakeholders regarding price information flowing electronically?*

CARIN response

Today, health plans are providing significant price transparency to members and prospective members. But health plans are not necessarily providing this information in a seamless way. Making this data publicly available is expensive and some plans may have challenges. However, we remain firm in our belief that consumers must have access to price information. We encourage the administration to continue efforts to both educate plans and provide economically feasible methods for data (and price) transparency.

ONC language

- *Would updates to the CMS-managed HIPAA transactions standards and code sets be necessary to address the movement of price information in a standardized way?*

CARIN response

As specific FHIR-based API implementation guides are developed by industry-led groups such as Argonaut, DaVinci, and the CARIN Alliance we believe CMS can update the HIPAA transaction standards to replace required EDI formats with the new FHIR-based API implementation guides over time. This will help to modernize the health IT infrastructure across the country and allow for a robust application economy to flourish. We believe this will take time, but our health plan members and others believe this will dramatically reduce transaction costs across the health care ecosystem and improve interoperability.

ONC language

- *How can price transparency be achieved for care delivered through value-based arrangements, including at accountable care organizations, demonstrations and other risk-sharing arrangements?*

CARIN response

There is not currently a standard way to provide price estimates for these arrangements. We believe the bulk-on-FHIR standard will help in providing accountable care organizations with the information they need to manage their patient populations.

ONC language

- *What future requirements should the Department consider regarding the inclusion of price information in a patient's EHI, particularly as it relates to the amount paid to a health care provider by a patient (or on behalf of a patient) as well as payment calculations for the future provision of health care to such patient*

CARIN response

For price transparency to make a meaningful impact, price estimates should be available publicly and be available via an easy to consume methods such as an API as well as a public facing website. Price transparency regulations should also emphasis the adoption of a standard framework for generating cost estimates. Without standardization there won't be a means to compare prices between entities, which will reduce the impact of price transparency. We recommend standards focused on allowing price estimates at both the individual service level as well as overall encounter level.

VIII.D Proposed Exceptions to the Information Blocking Provision

Request for information on a potential additional information blocking exception for complying with the Common Agreement for Trusted Exchange

We are considering whether we would should propose, in a future rulemaking, a narrow exception to the information blocking provision for practices that are necessary to comply with the requirements of the Common Agreement. Such an exception may support adoption of the Common Agreement and encourage other entities to participate in trusted exchange through HINs that enter into the Common Agreement. We ask commenters to provide feedback on this potential exception to the information blocking provision to be considered for inclusion in future rulemaking.

Preamble FR Citation: 84 FR 7552	**Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: Not applicable	

Request for information on a potential additional information blocking exception for complying with the Common Agreement for Trusted Exchange
Public Comment Field: We believe it is far too early to discuss including an information blocking exception as part of the common agreement in future rulemaking. More public/private sector dialogue should occur prior to finalizing the common agreement in any future rulemaking.

Section X – Patient Matching Request for Information

Opportunities to Improve Patient Matching
We seek comment on additional opportunities that may exist in the patient matching space and ways that ONC can lead and contribute to coordination efforts with respect to patient matching. ONC is particularly interested in ways that patient matching can facilitate improved patient safety, better care coordination, and advanced interoperability.
Preamble FR Citation: 84 FR 7554-55 **Specific questions in preamble?** *Yes*
Regulatory Impact Analysis: NA
Public Comment Field: In sum, the CARIN Alliance believes requiring providers and health plans to be in compliance with the NIST 800-63-3 standards at an IAL2 and AAL2 level or higher will *significantly* decrease the patient matching problem both within and across systems. To accurately match records held at different health care facilities, organizations typically compare patients' names, dates of birth, and other demographic data to determine if records refer to the same individual. Health care facilities use algorithms to conduct these matches, and also employ staff to manually review records. This process often fails to accurately link records because of typos entered into the system; similarities in names, birth dates or addresses among different patients; changing information, such as when individuals move or get married; and many other reasons. While some private sector technologies—such as referential matching, wherein third-party data are used to support matches—show promise, market forces have been unable to solve the patient matching problem for decades. In fact, patient matching requires collaboration between unaffiliated organizations, even competitors, that lack incentive to agree to a set of standards or develop

systems that seamlessly exchange information.

The CARIN Alliance supports the Pew Foundation's research that examines different ways to address matching challenges. This research revealed two critical ways that ONC can improve patient matching.

Standardize certain demographic data already collected

First, ONC should require the use of standards for certain demographic data elements—an approach long recommended by many other organizations, including Audacious Inquiry in a report contracted by ONC.

In Pew-funded research published recently in the *Journal of the American Medical Informatics Association*, experts at Indiana University studied whether the standardization of different data elements improves patient matching rates.[i] Researchers attempted to match records in four databases, standardized the data in those databases, and then retried matching the records to determine whether that standardization yielded better results. The researchers culled tens of thousands of records from the Indiana Health Information Exchange; a county public health registry; Social Security's Death Master file; and a newborn screening laboratory. Each of these databases had already been reviewed to ensure that the record matches were accurate, which allowed researchers to understand the number of correct and inaccurate matches both before and after the standardization of select demographic data.

The research revealed that the standardization of address to the standard employed by USPS, which details the preferred abbreviations for street suffixes and states, for example, would improve match rates by approximately 3 percent. One technology developer indicated that this would help their system match an additional tens of thousands of records per day. Separately, standardizing last name to the standard used by the Council for Affordable Quality Healthcare—while showing limited utility on its own—would further improve match rates up to 8 percent if standardized along with address.

As mentioned earlier, ONC's recent regulations already propose embedding address in the USCDI, but the agency could further improve match rates by requiring use of the USPS standard. To further promote the use of this standard, ONC should also coordinate with USPS to ensure that health care organizations can use the postal service's online, API-based tool—or another easily accessible mechanism—to convert addresses to the USPS standard. There may also be scenarios—such as for military personnel stationed abroad—where the use of the USPS standard is not feasible. ONC could restrict use of the USPS standard to domestic, non-military addresses if challenges arise in the broader use of the standard.

Adopt additional data elements for patient matching

Second, ONC should advance the use of regularly collected demographic data elements for patient matching. ONC currently requires EHRs to make some demographic data—such as name, birth date, and sex—available, and proposes to add address and phone number to the USCDI. However, health records contain other demographic data routinely collected that aren't typically used or

made available to match records.

For example, research published in 2017 showed that email addresses are already being captured in more than half of patient records. The documentation of email is likely higher today, given the adoption of patient-facing tools, like portals, that often require emails to register.

ONC could improve match rates by identifying and including in the USCDI readily available data elements—such as email address, mother's maiden name, or insurance policy identification number—that health information technologies should use for matching.

Specific responses to questions in patient matching RFI

ONC seeks input on various approaches to address patient matching, minimum data requirements, and measures to assess performance of different solutions.

First, ONC requests input on the potential effect that data collection standards may have on the quality of health data that is captured and stored. ONC also requests input on solutions that may increase the likelihood of accurate data capture, including the implementation of technology that supports the verification and authentication of certain demographic data. As mentioned above, use of the USPS standard for address would improve match rates, and does not require the capture of information in this format given the availability of online tools to conduct the conversion.

Second, ONC solicits information on additional attributes that could aid patient matching, and new data that could be added to the USCDI or further constrained within it to support patient matching. As previously mentioned, ONC should examine additional data routinely collected in EHRs to also use for matching—such as email address, health insurance ID, mother's maiden name, and others.

Third, ONC seeks comments on potential solutions that involve patients in the capture, update and maintenance of their own demographic and health data. Pew collaborated with the RAND Corporation to examine patient involvement in record matching. The research revealed two key ways for patients to support record matching. For one, patients could validate their demographic information by verifying their mobile phone number and other data. In addition, EHRs could support smartphone applications that use standard APIs to allow patients to update their demographic data. ONC and the technology industry could pilot these patient-led approaches.

Fourth, ONC requests input on other innovative approaches to address patient matching. Pew research revealed a promising approach to patient matching that has not yet been widely used in health care: biometrics, such as fingerprint or facial recognition scans. In Pew-led focus groups on patient matching, patients overwhelmingly preferred the use of biometric over other options. Patients in the focus groups indicated that they already use biometrics in other aspects of their lives—such as to unlock smartphones or board airplanes—and should be able to use the same approach for record matching. The CARIN Alliance is supportive of the work the FIDO Alliance is doing in developing a universal two-factor authentication (U2F) open standard that uses the combination of your fingerprint biometric and a cryptographic key embedded in the hardware of your mobile phone to securely authenticate you online with any application. Within the next few years, the FIDO standard will be ubiquitous across all major browsers and operating systems

making it readily available to any health care organization in the country.

Finally, ONC seeks input on performance measures and indicators that can be used to evaluate patient matching algorithms. Benchmarking different approaches would help shed a spotlight on matching deficiencies and the wide variation in quality across different algorithms. Technology developers could then use that information to improve their algorithms, and health care providers could adopt the most promising approaches. ONC should work with CMS to determine how to benchmark different matching approaches; this likely requires the identification of a large, real-world data set to test different algorithms. The use of real-world data, rather than synthetic data, is essential given that some innovative approaches—such as referential matching—use third-party databases to support their algorithms. ONC or CMS may be able to grantmaking authorities or other policies to obtain such a data set for benchmarking. This benchmarking could assess duplicate creation rates, the number of records correctly matched, and the frequency with which records are incorrectly merged.

[i] Shaun J Grannis et al., "Evaluating the effect of data standardization and validation on patient matching accuracy," Journal of the American Medical Informatics Association 26, no. 5 (May 2019): 447–456, https://doi.org/10.1093/jamia/ocy191