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Alex M. Azar II, J.D.
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 2020

Re: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Summary of Proposed Rule – RIN 0955-AA01

Dear Secretary Azar,

Thank you for the opportunity to provide feedback to proposed rule RIN 0955-AA01 to advance interoperability and support the access, exchange, and use of electronic health information. Many of the comments contained in this letter pertaining to the proposed rule from the Office of the National Coordinator for Health Information Technology (ONC) are also applicable to the proposed rule CMS-9115-P from the Centers for Medicare and Medicaid Services (CMS).

CAQH is a non-profit alliance of health plans and related associations working together to achieve the shared goal of streamlining the business of healthcare. In concert with a wide range of healthcare stakeholders, CAQH develops and implements shared, industry-wide, national initiatives to eliminate long-term administrative business inefficiencies, producing meaningful, concrete benefits for healthcare providers, health plans, and patients.

The CAQH Committee on Operating Rules for Information Exchange (CORE), an initiative of CAQH, is a non-profit, national multi-stakeholder collaborative that drives the creation and adoption of healthcare operating rules that support standards, accelerate interoperability, and align administrative and clinical activities among providers, payers, and consumers. CAQH CORE Participating Organizations represent more than 75 percent of insured Americans, including health plans, providers, electronic health record (EHR) and other vendors/clearinghouses, state and federal government entities, associations, and standards development organizations. CAQH CORE is designated by the Secretary of the Department of Health and Human Services (HHS) as the author of federal operating rules for the HIPAA administrative healthcare transactions. Operating rules are developed by CAQH CORE Participants via a multi-stakeholder, consensus-based process.

CAQH comments on proposed rule RIN 0955-AA01 are set forth below based on our history of working with stakeholders across the healthcare industry to promote interoperability and reduce administrative burdens in areas such as eligibility and benefit verification, prior authorization, attachments or exchange of medical documentation, claims submission and payment, value-based payment, and provider data. Our comments fall under the following overarching themes:

- CAQH supports the consistent use of existing and emerging standards and operating rules to drive interoperability across the industry regardless of the mechanism of exchange. We specifically urge you to encourage ways to enable consistency in data content so that, regardless of the standard or intended use, the exchange of information between plans, providers, and patients can be seamless without undue burden placed on the IT and operational systems of plans and providers.

- Industry should be encouraged to collaboratively innovate and adopt new/updated standards like FHIR and operating rules with strong ROI, regardless of arbitrary regulatory timeframes; however, clarity is needed regarding a base standard supported by all industry participants.

- As the healthcare industry transitions from fee-for-service to value-based payment, there is a need for clinical and administrative systems to work in synch to exchange information to support patients, providers, and plans. Attachment standards and operating rules are needed to align the exchange of clinical information and medical documentation across these systems.

Thank you for considering these recommendations and comments. Should you have questions, please contact me at rthomashauer@caqh.org.

Sincerely,

Robin J. Thomashauer
President, CAQH

CC:
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IV. Updates to the 2015 Edition Certification Criteria (*§ 170.205; § 170.215; § 170.299; § 170.315; Preamble FR Citation: 84FR 7439-7454*)

The ONC rule proposes to update the 2015 Edition by revising and adding certification criteria that would establish standards and implementation specifications for health IT certification to enhance interoperability and improve patient access to their records. CAQH has comments on several aspects of this portion of the proposed rule.

- **CAQH CORE agrees with the use of existing processes to update standards when allowed by law and appropriate to support innovation.**
- **CAQH supports consistent use of existing and emerging standards and operating rules regardless of mechanism of exchange.**
- **CAQH urges the adoption of a federal attachment standard to align the exchange of clinical information and medical documentation across the industry for use by plans, providers, and patients.**
- **CAQH recommends that the FHIR standard version required in the final rule support a broader set of provider directory requirements commonly used in the industry.**

Use of Existing Processes to Update Standards
The proposed rule specifically encourages use of standards developed by voluntary consensus-based bodies. CAQH agrees with ONC that broad industry participation and collaboration are essential. We support use of ONC's open and transparent Interoperability Standards Advisory (ISA) to publish its latest approved versions of standards, consistent with the Standards Version Advancement Process (SVAP). CAQH CORE supports and regularly provides feedback to the Interoperability Standards Advisory and was encouraged by the addition of administrative standards and operating rules in 2018. Further clarity in the ISA of which existing standards and operating rules, particularly related to data content, apply to the accessible content referenced in proposed rule CMS-9115-P § 422.119 (b), § 431.60 (b), § 457.730 (b) and § 156.221 (b) would provide helpful clarification for implementers of this section to promote broader interoperability.

In general, CAQH also supports enabling flexibility within existing regulations to allow the industry to maintain aspects of standards and operating rules outside the regulatory process. This is critical for the timely adoption of updated electronic processes for administrative and clinical data exchange. CAQH supports greater adoption of processes over specific requirements, such as the CAQH CORE Code Combinations maintenance process for the Phase III CAQH CORE Uniform Use of CARCs and RARCs. The CORE Code Combinations are maintained as a separate document from the rule to enable more rapid updates to meet industry need and prevent delays via the regulatory process. CAQH would recommend a similar process for adoption of updates to existing and new standards referenced in this rule.

Consistent Use of Standards and Operating Rules
Another issue addressed in the ONC proposed rule is the desire to give flexibility to implementers regarding use of content and vocabulary standards on a voluntary basis to satisfy requirements except when determined to be inconsistent with applicable law, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification transaction standards. CAQH supports consistent use of these standards and recommends including associated HIPAA-mandated operating rules when referring to transaction standards throughout the regulation, as appropriate. Operating rules are defined by statute as the "necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications."

CAQH supports the consistent use of existing and emerging standards and operating rules to drive interoperability across the industry regardless of the mechanism of exchange, or the intended sender or receiver of information. In particular, CAQH supports consistent use of data content so that, regardless of the standard or intended use, the exchange of information between plans, providers, and patients can be seamless without undue burden placed on the backend IT and operational systems of plans and providers.

Adoption of a Federal Attachment Standard
The proposed rule would adopt the use of HL7 Clinical Notes C-CDA as well as FHIR as its clinical data exchange standards. Sharing clinical data across stakeholders is of great interest to support claims payment, prior authorization, population health management, care coordination, and to help patients make more informed health care decisions. As the healthcare industry transitions from fee-for-service to value-based payment, there is also a need for clinical and administrative systems to work in synch to exchange information to support patients, providers, and plans. However, the industry lacks standards to streamline the exchange of clinical data across multiple stakeholders and use cases. Attachment standards and operating rules are needed to align the exchange of clinical information and medical documentation across the industry.

The healthcare industry has been waiting for HHS action on an attachment standard for many years. In 1996, HIPAA mandated the adoption of an electronic standard for attachments. The extended wait for a federal attachment standard has fueled a sense of uncertainty, deterred vendor development of a standardized approach, and resulted in numerous electronic solutions and manual work-arounds that stakeholders are asked to support.

Through its HHS designation as the Operating Rule Authoring Entity for HIPAA-mandated administrative transactions, a key goal of CAQH CORE is to accelerate the adoption of the forthcoming federal attachment standard and streamline the electronic communication of clinical information through the development of operating rules. In anticipation of a federal attachment standard, CAQH CORE has engaged in a variety of work efforts to educate and promote

industry adoption of electronic attachments and survey industry utilization and barriers to identify opportunities for the development of operating rules.

CAQH urges HHS to not only release an attachment standard soon, but to also ensure alignment between CMS and ONC regarding the exchange of clinical information and medical documentation across multiple use cases to support patients, providers, and plans.

Application Programming Interface Standards
This section of the proposed rule specifies the API standards and implementation specifications proposed for adoption. To support provider directory accuracy and consistency across the industry, CAQH recommends that the FHIR standard version required in the final rule support a broader set of requirements commonly used in the industry. The adopted FHIR version should not only support the exchange of provider names, addresses, phone numbers, and specialties, but also additional information commonly used by health plans such as whether the provider is accepting new patients, which is only supported by newer releases.

Inaccurate, incomplete, and outdated provider directory information is a longstanding problem that impacts plans, providers, and patients. CMS has conducted three annual reviews of Medicare Advantage online provider directories since 2016 and has determined that problems with directory quality persist. To improve the accuracy of provider data in health plan directories, CAQH launched DirectAssure. This solution is an industry-led, fully automated approach, enabling the more than 1.4 million providers participating in CAQH ProView to easily review and update their self-reported professional, demographic, and directory information and share it with multiple health plans at once. To promote broader use of the API standard beyond the intended uses specified in proposed rule CMS-9115-P, the adopted FHIR version should support additional provider directory use cases.

X. Patient Matching Request for Information (*Preamble FR Citation: 84FR 7554-7555*)

In this section of the proposed rule, ONC requests comments on ways to standardize data sources to achieve patient identity matching. Several CAQH CORE Operating Rules contain data submission and verification requirements to improve patient matching, including the [Phase II CAQH CORE Eligibility Operating Rules](#) and the [Phase V CAQH CORE Prior Authorization Operating Rules](#).

CAQH CORE developed operating rule requirements for the eligibility (X12 270/271) and prior authorization (X12 278) transactions addressing aspects of the identification of individuals to enhance the automated processing of those transactions and to reduce errors, leading to faster delivery of appropriate patient care. The operating rules for both transactions require a provider to submit data in a standardized way in addition to a requirement on the health plan to normalize the data in the response. In addition, the operating rules for the prior

authorization transaction require providers to submit last name, first name, and DOB to ensure consistent submission of patient identifying information.

Another challenge affecting patient matching is healthcare providers submitting names with special characters embedded which can result in a significant percentage of query rejections if the data as submitted does not match exactly with what is in the health plan system. Normalization applies to specific characters in the patient last name including punctuation values, special characters, upper case letters, name suffixes, and prefixes. Both the CAQH CORE operating rules for eligibility and prior authorization require character strings to be removed during name normalization and recommend a set of punctuation values to be used to delimit last name from suffix or prefix. This normalization promotes successful adjudication of information included on the request when reviewed by the health plan as it pertains to patient identification.

The AAA error segment is also utilized to communicate error conditions within the eligibility and prior authorization operating rules. Consistent and uniform use of AAA Error and Action Codes is required in response when certain errors are detected in the request to send the most comprehensive information back to the provider for timely correction. The goal of this operating rule requirement is to use a unique error code wherever possible for a given error condition so that the re-use of the same error code is minimized.

The unique identification of an individual is not only an essential requirement for the successful use of the eligibility and prior authorization transactions, but is also a critical component of identity management – which includes authentication, authorization, transaction control, audit, etc. The CAQH CORE operating rule requirements for the eligibility and prior authorization transactions allow for care to be delivered faster due to more accurate information submission. They also lead to reduction of surprise claim denials ensuring more predictability and less hassle for the provider. We recommend ONC take into consideration these types of best practices in its future rulemaking on patient matching.