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June 3, 2019

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: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers – CMS-9115-P

Dear Secretary Azar,

Thank you for the opportunity to provide feedback on proposed rule CMS-9115-P to improve access to, and the quality of, information for Americans to make informed healthcare decisions, while minimizing reporting burdens on plans or providers. Many of the comments contained in this letter pertaining to the proposed rule from the Centers for Medicare and Medicaid Services (CMS) are also applicable to the proposed rule RIN 0955-AA01 from the Office of the National Coordinator for Health Information Technology (ONC).

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 CMS-9115-P 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 regardless of innovations adopted by willing trading partners.

- 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.

- The accuracy of provider data for use in directories and to facilitate the electronic exchange of information is associated with the ease of provider engagement within a provider's workflow.

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

Sincerely,

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II. Technical Standards Related to Interoperability, B. Content and Vocabulary Standards, C. API Standard, and D. Updates to Standards (§ *422.119 (c);* § *431.60 (c);* § *457.730 (c);* § *156.221 (c); Preamble FR Citation: 84FR 7623-7626*)

The CMS proposed rule seeks to incorporate existing standards into its regulatory framework for content and vocabulary standards, as well as allow flexibility to use updated standards to support access to and exchange of health data and plan information for patients through APIs. CAQH has comments on several aspects of this portion of the proposed rule.

- **CAQH supports consistent use of existing and emerging standards and operating rules regardless of mechanism of exchange.**
- **CAQH supports industry ability to innovate and adopt updated standards and operating rules, but requests clarity regarding a base standard to be supported by the industry.**

Consistent Use of Standards and Operating Rules

The CMS proposed rule seeks to give flexibility to implementers regarding use of content and vocabulary standards to satisfy requirements, but also specifies that standards required by mandate must continue to be followed, and specifically lists 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.

The proposed rule also recommends using the Office of the National Coordinator's (ONC) 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 § 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.

Use of Updated Standards and Need for Baseline Standard Clarification
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 regardless of innovations adopted by willing trading partners.

In general, CAQH 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.

In addition, CAQH supports the ability of willing trading partners to innovate and pilot test with new and updated standards. However, there is a need for CMS to clarify the language in the Technical Requirements sections of the regulation (for example, § *422.199 (c)(4))* to clarify the baseline requirements that must be supported by trading partners. Ensuring industry-wide progress by accelerating adoption of updated standards is highly desirable and achievable. However, this goal can only be achieved if there are willing trading partners testing and adopting new and updated standards, while also supporting a baseline standard for industry consistency.

III. Patient Access through APIs, C. Open API Proposal for MA, Medicaid, CHIP and QHP Issuers in FFEs (§ *422.199 (b);* § *431.60 (b);* § *457.730 (b);* § *156.221 (b); Preamble FR Citation: 84FR 7627-7634*)

This section of the proposed rule scopes the type of information to be made accessible through the open API. CAQH has comments on several aspects of this portion of the proposed rule.

- **CAQH supports consistent use of data content from existing standards via APIs for patient access, but clarity is needed regarding the source of information regarding enrollee cost sharing.**
- **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.**

Enrollee Cost Sharing Information Available Through an API
This section of the proposed rule scopes the type of information to be made accessible through the open API, such as adjudicated claims, encounters with capitated providers, provider remittances, enrollee cost-sharing, and clinical data. However, clarification is needed regarding the source of enrollee cost-sharing information and whether this information is intended to be sourced from adjudicated claims data and/or the eligibility and benefit verification transaction. Enrollee cost-sharing information from an adjudicated claim could provide more accurate information, however, the HIPAA-mandated X12 270/271 eligibility and benefit verification transaction set and the associated Phase II Operating Rules could support the sharing of initial cost-sharing information with a patient before a visit.

Specifically, the X12 270 eligibility and benefit verification transaction set is used to request information from a healthcare insurance plan about what services are covered for a patient or health plan subscriber, and patient financial responsibility. It may also be used for questions about the coverage of specific benefits for a given plan, such as wheelchair rental, diagnostic lab services, physical therapy services, etc. The X12 270 transaction is used in conjunction with the X12 271 transaction which is the response and is used to transmit the information requested in an X12 270. The Phase II CAQH CORE Operating Rules for the X12 270/271 eligibility and benefit verification transactions include requirements for specific patient financial and eligibility information to be shared in the transaction. As new information needs are identified, additional operating rules could be considered to support more robust data exchange via this commonly exchanged transaction set and share that information with a patient through an API.

Adoption of a Federal Attachment Standard
CAQH urges CMS to ensure requirements for the APIs create value while not adding to health plan or provider administrative burden. 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.

IV. API Access to Published Provider Directory Data (*Preamble FR Citation: 84FR 7639-7640*)

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. CAQH Participating Organizations serve more than 85% of Medicare Advantage beneficiaries. Through our work with plans and providers, both nationally and at the state level, we are demonstrating collective progress towards improving directory accuracy and welcome interest from CMS in advancing public-private techniques and solutions.

In this rule, CMS proposes to require specified health plans to make their provider directories available to enrollees and prospective enrollees through an API using a specific FHIR standard within 30 calendar days after changes to the provider directory are made to assist patients in making informed health care decisions. In addition, the proposed rule exempts QHP issuers from the API requirement as these plans are currently required to make their provider directory information available in a machine-readable format.

CAQH believes that making provider directories available through API technology is a step in the right direction. Improving directory accuracy, completeness and timeliness is a focus for CAQH and our member health plans, and we believe that collective industry action, enhanced provider engagement, and public/private collaboration – when combined with emerging technologies such as APIs – will lead to meaningful progress that will benefit healthcare consumers.

To support provider directory accuracy and consistency across the industry, CAQH recommends that the API requirements be applied broadly across the industry and 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. In addition, making provider directories available through API technology should be implemented broadly across the market, not just limited to the entities specified in the proposed rule.

V. Coordination across Payers (§ *422.119 (f);* § *438.242 (b);* § *156.221 (f); Preamble FR Citation: 84FR 7640-7642*)

CMS proposes that payers regulated under this section of the rule maintain a process for the electronic exchange of the data classes and elements included in the UCSDI Version 1 data set standard proposed in the ONC proposed rule. At the request of a current enrollee, the payer must receive the data from any other health plan that has provided coverage to the enrollee within the preceding five years, for five years after disenrollment send data to any other plan that currently covers the enrollee, and for a period of five years after disenrollment send data to a recipient designated by a current enrollee. In addition, CMS proposes to allow multiple methods for the electronic exchange of this information, including use of an API. The rule also states that HIPAA requirements will apply. CMS seeks comment on how plans should exchange information in these situations.

CAQH seeks clarity regarding this section, both in the Preamble as well as the regulatory language, to ensure the industry understands how to legally implement this section within the regulatory structure. In addition, CAQH reiterates our comments regarding the need for a federal attachment standard and operating rules to align the exchange of clinical information and medical documentation across the industry so that industry stakeholders are not expected to support multiple electronic solutions.

IX. Provider Digital Contact Information (*Preamble FR Citation: 84FR 7648-7649)*

In the rule, CMS proposes to increase the number of providers with valid and current digital contact information available through NPPES by publicly reporting the names of providers who do not have digital contact information included in the NPPES system. In addition, CMS states that provider NPPES information goes through a revalidation process every three to five years depending on the provider or supplier type. CMS requests comment on the most appropriate way to pursue public reporting to improve the accuracy of provider digital contact information.

CAQH ProView is the trusted electronic solution and industry standard for capturing and sharing healthcare provider self-reported data. More than 1.4 million providers enter and maintain a wide range of information within CAQH ProView, each creating a comprehensive “provider profile” to share among the 900 health plans and healthcare organizations they choose. Health plans and providers use CAQH ProView to streamline credentialing, improve network provider directories, speed claims processing and adjudication, and simplify administrative processes requiring routine updates to demographic and professional provider data.

Based on CAQH experience, the accuracy and timely availability of provider data is directly related to the ease of provider engagement within a provider’s ongoing workflow. For this reason, it is unlikely that a public reporting of providers will result in improvement in the quality of provider information, including valid and current digital contact information, in the NPPES system.

XI. RFI on Advancing Interoperability Across the Care Continuum (*Preamble FR Citation: 84FR 7653-7655*)

The CMS proposed rule seeks comment on expanding interoperability to support better care coordination, discharge planning, and timely transfer of essential health information into additional practice settings with a focus on post-acute care, behavioral health, and home and community-based services. In addition, CMS is soliciting feedback on adoption of leading health IT standards and piloting emerging standards.

Interoperability in Additional Care Settings

CAQH supports the goals contained in this RFI as effective clinical care requires more interaction among clinicians and a wider variety of practices. Value-based payment models are transforming a sizable portion of the U.S. healthcare economy by aligning provider compensation with improvements in quality and cost. The success of value-based payment is fundamentally dependent upon reliable business interactions between all healthcare stakeholders. The scope and scale of direct collaboration required for value-based payment stands in stark contrast to the more limited stakeholder interactions in the fee-for-service market.

That said, requiring technology is only a first step toward automation and streamlined clinical workflows. We urge CMS to consider the business perspective as well. Specifically, the vital role of operating or business rules to govern the processes that support technical specifications. Common expectations for when, what, and how data is shared is critical for true interoperability. We encourage CMS to consider how operating rules can further drive interoperability in future rulemaking regarding interoperability in additional care settings.

Adopting Leading Health IT Standards
CAQH agrees with the principles contained in this portion of the RFI to advance health IT standards. Current efforts are making meaningful progress to address the challenge of complexity in healthcare data exchange. Moreover, there is a need for consistency in data content so regardless of the standard, the exchange of information will be seamless. However, as previously mentioned, there is a critical need for business requirements/operating rules to support standards and technical requirements to drive the industry forward. Operating rules can support a transaction regardless of the underlying standard or technology and ensure common expectations for data exchange among stakeholders.

CAQH CORE Participating Organizations have tackled some of the most difficult healthcare administrative tasks with a shared goal of aligning administrative and clinical activities among providers, payers, and consumers. CAQH encourages CMS to consider a similar model as you seek to standardize data exchange operations across the healthcare industry. Use of technology is only part of the solution; every sector of the healthcare industry must work in lockstep to provide patients with meaningful information they can use to make important healthcare decisions with their providers.

Piloting Emerging Standards
The RFI on supporting pilots for emerging standards is aligned with CAQH CORE priorities to conduct more piloting and testing of operating rule requirements. In 2019, CAQH CORE is launching several pilot testing initiatives to address changing demands and technological advancements. These include:

- Applying agile/lean methodologies to the rule development process.
- Working with CAQH CORE Participating Organizations to develop a pilot model to build into the operating rule development process more robust feasibility testing and value assessments.
- Testing concepts before they are released for implementation, including conducting an impact analysis, to inform whether to move forward with a specific requirement.
- Measuring ROI through collaboration with the CAQH Index, the industry resource for benchmarking progress associated with use of electronic administrative transactions, which can be used to encourage broader industry adoption.

As CMS considers the details of this future rulemaking, CAQH CORE would be pleased to collaborate to further develop criteria and best practices for launching pilots to ensure successful adoption and ROI of emerging standards.

XIII. RFI on Policies to Improve Patient Matching (*Preamble FR Citation: 84FR 7656-7657*)

In this section of the proposed rule, CMS 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 CMS take into

consideration these types of best practices in its future rulemaking on patient matching.

I. Background and Summary of Provision, D. Past Efforts (*Preamble FR Citation: 84FR 7612-7614)*

This section of the proposed rule discusses CMS efforts to develop a prototype Documentation Requirement Lookup Service for the Medicare FFS program populated with the list of items/services for which a prior authorization is required for Medicare FFS.

Each step of the prior authorization process is currently labor-intensive and generates time-consuming and costly administrative burden for providers, as well as payers, and can delay patient care. According to the 2018 CAQH Index, 51 percent of prior authorizations are submitted manually, 36 percent are submitted via web portal or interactive voice response, and 12 percent are submitted via the HIPAA-mandated X12 278 prior authorization transaction.

To date, CAQH CORE Participants have developed two phases of prior authorization operating rules.

The Phase IV CAQH CORE 452 Health Care Services Review – Request for Review and Response (278) Infrastructure Rule establishes foundational requirements that build consistency with other operating rules for HIPAA transactions, including receipt acknowledgement, connectivity methods, required response times, minimum system availability, and a common companion guide format.

The recently passed Phase V CAQH CORE Prior Authorization Operating Rules enhance and standardize the data shared between plans and providers, eliminating unnecessary back-and-forth, accelerating adjudication timeframes, and freeing staff resources spent on manual follow-up. In particular, the rules standardize data related to the exchange of clinical information and offer providers a more consistent, efficient, and predictable process across all the plans with which they participate.

CAQH CORE is also working to develop, update, and pilot test additional prior authorization operating rules to reduce the timeframe for a prior authorization decision, help providers determine whether a prior authorization is needed, and improve the way attachments and medical documentation are exchanged. CAQH CORE would be happy to discuss our findings and efforts to pilot these concepts with CMS and collaborate on future enhancements to the prior authorization process.