March 13, 2023

Chiquita Brooks-LaSure, MPP, Administrator
Centers for Medicare and Medicaid Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

Attention: CMS-0057-P
Submitted electronically to http://www.regulations.gov

Dear Administrator Brooks-LaSure:

The Sequoia Project is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the advancing interoperability and improving prior authorization proposed rule. We appreciate CMS's demonstrated record of responding thoughtfully to the comments that it receives on such proposed rules from its many stakeholders.

The Sequoia Project is a non-profit, 501(c)(3) public-private collaborative that advances the interoperability of electronic health information for the public good. The Sequoia Project previously served as a corporate home for several independently governed health IT interoperability initiatives. The Sequoia Project currently supports the RSNA Image Share Validation Program and the Interoperability Matters Cooperative. We are also honored to have been selected by the Office of the National Coordinator for Health IT (ONC) to be the Recognized Coordinating Entity (RCE) for the Trusted Exchange Framework and Common Agreement (TEFCA).

These comments reflect our experience supporting large-scale, nationwide health information sharing initiatives, including active work with several federal government agencies. Through these efforts, we serve as an experienced, transparent, and neutral convener of public and private sector stakeholders to address and resolve practical challenges to interoperability. Our decade of experience building public-private collaborations and launching highly successful nationwide health IT initiatives provides us with a unique perspective on the proposed rule. The comments and recommendations in this letter reflect this expertise independent of our role as the TEFCA RCE.

Overview

The Sequoia Project supports CMS' focus on interoperability and patient access to data and its efforts to give payers and providers greater flexibility while reducing their burdens. Highlights of our comment letter include:

Patient Access API

- The industry and the government should work collaboratively to communicate with and provide support to patients to ensure they understand 1) options for how to access their information in a way that allows them to use it, 2) what information they have a right to access, and 3) the privacy and security implications of the different options available for accessing that information.
- CMS should align and coordinate with other federal agencies that regulate the privacy and security of health apps, as well as industry stakeholder to develop and promote standards, guidelines, or proposed requirements for health apps to follow when providing individuals with access to their health information.

Payer to Payer API

- CMS should provide payers with an optional alternative path to comply with the Payer to Payer API requirements in the proposed rule by participating in and making data available via TEFCA.

Electronic Prior Authorization Measure for MIPS and Promoting Interoperability

- CMS should include an optional, alternative measure that allows eligible clinicians, hospitals, and critical access hospitals (CAHs) to claim credit by attesting to use of a HIE/HIN to request prior authorization for medical items and services (excluding drugs).

Interoperability Standards

- CMS should *require* that, as a floor, the proposed APIs be conformant with the most recently approved standards in the SVAP within 12 months of approval.

Behavioral and Community Health Data Exchange RFI

- CMS should dedicate their resources and authority towards driving adoption of the technical infrastructure needed to populate FHIR APIs with meaningful data and providing incentives for behavioral health and community-based providers to participate in national networks and frameworks.

TEFCA RFI

- CMS should participate in TEFCA and use its levers to encourage and incentivize regulated providers and payers to participate in TEFCA.
- CMS should collaborate with agencies across HHS to make the initial use cases under TEFCA successful before issuing requirements for regulated entities to participate.
- CMS should focus on providing positive incentives and optionality, particularly as TEFCA becomes operational.

Detailed Comments

Section II.A — Patient Access API Privacy Request for Information

> *RFI Question: Given the Common Agreement's privacy and security requirements, and particularly those that will apply when patients access their health information through a participating IAS Provider, we request comment on whether CMS should explore requirements or ways to encourage exchange under TEFCA as a way to ensure that more patients are informed about the privacy and security implications of using health apps to access their health information?*

We appreciate CMS's commitment to educating and informing patients about the privacy and security risks of using third party apps to access health information. By making it easier for health information to be shared securely online, the TEFCA can reduce the burden many patients experience as they navigate the health system.

As CMS notes, the Common Agreement includes certain privacy and security requirements that apply to Individual Access Service (IAS) Providers, many of which may be health apps that are not otherwise subject to the HIPAA Rules. In particular, Section 10.3 of the Common Agreement requires that IAS Providers develop and make publicly available a Written Privacy and Security Notice. The RCE published a draft Standard Operating Procedure (SOP) with proposed implementation specifications for the Privacy and Security Notice requirement on June 21, 2022 and collected stakeholder input. ONC and the RCE have been carefully considering the feedback received and will revise and release a final draft accordingly. The feedback is posted publicly on the RCE website.[1]

While we anticipate that this requirement will provide individuals with some increased access to the information needed to understand their individual rights, the challenges associated with meaningfully informing individuals about privacy and security risks of the apps they use to access health data are more complex than what TEFCA alone can solve. The requirements under TEFCA may provide some additional level of transparency for those individuals who already seek out and understand this information, but TEFCA is not, nor is it intended to be a tool to address the broader, underlying issues that prevent most individuals from understanding their rights and the privacy and security practices of the health apps they use, including lack of interest or awareness, difficulty comprehending contract language, and convenience.

The industry and the government should work collaboratively to communicate with and provide support to patients to ensure they understand 1) options for how to access their information in a way that allows them to use it, 2) what information they have a right to access, and 3) the privacy and security implications of the different options available for accessing that information. This

[1] https://rce.sequoiaproject.org/ias-provider-privacy-and-security-notice-and-practices-sop-feedback/

must be communicated in a way that all people can understand, regardless of circumstance. Otherwise, the potential of any guidance or requirements will only be realized by a small portion of the population.

> *RFI Question: How could CMS encourage health apps that are not subject to the HIPAA Rules to connect to entities that exchange information under TEFCA?*

CMS has limited ability to directly incentivize health apps to participate in information sharing via TEFCA. However, the agency can indirectly drive participation by engaging in TEFCA for its own operations. The Sequoia Project recommends that CMS participate in TEFCA and use its levers to encourage and incentivize regulated providers and payers to participate in TEFCA. We believe such widespread participation by major data holders will drive participation by health apps not otherwise subject to the HIPAA Rules.

Additionally, CMS should align and coordinate with other federal agencies that regulate the privacy and security of health apps, as well as industry stakeholder to develop and promote standards, guidelines, or proposed requirements for health apps to follow when providing individuals with access to their health information.

Section II.C Payer to Payer Data Exchange on FHIR

We recommend that CMS provide payers with an optional alternative path to comply with the requirements in the proposed rule by participating in and making data available via TEFCA. We recommend providing this option starting with the Payer to Payer API.

Please see Section III.E.2 on page 9 below for our detailed recommendation.

Section II.E Electronic Prior Authorization for the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program

The Sequoia Project supports providing a positive incentive for health care providers to use of electronic prior authorization processes, as long as the associated measure can be easily calculated. We also recommend that CMS include an optional, alternative measure that allows eligible clinicians, hospitals, and critical access hospitals (CAHs) to claim credit for the measure by attesting to use of a health information exchange (HIE) or health information network (HIN) to request prior authorization for medical items and services (excluding drugs).

The optional addition of participation in an HIE/HIN as a means of fulfilling this measure will provide an appropriate, voluntary incentive for provider organizations to participate in TEFCA. This option is consistent with the finalized HIE Bi-Directional and Enabling Exchange Under TEFCA optional alternative measures and promotes cohesiveness and alignment across federal interoperability initiatives.

If CMS were to include this as an optional measure, we recommend that CMS provide guidance on the role of HIPAA administrative transaction standards in large-scale national networks.

Section II.E Interoperability Standards for APIs

We understand why CMS has taken the approach of tying the standards requirements to the applicable standards required by the ONC Health IT Certification Program, even though, as CMS notes, ONC has already approved more updated versions of standards for optional use in the Certification Program under the Standards Version Advancement Process (SVAP).

The TEFCA Facilitated FHIR Implementation Guide (IG) Draft 2[2] specifies the use of FHIR version 4.0.1 with FHIR US Core implementation Guide v5.0.1. The IG requires actors to continue to support any capabilities previously supported for TEFCA purposes under a particular FHIR Release until support for that FHIR Release has been officially sunset by the RCE, which is intended to mitigate future challenges with version compatibility.

We appreciate CMS's acknowledgement of the potential risk for implementation variation that could limit effectiveness of the APIs due to not requiring use of the most recent standards and IGs. We believe that this risk is significant enough such that CMS should consider other approaches for imposing requirements that can stay up to date with the evolving standards and retain consistency across impacted entities.

As such, we recommend that CMS should *require* that, as a floor, the APIs be conformant with the most recently approved standards in the SVAP (CMS should coordinate with ONC to include more standards and implementation guides in the SVAP to align with the CMS rule). CMS could also include some transition time, (e.g., 12 months) to allow for sufficient development, and plan to address issues with versioning and backwards compatibility, while still moving the industry forward at a more rapid pace than the regulatory process allows.

Section III.B Electronic Exchange of Behavioral Health Information Request for Information

> *RFI Question: Can applications using FHIR APIs facilitate electronic data exchange between behavioral health providers and with other healthcare providers, as well as their patients, without greater EHR adoption? Is EHR adoption needed first? What opportunities do FHIR APIs provide to bridge the gap? What needs might not be addressed by using applications with more limited functionality than traditional EHRs?*

The Sequoia Project appreciates CMS' focus on improving electronic data exchange between behavioral health providers and other healthcare providers. FHIR APIs have immense potential for improving information sharing, but their effectiveness in facilitating meaningful data

[2] https://rce.sequoiaproject.org/wp-content/uploads/2022/12/TEFCA-Facilitated-FHIR-Implementation-Guide-Draft-2-Pilot-Version.pdf

exchange is contingent on the presence of comprehensive health information coded in a shareable format within the API. Without the systems and workflows to electronically capture and store data, behavioral health providers will not be able to effectively engage in bi-directional exchange with other healthcare providers.

While the EHR is the dominant system for data capture, storage, and sharing, as illustrated in The Sequoia Project's "Complexity of Designated Record Set (DRS)-Based Electronic Health Information (EHI) infographic[3], there are many systems outside of the traditional EHR that provide this functionality.

Providing all behavioral health providers with access to applications that use FHIR APIs is a valuable first step, but behavioral health providers must adopt technical infrastructure — including but not limited to EHRs — to capture, store, and share encoded data in a standardized format in order to enable meaningful, bi-directional data exchange with patients, caregivers, and other healthcare providers.

> *RFI Question: What levers and approaches could CMS consider using and advancing to facilitate greater electronic health data exchange from and to community-based health providers including use of relevant health IT standards and certification criteria for health IT as feasible? What costs, resources, and/or burdens are associated with these options?*

CMS should dedicate their resources and authority under the SUPPORT Act towards driving adoption of the technical infrastructure needed to populate FHIR APIs with meaningful data and transition community-based providers off paper and fax-based records. Such support should be in the form of financial incentives, regulatory relief, education, and on-the-ground technical assistance.

In parallel, CMS should provide incentives for behavioral health and community-based providers to participate in national networks and frameworks like TEFCA and Carequality.

Section III.E— Advancing the Trusted Exchange Framework and Common Agreement–Request for Information

TEFCA represents an important national investment in a federally recognized approach to nationwide health information exchange. The Sequoia Project believes this initiative will be most successful if there is widespread participation across the public and private sectors. During the initial rollout and growth of TEFCA, we believe CMS's participation in the health information network ecosystem will be critical to ensuring that TEFCA meets the needs of federal health programs.

[3] https://sequoiaproject.org/wp-content/uploads/2022/08/EHI-TG-Workstream_3-Infographic-FINAL.pdf

As a major payer and regulator, CMS should lead on use cases and capabilities for TEFCA where the private sector has not been able to drive adoption and that require governmental engagement, actions, and levers to move the market. In doing so, CMS would join with other federal agencies, such as the Department of Defense, Department of Veterans Affairs, and Social Security Administration, that stand to benefit from nationwide exchange for a range of use cases.

As a neutral convener of public and private sector stakeholders, The Sequoia Project is eager to engage with CMS to explore how TEFCA can best support the agency's own operational needs, such as for receiving information needed for quality reporting. The Sequoia Project stands ready to provide additional information on TEFCA and looks forward to continued engagement with CMS staff.

1. *How could the requirements of the Common Agreement and the QTF help facilitate information exchange in accordance with the final policies in the CMS Interoperability and Patient Access final rule (85 FR 25510) around making clinical and administrative information held by health plans available to patients?*

TEFCA is building toward FHIR-based exchange that will support patient access to clinical and administrative information held by health plans together with the information held by providers through nationwide exchange. Once fully operational, TEFCA will support the ability to gather health information from across multiple organizations, including health plans, into the application of an individual's choice – something that is not widely supported today.

While the initial versions of the Common Agreement and QTF do not explicitly incorporate FHIR, they also do not prohibit use of FHIR within the required policy and technical architecture. For example, there are no restrictions on how QHINs enable exchange within their own networks. Furthermore, the QTF does not prohibit the exchange of FHIR payloads (e.g., FHIR resources and documents) between QHINs using required IHE-based transport. We anticipate that some QHINs will immediately support and use FHIR within their own networks and will convert to the appropriate IHE standards when communicating with other QHINs. This will allow health plans to exchange information in their FHIR-based APIs with other entities engaged in TEFCA-based exchange.

While allowing QHINs to optionally offer to support exchange of FHIR resources, the currently published Common Agreement v1[4] and QTF v1[5] do not support FHIR-based exchange as required by the CMS Interoperability and Patient Access final rule (85 FR 25510) and this proposed rule. The RCE and ONC have published a FHIR Roadmap[6] for TEFCA exchange that describes the planned stages for FHIR availability in TEFCA. Stage 1, or the current state,

[4] https://rce.sequoiaproject.org/wp-content/uploads/2022/01/Common-Agreement-for-Nationwide-Health-Information-Interoperability-Version-1.pdf
[5] https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf
[6] https://rce.sequoiaproject.org/wp-content/uploads/2022/01/FHIR-Roadmap-v1.0_updated.pdf

supports QHIN-to-QHIN exchange leveraging Integrating the Healthcare Enterprise (IHE) profiles to transport documents between QHINs, including C-CDAs and FHIR Documents. Stage 2, Facilitated FHIR, will enable QHINs, Participants, and Subparticipants to engage in point-to-point FHIR-based exchange with Participants and Subparticipants from different QHINs without transacting through a QHIN as an optional exchange modality. Stage 3, Brokered FHIR, will enable QHINs to serve as intermediaries for FHIR API transactions between Participants and Subparticipants from different QHINs, primarily for their Participants and Subparticipants who are unable to support Facilitated FHIR on their own.

The RCE and ONC have begun development of Stage 2 and published the Facilitated FHIR Implementation Guide Draft 2,[7] which they plan to pilot in the Spring of 2023. However, operationalization of Facilitated FHIR for TEFCA is dependent on updates to the Common Agreement and QTF, slated for 2024. At such point, Facilitated FHIR will be optional for QHINs, Participants, and Subparticipants.

2. *How could TEFCA support proposed requirements for payers under this rule related to provider data access and prior authorization processes?*

Once the Common Agreement and QTF are updated to support Facilitated FHIR-based exchange, health plans could use TEFCA to make some or all of the required APIs available to QHINs, Participants, and Subparticipants in TEFCA. TEFCA provides a common set of terms and conditions and technical specifications that enable trust and could allow payers to sign one agreement and connect to one network in order to meet the requirements of the proposed rule.

As this proposed rule is written, participation in TEFCA alone would not necessarily satisfy all of a payer's requirements for each of the proposed APIs unless a payer could be sure that all of the payers, providers, and patients that it's required to exchange data with under this proposed rule also participate in TEFCA (for example, it's possible that not all providers in a payer's contracted network would participate in TEFCA).

We recommend that CMS provide payers with an optional alternative path to comply with the requirements in the proposed rule by participating in and making data available via TEFCA. We recommend providing this option starting with the Payer to Payer API.

We believe that this alternative option could provide efficiencies for payers but only if the payer could meet all of the obligations of the Payer to Payer API through TEFCA without also having to make the required data available outside of TEFCA. Note that we do not currently recommend this option for the Patient Access API and the Provider Access API due to concerns related to provider and patient burden.

[7] https://rce.sequoiaproject.org/wp-content/uploads/2022/12/TEFCA-Facilitated-FHIR-Implementation-Guide-Draft-2-Pilot-Version.pdf

Below, we describe some suggested contours of this proposed option based on current policies in Common Agreement v1 and anticipated updates for Common Agreement v2. We encourage ongoing dialogue between CMS, ONC, and the RCE to further define this approach and ensure alignment across interoperability initiatives.

- Payers must sign an applicable Framework Agreement with a QHIN, Participant, or Subparticipant.
- Payers must respond to requests for Required Information, including the CMS required data, by any QHIN, Participant, Subparticipant, in accordance with applicable law.
- Payers must have the capability to respond to requests from other QHINs, Participants, and Subparticipants, in accordance with applicable law, using QHIN-brokered IHE transactions. This could mean choosing a QHIN that can translate FHIR API transactions into FHIR payloads for IHE transport.
- In addition to the requirement above, Payers could *optionally* publish a FHIR API in the RCE Directory Service for all QHINs, Participants, and Subparticipants that request access to it, in accordance with applicable law.
- Payers could request patient data from all QHINs, Participants, and Subparticipants, in accordance with applicable law, using a combination of QHIN-brokered IHE transactions and/or Facilitated FHIR.
- Payers would not be required to respond to API access requests from requesting payers that make requests external to TEFCA.[8]

This option can help to simplify connections between payers and reduce some of the burden and cost associated with maintaining the required APIs, as well as the associated data use agreements, requirements for authorization and authentication, and maintenance of opt-in consents and attestations. If this were an option, we anticipate that certain QHINs would provide value-added services by maintaining and managing the additional Payer to Payer proposals, including the "opt-in" requirements, making the exchange even more seamless for payers that choose this path.

In addition to the efficiencies that this option would create for meeting the CMS rule requirements, the CMS impacted payer and non-impacted payers and providers alike would benefit from increased access to information due to the reciprocal nature of the data sharing agreement, thus attracting more voluntary participation in TEFCA overall.

[8] This would not impact any other requirements that may obligate a payer to respond to a request from another payer outside of TEFCA, per applicable law.

3. *How should CMS approach incentivizing or encouraging payers to enable exchange under TEFCA?*

CMS has an important opportunity to promote alignment across interoperability initiatives by including TEFCA as an option for sharing information needed for care (as suggested above), for program activities, and for reporting to CMS. In doing so, the agency should look across provider and payer regulations that address interoperability, such as the Promoting Interoperability Program and the Interoperability and Patient Access rules. The agency should also consider multiple use cases, including public health and health care operations, such as sharing data needed for quality measurement and reporting. In doing so, however, The Sequoia Project recommends that the agency focus on providing positive incentives and optionality, particularly as TEFCA becomes operational.

4. *Under what conditions would it be appropriate to require this approach by payers subject to the proposed regulations in this rule and previously finalized regulations in the CMS Interoperability and Patient Access final rule (85 FR 25510)?*

The Sequoia Project recommends that agencies across HHS first collaborate to make the initial use cases under TEFCA successful before issuing requirements for regulated entities to participate. Given its role as a payer and a regulator of health plans through Medicare, Medicaid, and the Health Insurance Marketplace, The Sequoia Project encourages CMS to actively participate in work to advance health information exchange in support of payment and health care operations use cases.

If at all, CMS should not consider requiring participation in TEFCA until, at least, the RCE has rolled out Stage 3 of the FHIR Roadmap and when TEFCA has been operationalized at some level of scale to support QHIN Brokered FHIR exchange. At this point, payers, providers, and patients will have sufficient optionality to use whichever standard best suits their needs to exchange meaningful data across the network.

5. *What concerns do commenters have about potential requirements related to enabling exchange under TEFCA? Could such an approach increase burden for some payers? Are there other financial or technical barriers to this approach? If so, what should CMS do to reduce these barriers?*

One of the key goals of TEFCA is to provide value and reduce the complexity of exchange by establishing a shared set of policies and technical approaches to support nationwide exchange. Below are some concerns we have heard from members about potential requirements related to TEFCA:

- **Disruption**: In the initial stages of rollout, care needs to be taken to minimize burden and avoid disruption to existing nationwide interoperability frameworks.
- **Inconsistent Expectations**: There is a strong desire to align CMS requirements with TEFCA so that there are clear and consistent expectations across regulated entities.

- **Financial Burden**: There are a range of health care providers – such as smaller physician practices, behavioral health providers, and many post-acute care facilities – that are not yet actively engaged in health information exchange and may need additional educational and financial supports to connect. We encourage CMS to consider how it can best address those needs, with a focus on positive incentives rather than mandates.
- **Low or No Participation in Exchange Purposes Beyond Treatment**: The implementation of Exchange Purposes beyond Treatment will take a deliberate and consultative approach that brings all players along. CMS participation as a major payer will be crucial, as will close coordination across other federal agencies involved in TEFCA, such as ONC, CDC, VA, SSA, AHRQ, and HRSA.

The Sequoia Project looks forward to working with CMS to provide additional information and engaging in additional discussion about how best to work collaboratively to realize the promise of nationwide exchange to improve health and health care and realize value.

Conclusions

We thank CMS for providing the opportunity to comment on this proposed rule. Again, we strongly support CMS's intention to align and advance federal interoperability initiatives. We urge CMS to offer positive incentives for participation in public and private sector health information exchange solutions and encourage CMS to collaborate with the industry and federal partners to increase value and reduce burden associated with nationwide data sharing.

The Sequoia Project is eager to assist CMS in advancing secure, nationwide interoperable health information exchange for the public good.

Most respectfully,

Mariann Yeager
CEO, The Sequoia Project