



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:

Carequality 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.

Carequality is a non-profit, 501(c)(3) organization that provides a national-level, consensus-built, common trusted exchange framework to enable exchange between and among health data sharing networks. Although The Sequoia Project previously served as a corporate home for Carequality, Carequality now operates as a separate non-profit corporation.

Carequality supports the exchange of more than 350,000,000 clinical documents each month across the nation's leading health information networks and their customers. To do so, it brings together diverse groups, including electronic health record vendors, health systems, payers, health information exchanges, and other types of existing networks to determine technical and policy agreements to enable data to flow between and among networks, platforms, and geographies.

Carequality is a sub-recipient of the Cooperative Agreement between the Office of the National Coordinator for Health IT (ONC) and the Sequoia Project to serve as the Recognized Coordinating Entity (RCE) for the Trusted Exchange Framework and Common Agreement (TEFCA). The RCE is responsible for developing, implementing, and maintaining the Common Agreement. The comments and recommendations in this letter reflect our experience in developing and operationalizing large-scale, nationwide health information sharing initiatives independent of our role supporting TEFCA.



Detailed Comments

Section II.A — Patient Access API Privacy Request for 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, national networks and frameworks like Carequality and TEFCA can reduce the burden many patients experience as they navigate the health system.

In 2021, Carequality formed the Patient Matching Workgroup, which is tasked with the development of policies and technical requirements that will encourage an expansion of the use of the Patient Request Permitted Purpose within the Carequality framework. The Workgroup is public and comprises a diverse set of stakeholders including health IT vendors, patient advocates, federal agencies, HIEs, associations, and more.

The Workgroup is currently in the process of amending the Carequality Framework Policies to include specifications for the Patient Request Permitted Purpose, including requirements for identity verification and demographics.

The policies agreed to by the Workgroup served as the basis for the TEFCA Individual Access Services (IAS) Exchange Purpose Implementation SOP published in 2022. Since the publication of the TEFCA SOP, the Carequality Workgroup has continued its discussions to refine the Patient Request Permitted Purpose with critical enhancements to promote trust. The RCE plans to update the TEFCA IAS Implementation SOP to align with the Carequality policy, when final.

We invite CMS to join the Workgroup discussion to better understand and participate in the formulation of policies that underlie the TEFCA.

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?

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 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. Carequality 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.

For example, the Carequality Patient Matching Workgroup, discussed above, identified limitations on the use of patient access use cases across national networks due to challenges with patient demographic matching and fears of penalties for HIPAA disclosure violations caused by an identity mismatch. Systems that are otherwise technically capable of doing demographic

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



matching for treatment-based use cases hesitate to respond to patient access queries because the risk of penalties for a mismatched disclosure to a non-HIPAA entity is much higher than the risk of penalties for a mismatched disclosure to a HIPAA covered entity.

Feedback from that Workgroup noted the need for federal agencies, including the HHS Office for Civil Rights (OCR), CMS, and the Office of the National Coordinator for Health IT (ONC) to collaborate to:

- 1. Create a standardized way to match identities that would mitigate the risk of fines, fees, and publicity resulting from a mismatched response;*
- 2. Develop guidance that provides consideration for covered entity query responders who return a mismatch to a non-HIPAA entity but otherwise meet certain industry best practices for matching, including standards developed in #1; and/or*
- 3. Develop rules or guidance that extend HIPAA's protections of mismatched disclosures between covered entities to scenarios where a covered entity shares mismatched information with a non-HIPAA entity for a patient access use case.*

Without additional guidance on this topic, the patient access use case will struggle to gain traction on large-scale HINs like TEFCA and Carequality.

We invite CMS to join the Carequality Workgroup discussions to better understand these issues and participate in the formulation of policies that underlie the TEFCA.

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

Carequality supports providing a positive incentive for health care providers to use electronic prior authorization processes, as long as the associated measure can be easily calculated. We also recommend that CMS include an optional, alternative approach 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 national frameworks like Carequality and 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 work with OCR to provide guidance on the role of HIPAA administrative transaction standards in large-scale



national networks. Carequality is prepared to convene a workgroup to develop specifications for exchange for prior authorization via a HIE/HIN and would welcome CMS's involvement.

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 published Carequality FHIR Implementation Guide (IG)² specifies the use of FHIR version 4.0.1 with FHIR US Core Implementation Guide v3.1.0, and points to several additional FHIR IGs from Da Vinci, CARIN, and others for optional use. Our public FHIR Workgroup is currently updating the Carequality FHIR IG for the latest version of US Core and to allow for use of additional FHIR IGs organizations want to support. The IG requires actors to continue to support any capabilities previously supported for Carequality purposes under a particular FHIR Release until support for that FHIR Release has been officially sunset by Carequality, 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?

² [Resources - Carequality](#)



Carequality 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 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)" infographic³, 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

Carequality acknowledges TEFCA's value in the nationwide interoperability infrastructure, particularly as a federally recognized approach to nationwide health information exchange. However, it is important to note that Carequality, which was created through industry consensus and collaboration, has operated as the nation's leading network-to-network trust framework for

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



nearly a decade. These two frameworks share many qualities, including common legal terms, policy requirements, and technical specifications, many of which originated under Carequality.

There will likely be overlap between organizations connected to Carequality and those that connect to TEFCA, and many will have to participate in both initially. We believe these two frameworks can co-exist in the market for a period, but as TEFCA matures, there should be careful consideration to ensure alignment and continuity of nationwide exchange. CMS and ONC should work closely with Carequality and the implementer community to avoid disruption.

Carequality encourages CMS to participate in Carequality Workgroups to help develop the policies and specifications for use cases that have lagged in the private sector (e.g., patient access, payment, healthcare operations, and public health). Advancement of these use cases within Carequality will directly influence the success of such use cases through TEFCA.

- 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?*

The currently published Common Agreement v1⁴ and QTF v1⁵ 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 Roadmap⁶ for TEFCA exchange that describes the planned stages for FHIR availability in TEFCA. Stage 1, or the current state, 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 is based off of the Carequality FHIR Implementation Guide. 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.

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

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



Carequality already supports Stage 2 above—point-point FHIR-based exchange between participants in Carequality—for Carequality Implementers and their customers who choose to utilize Carequality’s FHIR implementation guide (IG), discussed previously.

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.

As noted above, Carequality could support these requirements today. If certain payers wanted to begin exchanging data in support of the CMS proposed requirements today, they could do so via Carequality. This would enhance their readiness when TEFCA does support these requirements.

Further, we recommend that CMS 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 TEFCA⁸.

We encourage CMS to participate in Carequality’s Workgroups to help shape these use cases as they develop within Carequality today. Advancement of these use cases within Carequality will directly influence the success of such use cases through TEFCA.

3. 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. In the initial stages of rollout, care needs to be taken to minimize burden and avoid disruption to current private sector initiatives with the same goals. Carequality is the largest nationwide interoperability framework, exchanging over 350,000,000 documents each month. CMS and ONC should work closely with Carequality and the implementer community to avoid such disruption.

That said, 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

⁸ See the Sequoia Project Comment Letter for details on this proposal.



supports to connect. We encourage CMS to consider how it can best address those needs, with a focus on positive incentives rather than mandates.

We also caution the agency that the roll-out of TEFCA and the implementation of Permitted Purposes beyond Treatment and Individual Access Services will take a deliberate and consultative approach that brings all players along. Therefore, 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. Carequality 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 participate in the Carequality workgroups to shape policymaking that will drive nationwide data sharing.

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

Most respectfully,

A handwritten signature in black ink, appearing to read "Seth Selkow", followed by a long horizontal line extending to the right.

Seth Selkow

Chair, Carequality Board of Directors