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May 11, 2023

Mariann Yeager
Chief Executive Officer
The Sequoia Project – Recognized Coordinating Entity (RCE)

Submitted via e-mail: rce@sequoiaproject.org

RE: Payment and Health Care Operations Standard Operating Procedures

Dear Mariann:

AHIP[1] is writing on behalf of our members to provide feedback on the Trusted Exchange Framework and Common Agreement (TEFCA) Draft Standard Operating Procedures (SOPs) released on April 3, for Payment: Risk Adjustment Exchange Purpose Implementation and Health Care Operations: Limited Exchange Purpose Implementation. While AHIP shared many of these comments during the December 15, 2022 and April 19, 2023 Listening Sessions, we thought it would be helpful to share written feedback.

AHIP has been working with our members to support the launch of TEFCA by offering educational forums and developing comment letters like this one. Working together, nationwide health care interoperability can be realized. To accomplish this, however, the use cases supported by TEFCA must appeal to a broad range of entities including not only health care providers, but also health plans, public health agencies, consumers, clearinghouses, and other integral entities.

Heretofore the focus of TEFCA has been provider-to-provider and provider-to-consumer exchanges for treatment purposes. We concur with that prioritization of initial use cases; however, the logical next step is for health care payment and operations use cases that integrate health plan functions and encourage their participation. In our view, the proposed standard operating procedures (SOP) for Risk Adjustment offers little value for most health plans, and at the same time would create burden and complexity for them. This undermines the use case serving as an entry point for health plan participation and potentially harms the long-term goals of TEFCA. The proposed SOP for Healthcare Operations has more potential for delivering value to health plans but would benefit from further

[1] AHIP is the national association whose members provide coverage for health care and related services to hundreds of millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

clarity and potential narrowing to ensure operational feasibility, generate trust in the how the information will be used, and balance the utility across stakeholders and use cases.

As noted in our previous comments, we strongly support the use of the Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard in implementing TEFCA from the start and are concerned about the timelines articulated in the FHIR® Roadmap for TEFCA Exchange.[2] The Centers for Medicare & Medicaid Services (CMS) Interoperability and Patient Access final rule requires impacted payers to build and maintain FHIR-enabled APIs to share data with stakeholders across the system. Impacted payers are already sharing data with patients via the Patient Access API. CMS has also proposed a compliance date of January 1, 2026, for health insurance providers to support data exchange with providers and other payers via the Provider Access API and Payer-to-Payer API in its Interoperability and Prior Authorization proposed rule. At the same time through a combination of the CMS rules and ONC rules, providers and their vendors must also maintain FHIR-based APIs. The modernized technology is built and should be used. Moreover, the previously released TEFCA FHIR Roadmap does not align with the CMS interoperability initiatives and implementation timelines. Allowing payers to meet these requirements through TEFCA would encourage payer participation and facilitate data exchange for all stakeholders. In our comments below, we outline several alternative use cases the RCE should prioritize that would align with the CMS interoperability rules.

Thank you for the opportunity to provide feedback on the SOPs for Payment and Health Care Operations. We hope that you found our perspectives constructive and helpful. AHIP stands ready to work with you to devise strong, targeted, and valuable use cases to encourage health plan participation in TEFCA. A functioning national network stands to benefit all involved, but most importantly our enrollees.

Sincerely,

Danielle A. Lloyd
SVP, Private Market Innovations & Quality Initiatives
AHIP

[2] https://rce.sequoiaproject.org/wp-content/uploads/2022/01/FHIR-Roadmap-v1.0_updated.pdf

RISK ADJUSTMENT

AHIP is concerned that the SOP for Risk Adjustment associated with health plan payment is not a use case that is beneficial to the broad universe of health plans. There is no risk adjustment for payment purposes for commercial insurance. Qualified Health Plans (QHPs) have a form of plan level risk adjustment associated with the relative costliness of enrollees based on claims data, but not clinical data. While the Affordable Care Act (ACA) Risk Adjustment Data validation audits (HHS-RADV) permitted medical record information to be introduced to support a claim, those provisions were removed as part of the Final 2024 Notice of Benefit and Payment Parameters for the 2022 benefit year and beyond. Thus, the only potential value of sharing clinical information as part of this use case would be for Medicare Advantage Organizations (MAOs) and Medicaid Managed Care Plans (MCOs), which are required to submit diagnoses to CMS and the States, respectively, for the purposes of health plan payment risk adjustment. MAOs are also able to use medical record documentation as support in the Medicare Risk adjustment Data Validation Program (MA- RADV). Thus, the potential benefit would only apply to a subset of health plans nationwide.

At the same time, given the complexity of issues and regulatory changes affecting the Medicare Advantage (MA) risk adjustment program, it is unclear whether MA plans would benefit from this use case or if, in fact, it would lead to added cost, burden and complexity for them. And, for most of other plans, including a Risk Adjustment use case that requires responses to providers offers little value and creates burdens. More broadly, starting with a use case that provides burden and not value for most plans could undermine the shared goal of encouraging health plan participation in TEFCA in both the short and long term. For TEFCA to be optimally effective, health plans need to play an integral role. ***Thus, we recommend that the RCE withdraw the proposed Risk Adjustment SOP and revisit it in the future.***

In the event that the RCE proceeds with this use case, below we provide specific comments on the proposed SOPs.

1. Definitions

Health Care Operations

Given this is the payment use case, it is unclear why “Health Care Operations” is defined. This could be misleading to readers, and it should be removed.

Health Care Provider

The RCE proposes to define “Health Care Provider” using the information blocking regulation definition at 45 CFR §171.102 and the Health Insurance Portability and Accountability Act (HIPAA) definition under 45 CFR §160.103. The two definitions are presented as one or the other, seemingly giving the reader a choice as to which definition to follow. To avoid confusion and differential application, only one definition should apply. Since TEFCA is being structured to incorporate the HIPAA requirements, it would be prudent to select the HIPAA definition unless another definition is necessary to narrow applicability. If two definitions are necessary,

the RCE should provide additional context as to why that is the case in the SOP. ***The RCE should only list the HIPAA definition of Health Care Provider.***

Health Plan and Payor

The SOP lists two different and potentially conflicting definitions. "Health Plan" has the meaning from the HIPAA regulations at 45 CFR §160.103, which is broad, expansive, and lists specific exclusions. The HL7 definition of "Payor" is a "Public or private party which offers and/or administers health insurance plan(s) or coverage and/or pays claims directly or indirectly. Examples include Insurance company, Health Maintenance Organization, Medicare, Third-Party Administrator, Repricer."

Only one definition should apply to avoid confusion and differential application. Since TEFCA is being structured to incorporate the HIPAA requirements, it would be prudent to select the HIPAA definition unless another definition is necessary to narrow the applicability. If two definitions are necessary, the RCE should provide additional context as to why that is the case in the SOP. ***The RCE should only list the HIPAA definition of Health Plan.***

Payment

The RCE proposes to rely on the definition of "Payment" at 45 CFR §164.501, "Risk adjusting amounts due based on enrollee health status and demographic characteristics." As noted above, QHP risk adjustment is predicated on spending not health status or demographic characteristics. This definition, however, would be appropriate for MAOs and MCOs.

However, this definition could also be applicable to Health Care Provider risk adjustment by Health Plans. The Purpose section, as discussed below, suggests that the use case is specific to Health Plan payment. If so, that should be clarified in the definition section.

2. Purpose

The Purpose section describes Risk Adjustment as:

> Risk Adjustment is generally understood to be the statistical processes that take into account the underlying health status and health spending of the individuals in an insurance plan when looking at their health care outcomes or health care costs. Risk adjustment levels the playing field so that health plans are appropriately compensated for taking on high risk patients, which increases access to healthcare for all individuals.

This is generally consistent with the cited definition of "payment" that covers:

> The activities undertaken by: (i) Except as prohibited under § 164.502(a)(5)(i), health plan to obtain premiums, to fulfill their coverage responsibilities and provide benefits under the plan, and to obtain or provide reimbursement for the provision of health care, including risk adjustments.

Together, the definition and purpose seem to support the use case of health plan risk adjustment for payment purposes.

However, the description of risk adjustment within the Purpose Section also includes "health care outcomes," which could be interpreted as referring to quality measurement that also includes forms of risk adjustment. That is not consistent with the HIPAA definition of payment,

but rather the definition for "health care operations," which encompasses "quality assessment and improvement activities." Thus, what is being proposed seems to mix the concepts under HIPAA for payment and healthcare operations and should be clarified to only include health plan payment purposes.

One option is to use a CMS definition[1] that does not include quality measurement to replace the first sentence:

> A way to calculate what to pay a health plan based on a patient's demographics, health, their likely use of health care services and the costs of those services. Risk adjustment levels the playing field so that health plans are appropriately compensated for taking on high risk patients, which increases access to healthcare for all individuals.

In addition, the reliance on the HIPAA payment definition and the inclusion of "healthcare outcomes" in the description also creates confusion over the applicability of the use case to provider payment and/or quality measurement, neither of which are supported by the stated purpose. The cited definition of "payment" also covers the activities of health care providers to obtain reimbursement for the provision of health care from health plans. Within value-based arrangements, for example, health plans may risk adjustment payment benchmarks. However, this is generally done so using claims data and not medical record review. Moreover, sharing information with providers to fill care gaps and properly document would fall under Health Care Operations. ***Thus, the RCE should clarify that this use case is not applicable to provider risk adjustment for payment purposes.***

3. FHIR Roadmap

The SOP states in the FHIR Roadmap section:

> This SOP is limited to the QHIN exchange modalities defined in the QHIN Technical Framework (QTF). The Recognized Coordinating Entity (RCE) recognizes that HL7 Fast Healthcare Interoperability Resources (FHIR) can allow for more dynamic exchange that makes it easier for entities to share data. The RCE intends to update the Common Agreement and QTF and publish the Facilitated FHIR Implementation Guide to enable FHIR-based exchange in alignment with the published FHIR Roadmap3 for TEFCA exchange.

AHIP understands the need to start with the Integrating the Healthcare Enterprise (IHE) profiles for treatment purposes as that standard is already in use for provider network-based health information exchange today. However, we are concerned about building de novo use cases, particularly ones designed for health plan participation, that are not built based on FHIR. Health plans and providers have already built FHIR-based API technologies for a combination of policies in CMS and ONC rules. The HL7 DaVinci Project is currently working on a risk adjustment use case. The use cases should be "skating toward the puck" and harnessing this modernized technology from the start rather than building on the old technology and creating duplicative work to convert to FHIR later. Moreover, using FHIR would better enable the tailoring of data requested and returned to better reflect the specific need. ***If the RCE considers a Risk Adjustment use case in the future, it should not be implemented until it can be built and operated using mature FHIR standards including testing at scale with broad participation.***

[1] https://innovation.cms.gov/key-concept/risk-adjustment

In addition, for the legacy security protocols, the industry must ensure dynamic registration and security by shifting to Unified Data Access Profiles (UDAP). This will assist in reusing digital identities that support data exchange, thereby ensuring trust by allowing for digital identification of parties and support future API adoption.

The SOP also references CMS rulemaking:

> The RCE will update this SOP in accordance with those specifications and align the updates with the API requirements in the Centers for Medicare and Medicaid Services (CMS) Advancing Interoperability and Improving Prior Authorization Processes Final Rule, which, as of March 2023, is a proposed rule. Additionally, the RCE intends to require a Response to this Exchange Purpose in coordination with the updates to incorporate FHIR.

It is unclear why this rule is referenced in the Risk Adjustment SOP. That particular rule does not address risk adjustment whether health plan, provider, payment or quality assessment. ***The RCE should remove the mention of the CMS rule to avoid confusion.***

4. Risk Adjustment Definition

The SOP states that "Risk Adjustment means the following: Risk adjusting amounts due based on individual and/or enrollee health status and demographic characteristics." Both MAOs[2] and MCOs[3] rely on "health status" as part of risk adjustment. AHIP assumes that diagnosis was meant to fall under "health status," however, it may be worth calling it out given it is a critical driver of risk adjustment, it is under a different data class within the USCDI, and health status can refer to other factors such as functional status. Consistent with the proposed definition, the remaining factors used for MAOs could be described as demographic factors: Age, Sex, Socioeconomic status, Disability status, Medicaid eligibility, and Institutional status. However, under Medicaid, states may also allow submission of National Drug Codes for certain medications administered to Medicaid enrollees to justify risk adjustments. Medications are also under a different data class within the USCDI. ***The RCE should consider expanding the definition to include "diagnoses, health status, medication use, and demographic characteristics" or alternatively add "factors such as."***

5. Permitted Actors

The draft SOP Permitted Actors section states:

> Only Health Plans and Health Care Providers may request TEFCA Information for the purpose of Risk Adjustment. QHINs, Participants and Subparticipants MUST use the code RISKADJ when initiating a QHIN Query or QHIN Message Delivery for Risk Adjustment.

It is not clear why the Health Care Operations SOP also includes "that are Covered Entities" after "Providers" and this one does not. The RCE should clarify why it would be needed in one context and not the other. Moreover, it is not clear why Business Associates are not explicitly

[2] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-G/section-422.308
[3] https://www.macpac.gov/wp-content/uploads/2022/03/Managed-care-capitation-issue-brief.pdf

granted eligibility to make requests on behalf of covered entities given they are already subject to HIPAA requirements. ***The RCE should add "(or their Business Associates, agents, or contractors)" to the Permitted Actors after "Providers."***

If the use case is specific to plan risk adjustment for payment purposes, it is unclear why a provider would be a requestor. It would be a health plan requesting information from a provider whether it is for plan payment or provider payment. Moreover, as noted above, provider risk adjustment is not part of the stated purpose and is generally based on claims data not medical record information. ***We recommend that the RCE remove providers as permitted requestors.***

The proposed SOP also requires the use of RISKADJ code as part of this request and response. Both payment and operations under HIPAA are governed by the notion of the "minimum necessary" information being shared and thus specificity around the purpose is wise. This will help health plans and providers retain documentation and conduct audits to ensure data is being shared for appropriate purposes with appropriate parties under HIPAA and other laws and regulations. ***We support requiring a code to indicate the use but suggest the RCE modify the code to HPRISKADJ for clarity of purpose and PRISKADJ if provider level risk adjustment is added to the purpose.***

6. Procedure

6.1 The QHIN Query Request

(b) Requestor Identifying Information

Under Requestor Identifying Information the text states:

> i If the Request is originating from a Health Care Provider, it MUST include:
>
> 1. the Health Care Provider's individual or organizational NPI and/or TIN, as applicable; and
> 2. the Health Care Provider organization's RCE Directory HomeCommunity.ID.

As stated above, only health plans should be able to request such data under this particular use case given its stated purpose of health plan risk adjustment. Even if provider risk adjustment is added, health plans would still be the only requestors. ***The RCE should remove Providers as requestors and make conforming changes to the remaining text.***

(c) Patient Identifying Information

Similarly, under Patient Identifying Information, under ii) the text again notes "If the request originates from a Health Plan…," when only health plans should be requestors. ***The RCE should make conforming changes by combining the two bullets and ensuring it is clear that only health plans may be requestors.***

6.2 QHIN Query Response

(b) Health Care Provider Response

It is unclear why the draft SOP says actors "SHOULD" respond and then uses "If" a Health Care Provider responds. If the Health Care Provider has relevant information, it should be required to respond. Otherwise, the benefit of the SOP is unclear, and providers could simply not reply to any plan requests. ***The* RCE *should modify the language from "SHOULD" to "MUST" such that Health Care Provider responses are required if a health plan makes a request.***

In addition, the draft SOP outlines that, if a Health Care Provider responds, it should do so with the specific elements of the USCDI The RCE does not propose to include all the data classes and elements of the USCDI, but rather a subset from v2 and v3. AHIP appreciates this considering the "minimum necessary" standards under HIPAA. This list, however, still exceeds the information health plans are permitted to use for risk adjustment purposes. For example, vital signs and lab test results are not permissible as justification. The key components are the following data classes: Clinical Notes, Encounter Information, Health Status Assessments, Problems, Provenance, Medications, and Patient Demographics. For all these classes except Health Status Assessments, the RCE proposes to use v.2 even though ONC (and CMS by reference) currently names v.1 in its regulations and proposes to name v.3 in its pending proposed rule. It would be more appropriate to align with the SVAP process and name v.3 that has the updated value sets referenced. Our members would be happy to work with the RCE to identify the necessary classes and elements should be included based on whichever version is selected. ***The RCE should require only the data classes that can be used for health plan risk adjustment and align with the most recent version ONC finalizes as part of their ongoing rulemaking.***

(c) Health Plan Response

Per our earlier comments, for this particular use case, only health plans should be requestors and only health care providers should be responders. ***The RCE should remove subsection (c) from this section.***

In addition, sending claims data to Health Care Providers is completely inconsistent with the stated purpose of health plan risk adjustment. Even if the RCE choses to include Health Care Provider risk adjustment, that again is providers furnishing data to health plans not the other way around. And, again, sharing population level claims files with providers is for quality measurement and assessment, which is part of operations not payment. Moreover, sharing population health data files between health plans and providers is part of CMS' Interoperability and Prior Authorization proposed rule as a FHIR-based API exchange. ***The RCE should exclude the sharing of adjudicated claims data in its Risk Adjustment use case and instead consider it as part of its Health Care Operations use case once the final rule is published and the FHIR standards and IG are tested and mature.***

(d) Social Determinants of Health (SDOH)

The SOP states that Query Responders MUST include SDOH ICD-10-CM encounter reason codes ("Z-Codes"), if available. While AHIP has advocated for the standardization, collection, and sharing of SDOH data to reduce health disparities, these factors are not used for health plan

risk adjustment for payment purposes. Even in those federal programs that are newly adjusting aspects of payment within provider value-based arrangements for SDOH, they are using the area deprivation index—not individual social needs.[4] However, this information is critical to quality measurement and care improvement. ***The RCE should remove SDOH data from the Risk Adjustment SOP and maintain it in the Health Care Operations use case.***

6.3 RCE Directory Service

The SOP states:

> A Payor that is a QHIN, Participant, or Subparticipant listed in the RCE Directory Service MUST publish all of its participating Health Plans to the RCE Directory Service in order to identify the source of a Request as required in Section 6.1(b)(ii) of the SOP.

Up-to-date directories have long been a problem in health care, and AHIP recognizes that an accurate directory of digital endpoints is critical for the functioning of TEFCA. Thus, we appreciate the RCE's efforts to collect this information from participants. However, we believe to truly solve this it will take a national public private partnership. A TEFCA solution is necessary, but not sufficient. We note that CMS earlier this year put out a Request for Information (RFI) addressing the potential for a National Directory of Healthcare Providers & Services that could serve as a "centralized data hub" for health care provider, facility, and entity directory information nationwide. Thus, we hope that the RCE will be a vocal participant in any upcoming rulemaking undertaken by CMS.

Furthermore, we do not recommend defining requirements applicable to the RCE Directories in these SOPs. This would reduce confusion and streamline the SOPs. ***Instead, the RCE should include requirements related to the RCE Directory Service be defined in the "RCE Directory Service Implementation Guide."***

[4] https://www.cms.gov/newsroom/fact-sheets/accountable-care-organization-aco-realizing-equity-access-and-community-health-reach-model

HEALTH CARE OPERATIONS

AHIP believes the Health Care Operations use case shows more promise than the Risk Adjustment use case for encouraging health plan engagement.

1. Definitions

Health Care Operations

The SOP defines "health care operations" as having:

> …the meaning assigned to such term at 45 CFR section 164.501, except that this term shall apply to the applicable activities of a Health Care Provider regardless of whether the Health Care Provider is a Covered Entity.

AHIP supports aligning the terms and policies within TEFCA with HIPAA. However, this statement is confusing. Almost all "providers" are already subject to HIPAA, so it is unclear which individuals or entities would be added to the definition by this statement as drafted. Significant health care data is being collected, used, stored, and sold outside of HIPAA by third-party application developers that may, at some point, want to join TEFCA. To protect consumers, we agree that these entities should be bound by HIPAA through the governance documents to participate, but these entities are not and should not be described as "providers" if that was the intent. ***The RCE should create another definition to describe the entities outside of HIPAA to whom or from whom data might be obtained as part of TEFCA.***

Health Care Provider

The RCE proposes to define "Health Care Provider" using the information blocking regulation definition at 45 CFR §171.102 and HIPAA definition at 45 CFR §160.103. We note that that the two definitions are presented as one *or* the other seemingly giving the reader the choice as to which definition to follow. AHIP believes that only one definition should apply to avoid confusion and differential application. In our opinion, since TEFCA is being structured to incorporate the HIPAA requirements, it would be prudent to select the HIPAA definition unless another definition is necessary to narrow the applicability. If two definitions are necessary, the RCE should provide additional context as to why that is the case in the SOP. ***The RCE should only list the HIPAA definition of Health Care Provider.***

Health Plan and Payor

The SOP lists two different and potentially conflicting definitions. "Health Plan" has the meaning from HIPAA 45 CFR §160.103, which is broad, expansive, and lists specific exclusions. The HL7 definition of "Payor" is a "Public or private party which offers and/or administers health insurance plan(s) or coverage and/or pays claims directly or indirectly. Examples include Insurance company, Health Maintenance Organization, Medicare, Third-Party Administrator, Repricer."

AHIP believes that only one definition should apply to avoid confusion and differential application. In our opinion, since TEFCA is being structured to incorporate the HIPAA requirements, it would be prudent to select the HIPAA definition unless another definition is

necessary to narrow the applicability. If two definitions are necessary, the RCE should provide additional context as to why that is the case in the SOP. ***The RCE should only list the HIPAA definition of Health Plan.***

2. Purpose

The stated purpose of the use case in the SOP is:

> Use and disclosure of health information for the purpose of HCO Limited is an important tool for health care providers, health plans, and other healthcare stakeholders to support the core functions of their business and efficiently and effectively care for the individuals they serve. Use cases under this HCO Limited Exchange Purpose, including quality assessment and improvement and care management, allow stakeholders to enhance the quality of care provided, reduce healthcare spending, and improve health outcomes, while still protecting the privacy of individuals.

AHIP supports the Health Care Operations use case as a priority in the roll out of TEFCA. We believe all stakeholders support the goal of data sharing to support delivery system transformation leading to improved health outcomes and reduced overall spending. However, as we will discuss more below, the way in which the RCE has proposed to narrow the scope in the definitions section works against the goal of using the use case as a means of encouraging health plan participation in TEFCA. Furthermore, it is unclear whether this is specifically confined to payer and provider exchanges or whether payer-to-payer exchanges would also qualify. ***The RCE should specify in the final SOPs that this would apply to payer-to-provider, provider-to-payer, and payer-to-payer exchanges for Health Care Operations purposes.***

3. FHIR Roadmap

The SOP states:

> This SOP is limited to the QHIN exchange modalities defined in the QHIN Technical Framework (QTF). The Recognized Coordinating Entity (RCE) recognizes that HL7 Fast Healthcare Interoperability Resources (FHIR) can allow for more dynamic exchange that makes it easier for entities to share data. The RCE intends to update the Common Agreement and QTF and publish the Facilitated FHIR Implementation Guide to enable FHIR-based exchange in alignment with the published FHIR Roadmap for TEFCA exchange. The RCE will update this SOP in accordance with those specifications and align the updates with the API requirements in the Centers for Medicare and Medicaid Services (CMS) Advancing Interoperability and Improving Prior Authorization Processes Final Rule, which, as of March 2023 is a proposed rule. Additionally, the RCE intends to require a Response to this Exchange Purpose in coordination with the updates to incorporate FHIR.

The timelines outlined in the previously released TEFCA FHIR Roadmap raise significant concerns. CMS proposed an implementation data of January 1, 2026 in the Interoperability and Prior Authorization proposed rule for the Provider Access API and the Payer-to-Payer API, both of which we believe fall under this use case. These APIs would be FHIR-enabled and require impacted payers to exchange claims and clinical information (as defined by USCDI v1 as of now). Given the availability of recommended IGs, it makes the most operational sense for payers to build these resources in FHIR to meet the CMS requirements, rather than convert to FHIR later. AHIP recommends accelerating the adoption of FHIR-enabled exchange through TEFCA, as this would allow impacted payers to leverage the network to meet CMS Interoperability final

rule requirements. Prioritizing allowing the exchange of FHIR resources through the Health Care Operations SOP would align with current CMS requirements on impacted payers, providing a clear benefit to TEFCA participation. Moreover, using FHIR would better enable the tailoring of data requested and returned to better reflect the specific need. ***Thus, AHIP strongly recommends that this use case needs to be built from the start using the FHIR standard and aligned with CMS' final rulemaking.***

4. Health Care Operations: Limited Definition

The SOP sets forth the following limited definition of Health Care Operations for the purposes of this use case:

> Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.

"Health care operations," as defined in 45 CFR §164.501,[5] are certain administrative, financial, legal, and quality improvement activities of a covered entity that are necessary to run its business and to support the core functions of treatment and payment. While the full HIPPA definition is referenced here and in the definitions section, the activities listed here are only one of five types of activities outlined in the HIPAA definition— as suggested by the title including "Limited Definition." Specifically, it removes, evaluating provider performance, program integrity evaluations, and administrative functions.

For example, under the limited definition proposed for the use case, payers would not be permitted to request data for the purposes of reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, and health plan performance. Assessing provider performance is a key area for health plans, and it is one where TEFCA could help improve quality and reduce clinician burden through aligned measurement consistent with the multistakeholder work of the Core Quality Measure Collaborative (CQMC), which is a public private partnership between CMS and AHIP. As another example, having the medical record information to use in support of National Committee on Quality Assurance Healthcare Effectiveness Data and Information Set (HEDIS) measurement would be of great value to health plans and would contribute to the safety, quality, and affordability of care. However, such activities are included in evaluating health plan performance, which is — absent from the current, limited definition proposed for the use case.

The exclusions from the proposed definition have the practical effect of focusing on the portions of the definition that will have the most significant, positive impact provider operations and excluding of the portions that would have the most significant, positive impact on health plan operations. ***The RCE should either include the full scope of operations or narrow it to a very specific set of use cases that provide a balanced set of positive impacts on both provider and health plan operations.***

One potential way to narrow the scope would be to follow an approach consistent with the HL7 CDex IG.

1. **Bulk retrieval**—used to obtain recent claims and/or clinical history on certain patients. This could be used for new enrollees to a health plan gain the historical claim data from another plan or clinical data from providers. Or, for newly assigned beneficiaries to value-based care arrangements to obtain claims data from health plans and clinical data from providers. This could be structured to meet the obligations of plans in federal programs under the CMS Interoperability and Prior Authorization proposed rule's Payer-to-Provider API for the sharing of health data files and/or Payer-to-Payer API to share claims, clinical, and prior authorization data depending on how the rule is finalized.

2. **Encounter data**—used to obtain ongoing data feeds for health plans creating longitudinal health records for their enrollees or for assigned patients as part of value-based care arrangements to support operational and care improvements. For example, admit, discharge, transfer data can be key to health plans and accountable providers alike for managing a population's health.

3. **On demand**—for those health plans that do not store longitudinal health records, an ability to call for specific reports is important. As an example, quality measures could be run from provider data where the plan would only land the results to their systems (not the whole dataset). Or, even for those that do, there may be specific requests outside the other two flows of data at different time intervals. As an example, specific records could be requested to support NCQA quality measure audits. As another example, records or specific elements could be requested to satisfy provider quality reporting requirements and care delivery recommendations for closing care gaps and/or medication reconciliation could be returned. AHIP recommends this be for a very narrow set of purposes such as quality measurement, patient demographic data, and social determinants of health data—all areas there is likely support among providers and health plans— to balance utility across stakeholders, engender trust, and encourage participation.

We welcome the opportunity to work with the RCE to further flesh out these rubrics or develop a new way to the narrow the scope of the use case in a way that balances burden and value and yet can be expanded upon at a future date.

5. Permitted Actors

The SOP states that "Only Health Plans and Health Care Providers that are Covered Entities may request TEFCA Information for the purpose of HCO Limited." It is unclear why then the Health Care Operations definition in the definitions of section 1 includes "…regardless of whether the Health Care Provider is a Covered Entity" if no non-covered entities are included in the use case. If the intent is to add individuals or entities outside of HIPAA, those entities should be clearly defined and justified as to their inclusion. Moreover, it is not clear why Business Associates are not explicitly granted eligibility to make requests on behalf of covered entities given they are

already subject to HIPAA requirements. ***The RCE should add "(or their Business Associates, agents, or contractors)" to the Permitted Actors after "Providers."***

The SOP also states that "QHINs, Participants and Subparticipants MUST use the code HCOLTD6 when initiating a QHIN Query or QHIN Message Delivery for the HCO Limited Exchange Purpose." Given the HIPAA standard of "minimum necessary" governs Health Care Operations, more codes should be included to permit documentation, tracking and monitoring of how the data are used by actors. So, for example, using the proposed rubrics above there could be different codes for Bulk retrieval, Encounter data, Quality, and SDOH.

6. Procedure

6.1 QHIN Query Request

It is not clear why the health plan has to provide the Member/Subscriber ID when requesting data, but the provider does not. This would be useful information for patient matching in either direction.

6.2 QHIN Query Response

We recommend the SOP include an expected timeframe in which QHINs, Participants, and Subparticipants should respond to queries for this purpose so that the organization can plan accordingly. This could be included under both subsection (b) and (c) to apply to both providers and health plans.

For the purposes described in the Health Care Operations draft use case, we agree that it is justifiable to request the entire USCDI. Although, if the RCE significantly narrows the scope to, for example, only patient demographics and social determinants of health data, as we discuss in alternatives, it may not be justifiable to share the entire USCDI under the "minimum necessary" standard under HIPAA. Thus, the RCE will need to consider the scope of the data based on the final purpose. We are, however, unclear why the RCE would require v.2 of the USCDI for only the Encounter data class. ***The RCE should tailor the scope of the data to the final stated purpose and should require the most recent version of the USCDI the ONC finalizes as part of their ongoing rulemaking.***

The draft SOP also states that "[f]or any Social Determinants of Health (SDOH) data elements, Query Responder MUST include the SDOH Z CD-10-CM SDOH encounter reason codes ("Z-Codes"), if available." AHIP agrees that sharing information on social determinants of health could be beneficial to health care operations. Better data and data flow could assist with the provision of clinical care, such as assisting a patient without social supports during transitions of care or connecting a patient with resources in their community to address social needs that could impact medical care.

While requiring the sharing of Z-Codes could be beneficial, this information can be captured on health care claims today. The current challenges to obtaining Z-Codes are related to limited provider use of these codes, rather than the lack of a mechanism to exchange the data. More

importantly, there are other forms of SDOH data that cannot be exchanged via claims that are captured in the electronic health records and that could be shared within Healthcare Operations SOP.

NCQA is increasingly relying on Logical Observation Identifiers Names and Codes (LOINC) in their electronic clinical data system (ECDS) measures. NCQA's Social Need Screening and Intervention (SNS-E) measure uses LOINC codes to capture a person's responses on a series of screening questions on food, housing, and transportation security. This data can be challenging to exchange with providers who may be responsible for screening patients and health plans who are being assessed on the number of members screened and offered an intervention if necessary. Despite the data challenges, NCQA has added this measure to the HEDIS, and CMS has proposed it for use in the QHP Quality Rating System. Including the exchange of LOINC codes in this SOP would allow for more accurate measurement of health plan performance and reduce the burden on consumers who may be continually asked to report data.

Better data on patient demographics would also support health care operations. Health plans and regulatory bodies such as CMS and NCQA are increasingly interested in stratifying performance measures to identify and address health care disparities. Robust, accurate, actionable, and standardized demographic patient data is fundamental to advancing health equity and improving health outcomes. Accurate, complete, and interoperable data is necessary to effectively and efficiently detect disparities, inform effective solutions that take cultural preferences and socioeconomic circumstances into account, and assess what interventions are most impactful. Requiring responses to include demographic data aligned with the Office of Management and Budget's (OMB) standards could facilitate the detection of disparities and actions to reduce them.

While Z codes are an important step in the exchange of information on SDOH, work is still needed to fill in gaps in coding around social risks, whether building out or refining structured data on social risks (e.g., ICD-10 Z codes, LOINC codes, SNOMED codes) or building out codes to document the services that are provided to mitigate social risks (e.g., HCPCS codes and CPT codes). Standardized values are also needed to understand to what degree or magnitude there is a social risk need so that it can be addressed and interpreted similarly by all entities. ONC and the RCE could look to the to the Gravity Project[6] for standardized value sets, interoperable codes, and HL7 technical standards to document standardized data on social needs. Interoperable codes could include ICD-10 Z codes, LOINC codes, SNOMED codes, among others. Expanding the query response to align with the work of the Gravity Project could provide more complete and nuanced information on a person's social risks and needs.

6.3 RCE Directory Service

The SOP states:

[6] https://thegravityproject.net/

> A Payor that is a QHIN, Participant, or Subparticipant listed in the RCE Directory Service MUST publish all of its participating Health Plans to the RCE Directory Service in order to identify the source of a Request as required in Section 6.1(b)(ii) of this document.

Up-to-date directories have long been a problem in health care, and AHIP recognizes that an accurate directory of digital endpoints is critical for the functioning of TEFCA. Thus, we appreciate the RCE's efforts to collect this information from participants. However, we believe to truly solve this it will take a national public private partnership. A TEFCA solution is necessary, but not sufficient. We note that CMS earlier this year put out a Request for Information (RFI) addressing the potential for a National Directory of Healthcare Providers & Services that could serve as a "centralized data hub" for health care provider, facility, and entity directory information nationwide. Thus, we hope that the RCE will be a vocal participant in any upcoming rulemaking undertaken by CMS.

Furthermore, we do not recommend defining requirements applicable to the RCE Directories in these SOPs. This would reduce confusion and streamline the SOPs. ***Instead, the RCE should include requirements related to the RCE Directory Service be defined in the "RCE Directory Service Implementation Guide."***

ALTERNATIVES

As noted, AHIP remains concerned that overly broad use cases may create distrust early on in TEFCA's life cycle. At the same time, overly narrow use cases that do not balance utility across stakeholders will not serve to encourage broad participation. Below we suggest some use cases where health plans and providers would both see benefits and are of a size that building out mature FHIR standards in a reasonable time frame would be achievable as much of it is already underway. We note that each of these could be reasonably defined to be included in the Health Care Operations use case.

Admit, Discharge, Transfer

A good place to start would be a use case that is relatively simple and straight forward to get participants signed up, connected, and testing the system as well as build trust. One option that would benefit health plan operations are Admit/Discharge/Transfer (ADT) alerts from providers. As part of the Interoperability and Patient Access rule as well as the Information Blocking rule, providers must make ADT alerts available to other providers. However, they are not required to share such information with payers. Even if they were required, this would be difficult to achieve outside of TEFCA given the lack of a payer directory.

Knowing these key steps in a patient's inpatient care journey would enable health insurance providers to better assist in care coordination and follow-up. This is a known point when errors and communication breakdowns occur, and health insurance providers are uniquely positioned to intervene in these situations to ensure enrollees receive coordinated care across settings and over time. Real-time alerts would allow health plan to intervene in a timely fashion and facilitate providing pertinent and valuable clinical decision support information to providers as discussed below.

Given the technological infrastructure is already built, this would be a marginal addition for Certified Electronic Health Record (CEHRT) vendors to build and providers to adopt.

Quality Measurement and Population Health

The ultimate goal of information sharing is to improve health and healthcare for consumers. TEFCA could enable plans and providers to seamlessly share information to support the provision of high-quality care by supporting population health management, improving care coordination, and enabling better quality measurement. The electronic, bidirectional sharing of clinical information is one of the most-promising opportunities for using TEFCA. Accessing data would be faster, easier, cheaper, and more comprehensive. By facilitating the exchange of clinical data, TEFCA could allow health plans to better support providers in the provision of patient care.

First, clinical information from providers could be combined with health plan claims data to create population health management dashboards with actionable information for providers to improve care and outcomes. This data would allow providers to understand if their patients are up to date on necessary screenings and other preventative care and facilitate better chronic disease management. Health plans could also use this data to support their own case management efforts and better coordinate care. Plans have a unique, longitudinal view of a person's care and access to real-time, enhanced clinical data would better equip them to assist their members during transitions between providers.

Second, TEFCA could also facilitate the process of quality measurement. Quality measurement is crucial to understanding performance and driving improvements; however, currently it is burdensome on all parties to collect, report, collate, and analyze the necessary data. Technology holds promise to reduce the burden of reporting quality data while enhancing the information on quality available to all stakeholders. The interoperable exchange of digital quality measures (dQMs) can reduce the time and resources required to extract data from patient charts or other forms such as the surveys used to generate patient-reported outcome measures. It can also facilitate the collection of the information and the return of clinical decision support as part of the workflow.

ONC has launched the USCDI plus initiative to identify the data elements necessary to report dQMs. AHIP and CMS have partnered to convene the CQMC to identify the current measures that should be prioritized for transformation to dQMs and is working to cross walk these measures to specific FHIR resources. A quality measurement use case could build on these efforts to accelerate the transition to digital measurement by allowing effective, secure and efficient access to such clinical data for quality measurement and reporting from the "source" (i.e., the Electronic Healthy Record (EHR)).

The DaVinci Project is actively working on the Data Exchange for Quality Measures Implementation Guide, or DEQM, which provides a framework that defines conformance profiles and guidance to enable the exchange of quality information and quality measure reporting (e.g., for transferring quality information from a health care provider to a payer). The DEQM expects to use quality measures specified in accordance with the Quality Measure IG and QI-Core. This foundation could be built upon for a robust Health Care Operations use case.

Payer-to-Payer Exchange

Interoperability holds great promise for health insurance providers to facilitate better care for members and to take a more active role in care coordination. The payer-to-payer exchange required in the CMS Interoperability rules specifically provides the opportunity to diminish potential disruptions for consumers changing plans and to help ensure continuity of care. However, sharing large amounts of unnecessary data can have the opposite effect, requiring the new health insurance provider to sift through (and store) large amounts of irrelevant information looking for the facts necessary to effectively deliver benefits and care. Moreover, the technological infrastructure required to support the exchange is currently lacking. For example, there are not currently ways to easily match patients across payers, obtain consent for the exchange of data, and locate another payer's digital endpoints. By sending data through QHINs, payers would not have to build out extensive point-to-point connections, making the payer-to-payer data exchange more efficient and reducing the burden of implementation. This could also alleviate some of the technical challenges outlined below such as a lack of digital endpoints and accurate patient matching.

Prior Authorization

Another opportunity for increased efficiency that can be realized through the use of TEFCA is executing Prior Authorization transactions with providers. AHIP recognizes that this would require shifting from current standards (i.e., X12 278, 275 transactions) to FHIR-based solutions. As you are aware, AHIP has supported the migration to FHIR while being sensitive to the fact that some entities have not yet implemented transactions utilizing FHIR. In addition, while your team is still working on a roadmap to incorporate FHIR in its approach to TEFCA, it appears that is not going to be available from the start. TEFCA must implement facilitated FHIR capabilities quickly in order to be more consistent with current and proposed CMS regulatory requirements for other health plan implementations of FHIR-based APIs for information sharing. Additionally, we note that CMS would need to allow FHIR to be used for Prior Authorization (i.e., the only current standard permitted is the X12 standards) and such a change will take time as regulations would need to be developed, education performed, testing completed, and other processes.

The submission by providers to health plans and payers of supplemental clinical documentation in support of a health care claim is another potential area of value application of TEFCA for health plans and payers, although this would require the adoption of attachment standards, currently being considered in a recently released CMS proposed rule. We are hopeful that this will be a significant development that will yield higher value and greater efficiencies within the health care system.