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March 13, 2023

Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

The Electronic Health Record (EHR) Association is pleased to provide feedback in support of CMS efforts to improve the electronic exchange of healthcare data and drive healthcare interoperability.

As a national trade association of EHR developers, EHR Association member companies serve the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable, and secure health information technology.

In our letter sent to Administrator Brooks-LaSure on February 9, 2023, we strongly urged CMS to extend the deadline for comments on the CMS Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule (file code CMS-0057-P) to allow stakeholders to review and consider ONC's proposed regulation that will address several of the same concepts as those proposed by CMS. Closing the CMS comment period before ONC's proposed Patient Engagement, Information Sharing, and Public Health Interoperability rule is released means the industry is unable to compare and comment on any contradictory and insufficiently harmonized requirements, which will in turn cause unnecessary burden and duplicative work. For example, portions of the proposed CMS rule recommend workflows for prior authorization which require multiple parties (payers, regulated by CMS and providers, regulated by ONC) to support the two ends of the workflow. If any of the specifications for each party are in conflict, this bi-directional exchange across multiple health IT on all sides will not be successful. Therefore, the EHR Association recommends that CMS open a second comment period once the ONC NPRM is released to allow all stakeholders to revise comments as necessary.

On behalf of our 30 member companies, we appreciate the opportunity to once again lend industry insights and expertise to CMS rulemaking. We offer the following additional comments regarding the Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule (file code CMS-0057-P).

Sincerely,

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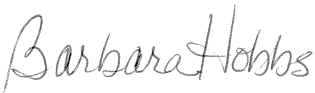

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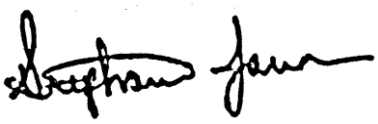

Stephanie Jamison
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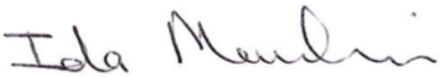

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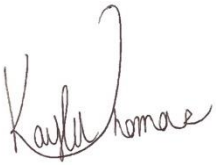

Kayla Thomas
Oracle Cerner

Established in 2004, the Electronic Health Record (EHR) Association is comprised of 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

The EHR Association appreciates CMS's focus on Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization API use cases and advancing their use of common, HL7 FHIR-based standards and implementations. The HL7 FHIR-based standards and implementation guides promote a level of consistency in terms of format, structure, and vocabulary, as well as allow for a variety of interoperability paradigms that best suit the interaction requirements between providers, payers, and patients.

However, we believe it is important that CMS guidance on the use of specific HL7 FHIR-based standards and implementation guide versions align with those promulgated by ONC through its Certification Program, including the Standards Version Advancement Process (SVAP). We largely agree with the choice of standards identified in Table 10 that would outline requirements for the implementation of either of the four API sets. We also appreciate the choice of prior authorization-specific implementation guides that should be used to support the prior authorization workflow, as the progression of the necessary expansion and maturation of these guides should occur before mandating their use. Further, potential certification related to well-defined standards and guidance should be considered.

Proposed standards requirements reflect the current versions in place for the ONC Cures Update Certification Program. Because ONC is expected to provide a more current set of versions for its next Certification Program update, it is imperative that CMS requirements and adoption timelines remain in sync with ONC's progression. We suggest that CMS uses a more general reference to ONC's Certification Program and SVAP to enable ongoing alignment with base and voluntary versions and the timelines by which they must or may be adopted by health IT participants in ONC's Certification Program and/or CMS programs.

Patient Access APIs

The EHR Association recommends that requiring publication of API endpoints – the digital location where an API receives requests or updates about a specific resource on its server – should be clarified. Providing endpoint information to patients, providers, and the developers of patient-focused technologies is important to facilitate establishing connections as easily as possible.

Provider Access APIs

Out-of-network providers are omitted from the proposed Provider Access API requirements, though they have identical needs to access their patients' records. The EHR Association suggests extending the same requirements to out-of-network providers, following the same process requirements for patient consent and attribution lists.

Privacy rules and the management of patient consent directives, particularly across jurisdictions, are complex. Additional input is needed to determine the appropriate purposes of use under which data should be shared, expectations regarding how that data is further used, and what level of patient

consent is necessary. It should be noted that the industry is not yet capable of the more complex rules of consent that may be needed, lacking adequate data segmentation standards and the infrastructure to document, manage, and access up-to-date privacy policy rules and patient consent directives to assess data sharing authorizations. Projects with great promise are in process but are not mature enough to advance requirements beyond a simple opt-in and opt-out, sharing all or nothing. The EHR Association urges CMS to work with ONC and industry stakeholders to advance these capabilities to enable providers and payers to provide patients with the tools to manage access to their data.

Payer-to-Payer APIs

We note that the continuity of authorized items and services is important to support the continuity of care and provide assurances to the patient their care can progress even as they change insurance plans while in the midst of critical, in-progress care, particularly for chronic diseases. We recognize this may introduce complexities at this stage but suggest this topic must be addressed to determine what, if any, changes are needed to support the continuity of authorizations across the various health IT systems.

Prior Authorization APIs

As noted, we await the ONC proposed rule addressing some of the concepts CMS has included within this NPRM. While we don't know what will ultimately be included in their proposed rule, we do point out that in our feedback to ONC's ePA RFI, we emphasized the maturation of the suggested implementation guides. We will describe this feedback further in the Standards and Implementation Guides section below.

EHRs are not the only health IT solution a provider would rely on to contribute to the proposed prior authorization workflow. A prior authorization process may be initiated in a scheduling system, practice management system, or the EHR. Meanwhile, other relevant data necessary to support the prior authorization may be located in different systems, and the prior authorization request will need to be shared with revenue cycle/patient accounting systems that require the authorization reference to produce a complete claim.

We note that various FHIR-based apps (whether as a standalone or within one of the involved health IT components) are emerging to enable cross-system prior authorization workflow orchestration. This clearly indicates the need for a set of well-defined implementation guides that support a well-orchestrated flow across multiple systems within a provider's health IT configuration, sometimes including those developed by varying health IT suppliers.

Standards and Implementation Guides

In that context, the recommended implementation guides for prior authorization support provide a reasonable starting point for the implementation of HL7 FHIR-based APIs in support of the many facets of the prior authorization process. As indicated in our response to the ONC RFI on Prior Authorization (EHR Association Comments to ONC on the ePrior Auth Request for Information) and as furthermore addressed in the HITAC's e-Prior Authorization Request for Information Task Force 2022 Transmittal Letter, the guides are not yet fully mature and do not sufficiently address the relevant health IT modularity and interactions necessary to enable the diverse configurations within payer and provider

organizations. Although the current guides are informative for establishing complementary APIs among participating modules, they are not robust or granular enough to support a practical certification process associated with the modular health IT configuration typically seen in many provider organizations.

Thus, the EHR Association appreciates that CMS has identified the guides as strongly suggested at this time, rather than required. This aligns with our recommendations to initially focus on payers as their workflows expose what APIs are necessary, while also providing the flexibility for software developers to address how best to do so within existing health IT configurations.

We suggest CMS further emphasize that the use of the guides is not limited to "literal" use, but also "interpretive" use to model interactions within the respective health IT configuration in a way that is illustrative rather than prescriptive. This will help to promote continuity and consistency of common standards across all participants in the prior authorization workflow.

The EHR Association urges CMS to consider the inclusion of the Da Vinci Clinical Data Exchange (CDex) Implementation Guide in the set of suggested implementation guides once it is published. We are concerned that the Health Care Attachment NPRM (which includes prior authorization attachments) proposes X12 standards that support only document-based attachments, while the HL7 FHIR-based prior authorization guidance aims to support small data sets that would be communicated without the need for documents. Providing an optimal prior authorization workflow in which only limited data may be necessary should not be encumbered by including documents that are larger than necessary and in a format inconsistent with all other aspects of the workflow. The Da Vinci CDex Implementation Guide would enable both variations, thus providing a more flexible and suitable exchange approach, and CMS should include it.

Staged Implementation

We recognize the challenges of staging the introduction of prior authorization capabilities for a limited but growing set of applicable items and services. The EHR Association agrees that payers should support all items and services able to be supported by ePA while providers have the flexibility to stage their adoption, as recognized in the MIPS Promoting Interoperability measure proposal, to support a smooth transition from the current, manual process to a full ePA workflow.

MIPS Promoting Interoperability

The EHR Association asks that CMS clarify that an eligible clinician using the prior authorization request to connect to the PARDD API is not required to use all capabilities (i.e., CRD, DTR, and PAS-based APIs) in order to meet the numerator qualification necessary to attest "Yes" to using the PARDD API at least once during the eligible clinician's reporting period, but rather that at a minimum, at least the Da Vinci PAS request is used. Considering the implementation complexities, one may see a combination of capabilities emerge in which the identification (CRD) and data collection (DTR) processes may initially be done outside of the PARDD API capabilities using a portal or other mechanism to support the provider, for example.

We additionally request clarification that the data used to support authorization requests must in part, but not necessarily entirely, originate from CEHRT – as data may be supplied by non-CEHRT but still use the authorization request capabilities of PARDD APIs. For example, certain health insurance data, clinical data, and other administrative data subject to follow-up requests or initial submissions may exist in non-EHR systems in use. This further underscores that the premise that any health IT wishing to be certified must support all USCDI, and USCDI as a driver to enable standards-based exchange, is increasingly less relevant. Rather, the various implementation guides would indicate what participating systems should support.

The EHR Association suggests a realignment of the purpose and use of USCDI as a library of data types, classes, and specifications from which interoperability requirements may be drawn. By addressing this now, the respective ONC and CMS programs will be better aligned for future consideration of certification.

Trusted Exchange Network

Regarding the role of TEFCA to enable and more easily scale the use of the proposed API sets, we offer the following considerations:

> The TEF Common Agreement has an opportunity to provide consistent data-sharing agreements between all parties, thus reducing the friction in establishing such agreements separately for each individual relationship.
>
> The TEF record locator service has the potential to ease patients' ability to connect to payers. However, as most interactions between payers and providers are very specific to targeted organizations, the TEF record locator services will have less relevance to a provider seeking to find a patient's record covered by a specific payer, particularly if the Payer-to-Payer API set enables patient data to follow the patient to another payer. However, the record locator services would provide value to a provider who needs to reach a particular payer who covered the patient in the past.
>
> The TEF FHIR Implementation Guide further provides an opportunity for a common trust framework to enable and scale connections between participants and subparticipants across and within QHINs, though QHINs have the opportunity to have QHIN-specific approaches among their own participants and subparticipants. As the first phase focuses on facilitated exchanges that would advance many of the use cases considered, subsequent use of brokered exchanges could be considered based on demonstrated cost-benefit of such approaches.

REQUESTS FOR INFORMATION

A. Request for Information: Accelerating the Adoption of Standards Related to Social Risk Factor Data

• What are best practices regarding frequency of collection of social risk and social needs data? What are factors to be considered around expiration, if any, of certain social needs data?

Today, there are many different ways in which social risk and social needs data are collected. Factors to consider should include the source of the information and how the information is gathered. For example, the patient filling out a survey or a provider documenting what a patient tells them during a visit would differ from the provider documenting an observation such as a lack of transportation or strained social relationship. Some information contributing to health equity efforts is unchangeable (race/ethnicity) and would rarely need to be revisited, whereas other social risk and social needs factors are much more malleable (housing status being one example) and should be verified as still accurate during future visits. The need to revisit is also relevant where a provider has made an effort to refer a patient or his/her family to a community-based organization (CBO) that might have provided assistance that would alter their level of need. This is particularly true given the rarity of bidirectional information flowing back from the CBO to the clinical provider.

• What are the challenges in representing and exchanging social risk and social needs data from different commonly used screening tools? How do these challenges vary across screening tools or social needs (for example, housing or food access)?

Different specialties have different areas of focus and therefore may collect different aspects of SDOH information. For example, housing information may not be as applicable to a dermatologist. A one-size-fits-all set of documentation or reporting requirements would result in increased provider burden.

The EHR Association recommends CMS focus on standardizing SDOH-related questions but not requiring every actor to collect every question. Additionally, certain questions may be asked to the patient directly, while others are filled out by a provider or their staff during the visit.

• What are the barriers to the exchange of social risk and social needs data across healthcare providers? What are key challenges related to exchange of social risk and social needs data between healthcare providers and community-based organizations? If Federal or other regulations are perceived or actual barriers, please identify the specific regulation, policy, or guidance and clarifying language that would be necessary to resolve the cited barrier. If no specific language or policy is known, please provide a citation where more information is available related to this barrier.

Variability in questions, responses, and the format of questions is a significant barrier to supporting the exchange of social risk and social needs data across payer and provider organizations, as is the lack of standards for the exchange of data with CBOs who do not use health IT and thus have numerous approaches to tracking information about the people they are serving.

The EHR Association suggests consistent, structured social risk and social needs questions, such as a federally defined format for SDOH-related questions or standardized questionnaires. Today, questionnaires may be the intellectual property of a specific organization, which makes the exchange and ingestion of this data unnecessarily complicated and thereby hinders optimal patient care.

It's also critical to note that while this question asks about exchange between providers, Community-based Organizations (CBOs) are a critical stakeholder group to consider when assessing the flow of information related to attempts to address social risk and social needs. In many ways, the technological state of CBOs today resembles the landscape of EHR adoption by healthcare providers fifteen years ago: many CBOs lack the resources or knowledge to adopt any type of robust technology appropriate for

their work and instead subsist on a combination of paper and basic technologies like Excel spreadsheets. Because funding is crucial for community-based healthcare providers to increase technology adoption necessary for electronic data exchange, CMS should be working with Congress, the Health Resources and Services Administration, and State agencies to explore targeted initiatives based on the successes of the HITECH Act, which was largely responsible for the widespread adoption of interoperable EHR technologies.

For example, a successful strategy might:

> Incite the adoption of interoperable technology by CBOs, both through direct subsidies or funding and through the inclusion of CBOs in larger value-based care payment models,
>
> Promulgate standards-oriented guidance specific to technologies that can be useful and efficient in further digitizing CBOs and social services agencies,
>
> Explore ways open APIs can be helpful in making information available, including encouraging (possibly through app development contests) the increased availability of API-based technologies that can support connectivity with and receipt of information from healthcare IT,
>
> Establish regional entities that can help social services agencies understand and choose among technological options and aid in their implementation,
>
> Finalize the HIPAA Coordinated Care NPRM issued in 2021, to enable increased interoperability among all stakeholders, including more sensitive social care entities,
> Reduce individual state-by-state variation in privacy laws that might impede interoperable exchange,
>
> Develop and establish vocational programs to produce more available staff with the core competencies needed for a more connected environment,
>
> Embrace the existing work already done through TEFCA to prioritize future adoption of social care use cases, as standards mature and trading partners come online.

Such an approach would ensure that the country builds upon the existing healthcare technology ecosystem, folding community care into the larger healthcare picture with their provider partners, not as a separate or standalone entity.

• What mechanisms (EHRs, Health Information Exchanges [HIEs], software, cloud-based data platforms, etc.) and/or standards are currently used to capture, exchange, and use social risk and social needs data? What challenges, if any, occur in translating, collecting, or transferring social risk factor data in these platforms to Z codes on claims?

Multiple options exist in EHRs to capture, exchange, and use social risk and social needs data today, including custom questionnaires in provider and patient workflows or, conversely, entirely ad hoc approaches varying from provider to provider in smaller organizations.

The EHR Association notes no specific challenges with translating social risk factor data to Z codes on claims.

We reiterate the need for more consistent standards to exchange this information in a more digestible and usable way.

• How can payers promote exchange of social risk and social needs data? Are there promising practices used by MA organizations, state Medicaid agencies, Medicaid managed care plans, commercial health plans, or other payers that can potentially be further leveraged in other settings?

The EHR Association encourages consistent standards across provider and payer settings in order to promote the effective exchange of social risk and social needs data. This consistency needs to address the terms used in capturing the data to make it easier for clinicians to understand and compare it with their own data, as well as the transmission itself.

• What specific strategies, tactics, or policies would help CMS and other Federal agencies facilitate greater standardization in the capture, recording, and exchange of social risk factor data? Are there best practices (related to contracting language, requirements in Federal programs, etc.) that could be adopted, and by which agency?

CMS should take advantage of and build upon existing standards within C-CDA and FHIR.

• What are the most promising efforts that exist to date in resolving the challenges previously cited in this proposed rule? Which gaps remain that are not being addressed by existing efforts?

Existing standards, such as C-CDA and FHIR, have helped progress the industry's ability to address these challenges.

• What privacy issues should be considered when formulating policy for collecting and exchanging social risk and social needs data? Are there certain data elements that patients may wish to exercise more control over than others?

More individual controls will make data collection and data exchange more complicated. The EHR Association notes the need to balance privacy with feasibility. Rather than requiring that a question must be answered, we recommend an opt-out option to reflect some patients' unwillingness to answer specific questions. For example, a homeless patient with children may be wary of answering questions about housing stability for fear of such information triggering a call to Child Protective Services.

• Please identify opportunities and approaches that would help CMS facilitate and inform effective infrastructure investments to address gaps and challenges for advancing the interoperability of social risk factor data.

The EHR Association suggests the following approaches for CMS to reduce provider burden while facilitating effective interoperability of social risk factor data:

> Start simple. More complex approaches add more burden to users, which hinders the delivery of care.

Encourage a consistent standard across actors.

Develop federally-standardized social risk questions.

Start with a small set of questions that can be generally helpful across care settings.

Allow practices to not address all questions when they are not applicable.

B. Electronic Exchange of Behavioral Health Information

• 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?

All APIs require a client application to interact with. Therefore, behavioral health settings need capabilities that can interact with the FHIR-based APIs made available to other healthcare providers and patients, as well as the reverse. Separate apps could provide such capabilities, as could EHRs or other health IT solutions – all IT represents an app at varying levels of complexity that can interact with another app when using standardized APIs such as HL7 FHIR-based RESTful APIs or traditional HL7 v2-based messaging APIs. Thus, the same steps for deploying EHRs before focusing on interoperability and then advancing into the use of FHIR-based APIs are essential for behavioral health, long-term care, and other settings not as advanced in the adoption of health IT to date.

• How can existing criteria under the ONC Health IT Certification Program ensure applications used by behavioral health providers enable interoperability? What updates to existing criteria, or new criteria, could better support exchange by these clinicians?

The ONC Certification program has a broader focus on general USCDI but could benefit from more details about behavioral health workflows, perhaps by way of a USCDI+ for behavioral health. The ONC criteria is a good starting point, but the industry will need more clarification on consent workflows and sensitive data handling. We suggest that CMS work with the health IT industry to advance topics such as tagging sensitive data or allowing increased delineation of opt-out/consent workflows.

• What levers could CMS consider using to facilitate greater electronic health data exchange from and to behavioral health providers? What costs, resources, and/or burdens are associated with these options? Is there additional sub-regulatory guidance and/or technical assistance that CMS or HHS could provide that would be helpful?

Financial barriers to technology adoption remain significant, and the EHR Association encourages CMS to expand on programs that incite behavioral health providers to adopt health IT systems and specifically those that can interact with other health IT using the ONC Certification Program's set of standards. Further, CMS should continue working closely with ONC and other agencies to establish a consistent approach with the goal of preventing the unnecessary burden created by conflicting requirements or standards.

• Are there state or Federal regulations or payment rules that are perceived as creating barriers to technical integration of systems within these practices? What additional policy issues, technical considerations, and operational realities should we consider when looking at ways to best facilitate the secure electronic exchange of health information that is maintained by behavioral health providers including sensitive health information?

The EHR Association reiterates the importance of consistency across federal and state regulations wherever possible. Unique state requirements introduce unnecessary burden and complexity.

• What are current drivers at the Federal, state, or local level that are effectively supporting greater adoption of health IT for behavioral health providers? What new regulations guidance, or other policy levers (including new authorities) could benefit community providers or include incentives for community providers to encourage greater adoption of health IT?

Ongoing support and funding for community-based and public health providers will allow them a greater ability to adopt standards-based technologies with sufficient interoperability capabilities.

• What methods and approaches have stakeholders utilized to help advance health IT adoption among behavioral health providers, for instance, effective practices for braiding/blending of funds and as part of value-based models? How are stakeholders effectively strengthening system capacity, connecting to care, and creating healthy environments today?

The Certified Community Behavioral Health Clinic (CCBHC) initiative has seen success in encouraging participation, establishing quality metrics, and introducing certification criteria expectations.

• 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?

As mentioned above, funding is crucial for the behavioral health provider community - including community-based health providers – to increase health IT adoption and electronic health data exchange. It is virtually impossible to efficiently exchange patient health data between environments that are so differently digitized than the average primary care practice or hospital vs. a therapist who is seeing patients for talk therapy or a small psychiatry office that relies on a rudimentary patient tracking software as opposed to a standards-based EHR. The digital divide is clearly real, as CMS knows, and it will likely take a HITECH-like program – some type of financial incentive structure related to health IT adoption - to broadly change that.

As far as the technologies to be used in the behavioral health space, the EHR Association recommends building upon CCBHCs' work and leveraging existing health IT standards that have a proven track record and live implementation, rather than creating new requirements. It is critical for the same standards to be used across different healthcare delivery environments for the exchange of information to be safe and effective. Infrastructure like the TEF that is in the process of being built can also be an effective tool for the behavioral health community to use, similar to others, but they need patient record technology in place to be able to connect.

• What privacy and security considerations would be the biggest barriers for community-based providers to engage in information exchange, and which could be addressed by Federal policy, which by technology, and which by process?

Behavioral health has a high level of complexity and existing requirements surrounding data privacy. The EHR Association continues to encourage consistency wherever possible regarding health IT expectations, leveraging existing proven standards, and allowing for maturation in standards for consent and data tagging before requiring more complex functionality.

C. Request for Information: Improving the Exchange of Information in Medicare Fee for Service

• How might CMS encourage more electronic exchange of medical information (for example, orders, progress notes, prior authorization requests, and/or plans of care) between providers/suppliers and with CMS and its contractors at the time an item or service is ordered? When possible, please describe specific recommendations to facilitate improved data exchange between providers or suppliers, and with CMS and its contractors, to support more efficient, timely, and accurate claims and prior authorization communications. Are there specific process changes that you believe would improve the exchange of medical documentation between ordering and rendering providers or suppliers? Are there particular policy, technical, or other needs that must be accounted for in light of the unique roles of ordering and rendering providers or suppliers?

We refer to our comments on prior authorization with respect to promulgating more mature standards that will enable a more efficient end-to-end prior authorization workflow that enables the appropriate and targeted sharing of essential information with the least amount of manual effort to collect the relevant data. The emerging standards allow for clear and well-defined data requirements to support a prior authorization request and how to submit it. Similarly, as we will address when we provide feedback in the Health Care Attachments NPRM, there is a similar need to have a consistent manner of identifying the essential clinical data with a claim, as well as how to request any additional data when it was not (yet) included with the claim. We recommend CMS work with Da Vinci and X12 in particular to enable a consistent approach through clarification on how to align the requests for initial and additional information for prior authorization and claim. This includes the consideration of Da Vinci's CDex implementation guide and exploration of how similar techniques can be applied for attachments while using X12 as the main transaction format. Such consistency of approach and tools will enable a reduction in documentation burden by reducing ambiguity on data requirements and methods.

• Are there changes necessary to health IT to account for the need for providers/suppliers (ordering and rendering) to exchange medical documentation, either to improve the process in general or to expedite processing to ensure beneficiary care is not delayed? How could existing certification criteria or updates to certification criteria under the ONC Health IT Certification program support specific exchange needs?

The EHR Association suggests a need for clarification regarding who would be expected to meet certification criteria. Historically, payers have not been subjected to such requirements, but for many of CMS' priorities to be realized, payers, suppliers, and providers will need to adhere to the same standards in order to ensure successful exchanges. This is particularly true when the exchange involves

increasingly complex workflows (such as prior authorization) that span providers, payers, and in this context suppliers as well, vs. more simple queries in which the requester is effectively forced to use the standard query formats to obtain the agreed-upon data.

We are supportive of recommending standards at this stage and, once these have sufficiently matured, requiring certification across the full workflow in order to reduce unnecessary burden. As a guideline, we recommend a minimum of 18 months – and more ideally, 24 – after standards are defined and sufficiently matured to allow development, testing, and deployment of the necessary functionality. Any certification requirements for new standards within a shorter timeline would cause significant expense and burden to health IT developers and users while addressing providers, suppliers, and payers separately and differently would have a high risk of creating disjointed workflows.

• What levers could CMS consider using to facilitate greater collaboration and exchange of information among providers/suppliers? What costs, resources, and/or burdens are associated with this type of collaboration? Are there changes that could reduce improper payments and the administrative burden often encountered by rendering providers/ suppliers who need medical record documentation from ordering providers or suppliers?

The EHR Association not only recommends that consistent standards are crucial for efficient collaboration but also increased clarity on the role of suppliers in the prior authorization and reimbursement processes such that a robust workflow can be established that minimizes improper payments and administrative burden. Data exchange will be hindered if only one side of the exchange (e.g., the EHR) is certified, or if there are conflicting standards between health plans suppliers, and providers, particularly when aiming to advance a complex workflow such as prior authorization involving multiple health IT technology systems across those stakeholders. Moving away from paper and faxes would have substantial opportunities to achieve the goals set out.

D. Request for Information: Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health

• What are key gaps in the standardization and harmonization of maternal health data? How can HHS support current efforts to address these gaps?

The EHR Association suggests that the USCDI and USCDI+ process would provide a vehicle to address data that is relevant to maternal health data, noting that the USCDI+ Public Health data set is starting to define relevant maternal health data in the context of public health. Collaboration with ONC and HL7, as well as industry stakeholders that can evolve and mature the necessary supporting standards (e.g., HL7 C-CDA and HL7 FHIR US Core), can further drive adoption by the relevant health IT, which in turn can be included in the relevant maternal health prior authorization processes.

We note, however, that not all EHRs or health IT solutions need to adopt and support all such data. The EHR Association has suggested that ONC recognize that USCDI should not be used as a monolithic tool, requiring all health IT that seek certification to support all USCDI. We suggest that CMS work with ONC to advance maternal health data standardization and adoption in that context, as well.

• What other special considerations should be given to data sharing for maternal health transitions?

Consideration is needed regarding how data should be shared or transitioned when maternal health records include both the parent's record and a child's record.

E. Request for Information: Advancing the Trusted Exchange Framework

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

The EHR Association suggests that the Patient Access API should be considered part of the individual right of access use case, enabling payers to participate accordingly under TEFCA. It remains a question as to what extent the Payer-to-Payer Access API would benefit from TEFCA from a technology perspective, but it would be beneficial if the common agreement were to establish a singular data-sharing agreement.

Actual data exchange, particularly HL7 FHIR-based exchange, would not necessarily flow through QHINs as currently anticipated in the TEFCA FHIR roadmap, which focuses on facilitated FHIR exchange first and brokered FHIR exchange only where truly necessary. As the TEFCA FHIR roadmap unfolds, the Payer-to-Payer Access, Provider Access, and Prior Authorization APIs will have varied needs to utilize the TEFCA CA, QTF, and SOP structure and should be evaluated as that roadmap unfolds. Consequently, we suggest that TEFCA is established and matured through increased adoption in care areas and individual access before expanding too rapidly for other use cases that will primarily rely on FHIR-based exchange.

• How should CMS approach incentivizing or encouraging payers to enable exchange under TEFCA? 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 EHR Association seeks clarification on how this applies across payers with or without Medicare offerings. Broad adoption of TEFCA is needed to achieve the greatest success and therefore must include all health plans, regardless of Medicare offerings.

We recommend CMS identifies future expectations of TEFCA requirements but allows adequate time for maturity and adoption. Though the common agreement may be all that is needed for certain use cases, the need for record location services, facilitated FHIR, brokered FHIR, and generally agreed-upon standards will vary as payers and providers gain more nuanced knowledge about whom to connect to for prior authorization, for example, versus finding all of a patient's relevant records.

• 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?

TEFCA requirements will create some burden and cost across payers and providers. However, this may be offset by eliminating point-to-point negotiations with one data-sharing agreement, common standards, etc.

The overall burden depends, in large part, on how TEFCA is implemented and the value it returns to its participants. Forcing TEFCA "just because" has the risk of imposing cost and burden for no value and becoming a “check the box” step rather than an option that providers choose to prioritize in terms of resources or that payers invest in sufficiently. As we have seen, a common agreement and agreed-upon standards are adequate in some use cases.

In terms of providers who are already actively engaged in data exchange through existing networks, flowing data through a QHIN should not be forced unless there is a clear benefit in cost and data completeness, such as identifying all of a patient’s record locations. A requirement to participate in two mostly equivalent sets of networks would be similarly unhelpful, creating cost and burden without adding value.