

March 13, 2023

The Honorable 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:

On behalf of the Healthcare Information and Management Systems Society (<u>HIMSS</u>), we are pleased to provide written comments to the Notice of Proposed Rule Making (NPRM) regarding 0938-AU87 CMS 0057 <u>Advancing Interoperability and Improving Prior</u> Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program. HIMSS appreciates the opportunity to leverage our members' expertise to share feedback on improving interoperability and appropriate access to prior authorization data for patients, providers, and payers.

HIMSS is a global advisor and thought leader and member-based society committed to reforming the global health ecosystem through the power of information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research, and analytics to advise global leaders, stakeholders, and influencers on best practices in health information and technology driven by health equity. Through our innovation engine, HIMSS delivers key insights, education and engaging events to healthcare providers, governments, and market suppliers, ensuring they have the right information at the point of decision. HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East, and Asia Pacific. Our members include more than 120,000 individuals, 480 provider organizations, 470 non-profit partners, and 650 health services organizations.

HIMSS supports the work completed thus far across the Department of Health and Human Services (HHS) to provide patients with more access to and control over their data. We endorse the emphasis in this regulation to achieve appropriate and necessary access to complete health records for patients, providers, and payers, while at the same time, working to reduce the burden across the healthcare ecosystem. HIMSS believes that patients should be at the center of their own care, and the thrust in this regulation, as well as in the CMS Interoperability and Patient Access Final Regulation, affirms that goal. By placing patients at the center of their own care, the regulation promotes greater patient empowerment and improved outcomes.

Changes to the prior authorization process as proposed in the regulation would also help improve the patient experience and access to care if executed effectively. HIMSS, in conjunction with the Association of Medical Directors of Information Systems (AMDIS), highlighted clinician burden issues associated with prior authorization processes in a <u>2019 response</u> to the <u>Strategy on Reducing Burden Relating to the Use of Health IT and EHRs</u>. Additionally, we have been happy to provide technical feedback to Congress during their consideration of the *Improving Seniors' Timely Access to Care Act*, which supports the development of the electronic prior authorization methods outlined in the proposed rule. We strive to ensure that health IT tools are leveraged appropriately to make prior authorization processes more efficient for patients and providers.

As a matter of principle, HIMSS believes that seamless, secure, ubiquitous, and nationwide data access and interoperable health information exchange should ensure the right people have the right access to the right health information in a usable format at the right time to provide the optimal level of care. The reduction of barriers to the appropriate exchange of health information through harmonizing privacy and security laws, regulations, directives, and industry-led guidelines is paramount to transforming the health ecosystem, modernizing care delivery, driving health innovation at the institutional and personal level, and enabling health research. HIMSS supports the standards-based approach and the use of Application Programming Interfaces (APIs) to make available information about prior authorization decisions to patients, providers, and payers through the Patient Access, Provider Access APIs connecting to a Prior Authorization Requirements, Documentation and Decision (PARDD) implemented by the impacted payers ascribed in the proposed rule.

HIMSS offers the following comments regarding the proposed requirements:

Access to new ONC Certification Proposed Rule proposed requirements and provider impact

HIMSS anticipates providers, health systems, and their market supplier partners will need to update the functionality of certified electronic health record technologies prior to the 2026 implementation deadline for providers to submit electronic requests for prior authorization materials, as well as to capture the data required to accurately report prior authorization requests to the CMS Merit-Based Incentive Payment System (MIPS) and the Promoting Interoperability program. Details on the specifications and updates that will be needed to facilitate this exchange are likely to be included in a future proposed rulemaking on CEHRT from the Office of the National Coordinator (ONC.) Without the information that will be contained in the anticipated ONC CEHRT proposed rule, it is difficult to provide CMS realistic feedback, particularly around timelines to ensure seamless appropriate access to prior authorization data.

HIMSS strongly recommends that CMS offer an additional public comment period for the Prior Authorization proposed rule once the ONC proposed rule is released, at a minimum of 45 days beyond the publication. This period would allow the industry an appropriate period to review all proposed changes to CEHRT or other impacts on the software development community and ensure that those changes can be safely developed, implemented, and incorporated into provider workflows to support the new regulatory requirements proposed in this rulemaking.

2026 Adoption Timeline

CMS appears to be underestimating the impact of the proposals related to prior authorization given the scope of the change being suggested. HIMSS members, including several deeply involved in the standards development and testing process for the proposed APIs, have expressed significant concern regarding the January 1, 2026, proposed deadline for going live with the PARDD, provider, and patient access APIs. The January 1, 2026, deadline only allows thirty-three months between the deadline for this comment submission and the required implementation deadline. That does not leave enough time for these APIs to be fully tested, field tested, validated, and to have the APIs successfully implemented into the business practices for both payers and providers.

Regarding the APIs, our membership has reported that many of the implementation guides are still in balloting. Testing hasn't been completed at scale, and successful tests have been using very simple prior authorization use cases. More complex authorizations have not been successfully tested using the APIs within the HL7® FHIR® Accelerator program and at an Integrating the Healthcare Enterprise (IHE) Connectathon. The 2026 deadline does not seem to be driven by any kind of feasible quantifiable testing minimum threshold to indicate that early adopters could successfully meet the 2026 deadline.

We are concerned that health systems, developers, and market suppliers' resources are being stretched to the breaking point. In addition to facilitating prior authorization access, the industry is racing to become compliant with the 21st Century Cures Act Final Regulation and the 2015 Edition Cures Update, the implementation of Trusted Exchange Framework and Common Agreement (TEFCA), and the transition to digital quality measures by a January 1, 2026, deadline. These implementations will need to happen against the backdrop of economic challenges created by the COVID-19 pandemic, leaving limited resources to support a rushed effort to bring prior authorization APIs to market without failing to fully and robustly field-test the APIs to ensure they will work properly when widely implemented.

Historically, HIMSS has, and continues to recommend, that any mechanism for a data exchange or reporting to HHS must be fully quality tested, field tested, and validated to produce the correct measurement or information before establishing an adoption deadline for industry. A full testing and field-testing process allows the standards for the APIs to be validated and will allow CMS and standards developers to identify any potential barriers to adoption, ensure robust privacy and security protections of data, and validate the accuracy of data being exchanged.

Accordingly, HIMSS recommends CMS postpone setting a deadline for mandatory adoption of the three APIs and corresponding reporting requirements until the standards and the APIs have been fully tested, field tested, and vetted to produce accurate and meaningful prior authorization data. HIMSS recommends that the final adoption deadline have a glidepath with specific milestones in testing and field testing the APIs have met before triggering the next step up to implementation. For example, all three APIs should be successfully field tested to express correct prior authorization information for payers, providers, and patients in cases of multi-faceted and complex prior authorizations. Our understanding is, to date, the APIs have only been successfully tested using very simple prior authorization test cases. The final implementation date should be set once all three APIs successfully test against scenarios ranging across those currently processed in the industry.

HIMSS also recommends CMS provide financial incentives for market suppliers, providers, and payers to participate in the testing and field-testing process. One of the primary challenges to standards development and testing is a lack of financial and regulatory incentives for stakeholders to participate. This lack of participation slows the testing process and presents gaps in field testing to identify unanticipated challenges. In challenging economic conditions where hospitals and providers are strained to maximum capacity, more robust incentives are needed to require the stakeholder participation needed to get these APIs to market.

Implementation and Reporting Burden on Providers

HIMSS membership is supportive of the concept of the provider-to-payer API link. The API should facilitate better continuity of care and address attribution issues associated with pay for performance programs that have frustrated providers for years. For example, an attributed primary care provider is responsible for tracking care a diabetic patient received from a nephrologist at a different health system; if the nephrologist didn't provide the standard of care leading to a poor outcome, the primary care provider is at risk of a negative payment adjustment.

While HIMSS supports the adoption of the provider-to-payer APIs, HIMSS expresses concern regarding CMS choosing to include a data collection reporting requirement for the MIPS and Promoting Interoperability programs on hospitals and providers. From a technology standpoint, any data collected regarding prior authorizations by health systems and provider practices are captured outside of their electronic health record, which means that to gather the data on electronic prior authorization requests would reflect a burdensome exercise for providers and health systems while offering only marginal clinical benefit to patients.

HIMSS also has concern about placing a financial risk on providers related to measuring payers' compliance with the API and prior authorization sharing requirements. HIMSS maintains policy principles that governments should not mandate a data reporting requirement for a CMS incentive program if the measure does not include actionable data to drive improvement in patient care. While access to prior authorization data does support improved care for patients, tracking the number of requests to impacted payers has next to zero benefit and would become a burdensome regulatory reporting requirements for the MIPS and Promoting Interoperability program, and instead exploring different mechanisms for tracking electronic prior authorization requests.

Patient Access to Prior Authorization Data: Opt-Outs and Educational Resources for Patients

Fundamentally, HIMSS supports patient access to prior authorization information to advance patient directed shared decision-making with providers. Prioritizing the sharing and exchanging of this clinically important prior authorization-related information between patients, providers, payers, and CMS will benefit patients.

However, the burden for educating patients regarding the potential value of accessible prior authorization data currently resides with the providers. We applaud the decision by CMS to include the option for patients to opt out of instead of a more cumbersome opt-in process. However, opt-in programs are not burden-free for providers. HIMSS acknowledges that the patient's ability to opt out can create segmented data captures and multiple workflows for providers that are dependent on patient preference for sharing their claims, encounter, or electronic prior authorization data. Patients are already receiving consent requests for a wide variety of data. The different data consents then dictate disparate storing requirements at a discrete level. Consents can be confusing for patients and tracking those different consents even within a single health system is very challenging for providers.

To advance patient-directed decision making and reduce burden for providers, HIMSS recommends CMS work with the healthcare community to create more resources for patients on the benefits of and positive outcomes that result from an individual's greater control of their health information. These resources should also include information on the potential risks such patient control poses and steps that an individual can take to mitigate those risks and safeguard their personal health information.

There is a foundational opportunity for CMS to build on its partnership with ONC and create additional resources to develop direct-to-patient and direct-to-provider education that would aid the patient-provide dialogue on consent and advise patients on the intent of patient control of information and appropriate data sharing. The additional resources that CMS (with ONC) creates would complement the work that payers and providers develop and serve to support the broader principles underlying this regulation, while also addressing the consent collection and education burden providers face.

MIPS and Promoting Interoperability Measurement for Prior Authorization Requests

HIMSS seeks clarification 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 PASbased APIs) 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 at a minimum at least the Da Vinci PAS request is used. Considering the implementation complexities, one may see a combination of capabilities emerge enabling the provider 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, for example.

We additionally request clarification that the data used to support authorization requests can in part, but not necessarily must 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 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.

HIMSS 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 Trusted Exchange Framework and Common Agreement (TEFCA) to enable and more easily scale the use of the proposed API sets, we offer the following considerations:

TEFCA 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 request information from 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 Qualified Health Information Networks (QHIN), though QHINs can have QHIN-specific approaches among their own participants and sub participants. 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 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 (e.g., housing status) and should be verified as still accurate during future visits. The need to revisit is also relevant where a provider has tried to refer a patient or their 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. As the healthcare community experienced in the early days of demographic and lifestyle data collection for the Meaningful Use program, a one-size-fits-all approach to data collection that doesn't take relevance to the specific patient-provider encounter can result in increased provider burden.

HIMSS recommends CMS focus on standardizing 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.

• 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 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.

HIMSS suggests consistent, structured social risk and social needs questions, such as a federally defined format for 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.

• 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?

HIMSS encourages the use of consistent standards across provider and payer settings 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 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. HIMSS notes the need to balance privacy with feasibility. Rather than requiring that a question must be answered, we recommend an opt-out option in consideration of patients' unwillingness to answer specific questions. For example, a homeless patient with children may be wary to answer questions about housing stability for fear of losing his or her children.

B. Request for Information: 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 interaction with a client application. It is in the mutual interest for behavioral health care settings, other healthcare providers, and patients to have capabilities to gain access to FHIR-based APIs made available to each other. Separate dedicated apps could provide such capabilities, as could EHRs or other health IT solutions.

At the foundational level, 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. Therefore, regardless of whether we are deploying EHRs before focusing on interoperability and then advancing into the use of FHIR-based APIs, the same steps are essential for all care categories or provider types. The use of FHIR-based APIs can help behavioral health, long-term care, and other settings close the gap that exists between their information sharing capabilities with those in the acute and ambulatory settings. Improved information gathering and sharing will ultimately support patient-provider engagement.

• 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 community 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. HIMSS encourages CMS to expand on programs that incentivize behavioral health providers to adopt health IT systems and specifically those that can interact with other health IT using 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 particular considerations for electronic data exchange for behavioral health providers who practice independently, are community-based, or are non-traditional providers? What about rural-based behavioral health providers? How could an API-based solution help address these considerations?

An increase in support of community-based organizations (CBOs), which were not part of the Meaningful Use program, will benefit the full workflow necessary for patient care and behavioral health. In many ways, the technological state of CBOs today resembles the landscape of EHR adoption by healthcare providers fifteen years ago. While bright spots exist, many CBOs lack the resources or knowledge to adopt technology and instead subsist on a combination of paper and basic technologies like Excel spreadsheets. CMS can work with the ONC, the Health Resources and Services Administration (HRSA), and other 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:

- Incentivize 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, including exploring ways open APIs can be helpful in making information available,
- 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. Incorporating community care into the larger healthcare strategy increases the likelihood that CBO information is interoperable, improving care coordination and avoiding creating unnecessary siloes.

While standards are still being matured, these policy and funding efforts could begin work now with a possible rollout over the next 3-5 years.

• 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?

HIMSS reiterates the importance of consistency across federal and state regulations wherever possible. Unique state requirements may introduce unnecessary burden and complexity. CMS and ONC should work together to support the innovation of modernized, interoperable state health and human services data systems across the spectrum of care by coordinating 1115 Waiver programs, that may in part help states develop Health IT Roadmaps for data exchange with behavioral and social care systems. CMS should also consider opportunities to expand the ONC's cooperative agreement program that is designed to strengthen and expand the ability of health information exchanges (HIEs) to support behavioral health and public health exchange to better inform community level interventions. Learning laboratories based on current initiatives such as the Indiana Data Hub may serve as exemplars for other states and localities to create roadmaps towards interoperable state HHS systems and may drive policy actions for sustainable solutions based on the information collected and shared.

• 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 greater ability to adopt standards and technology with greater 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 community-based health providers to increase health IT adoption and electronic health data exchange.

HIMSS 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.

• 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?

There are two unfortunately competing truths that need to be reconciled: the patient unequivocally needs to be protected, for both information privacy and security purposes; and healthcare delivery and coordination of care cannot be achieved without reliable data shared in an interoperable manner across various, sometimes competing, systems. Thus, a careful balance must be made between the need to keep the data private and secure, while remaining shareable across various environments to help ensure that patient care is not impeded.

The three key components of successful healthcare delivery are the people, processes, and technology. As we've long seen across all of healthcare, technology availability and capabilities have had dynamic and transformative impacts on healthcare achieving the quadruple aim. The same gaps exposed by the pandemic also caused an erosion in the public's trust in key parts of our healthcare system. Ensuring that the people and the processes work in tandem with the technology to support a resilient, secure, and robust health system capable of safeguarding patient information will define how effectively the care delivery will proceed and help maintain the public's trust. HIMSS 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

• 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?

HIMSS suggests clarification regarding who would be expected to meet certification criteria. Historically, payers have not been subjected to such requirements. However, both payers and providers will need to adhere to the same standards to ensure

successful exchanges, particularly when the exchange involves increasingly complex workflows, such as prior authorization, versus simple queries in which the requester is effectively forced to use the standard query formats to obtain the agreed upon data.

• 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?

HIMSS recommends that consistent standards are crucial for efficient collaboration. Data exchange will be hindered if only one side of the exchange is certified, or if there are conflicting standards between health plans and providers, particularly when aiming to advance a complex workflow such as prior authorization involving multiple HIT across provider and payer.

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?

HIMSS 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 health IT needs to adopt and support all such data. HIMSS has suggested that ONC recognize that USCDI not be used as a monolithic tool to require all health IT seeking 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. IHE-USA, in partnership with HIMSS, has begun updating the Maternal Health Interoperability Profiles to update their capabilities to reflect the modern era. We would welcome CMS's active involvement in the modernization effort to help improve access, information sharing, and ultimately technology's role in supporting maternal health.

Furthermore, CMS should review strategies undertaken in Washington State and West Virginia that support active engagement of health plans, birthing hospitals, licensed birth centers, and perinatal providers in quality improvement efforts and regular reporting to local/regional health information exchanges for improved surveillance, and integrated telehealth models for maternity care services. Vital statistics systems can be leveraged along with community exchange platforms and under 1115 Waiver programs to advance maternal health data sharing and analytics.

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?

HIMSS suggests that the Patient Access API should be considered part of the individual right of access use case. Thus, payers would be able 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 could benefit from the common agreement to establish a singular data sharing agreement.

Actual data exchange, in particular 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)?

HIMSS 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 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, but 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 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.

We look forward to the opportunity to discuss these issues in more depth. Please feel free to contact Eli Fleet, Director of Government Relations at <u>eli.fleet@himss.org</u>, or Jonathan French, Senior Director of Informatics at <u>jfrench@himss.org</u>, with questions or for more information.

Thank you for your consideration.

Sincerely,

Thomas M. Leany

Thomas M. Leary, MA, CAE, FHIMSS Senior Vice President and Head of Government Relations