January 4, 2021

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted via the Federal Regulations Web Portal, www.regulations.gov

RE: Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications [RIN 0938-AT99]

Dear Administrator Verma:

I am writing on behalf of the Workgroup for Electronic Data Interchange (WEDI), the nation's leading nonprofit authority for nearly 30 years on the use of health information technology (IT) to create efficiencies in health care information exchange. We want to commend you for the work the Centers for Medicare & Medicaid Services (CMS) has undertaken to reduce administrative burden and improve the prior authorization process.

This proposed rule expands upon the CMS Interoperability and Patient Access final rule published on May 1, 2020, which WEDI generally supported. This proposed rule emphasizes improving health information exchange for patients, providers, and payers to have access to complete health records. At the same time, it proposes improvements to prior authorization processes with the goal of reducing burden and keeping patients at the center of their own care.

WEDI broadly supports this proposed rule. We applaud the work by CMS to improve health information exchange and reduce administrative burden on all stakeholders. WEDI's mission and work are driven by easing administrative burden, putting patients at the center of their care, implementing consensus-based, mature standards that support automation, and maintaining appropriate safeguards for privacy, security, and confidentiality.

CMS has requested specific comments and information on this proposed rule. WEDI's comments are based on key guiding principles that are integral and essential considerations of any proposed rule provisions. Specifically:

- Meeting the goals of this proposed rule requires that relevant stakeholders have ready access to several key capabilities and functions. Providers must know whether payers require prior authorization for a service along with the required information needed by the payer for the authorization. It is important to focus first on making these criteria as widely available and useful as possible, even if multiple approaches may be necessary.
- It is important to design a transition to:
    - Promote seamless, automated data exchange through mature, clear, and unambiguous standards that have been thoroughly tested and demonstrate meaningful return on investment (ROI).
    - Integrate the data exchange easily within the provider and other end-users' workflows.

Additional details of our comments are included in the attachment to this letter. Due to the importance of this work and need to fully analyze the implications of these proposals, we urge CMS to consider issuing the regulation as an Interim Final Rule with Comment to allow further input from the industry.

As CMS further develops their approach to advancing interoperability, we encourage collaboration with the Office of the National Coordinator for Health Information Technology (ONC), as well as industry stakeholders such as WEDI. As an advisor to the Secretary of the Department of Health and Human Services (HHS) and a multi-stakeholder organization comprised of health plans, providers, vendors, and standards development organizations, WEDI offers the structure for cross-industry collaboration. WEDI has proven leadership engaging the industry to address the most impactful changes of our time, including the National Provider Identifier, ICD-10, health care attachments, and prior authorization.

The comments contained herein have been reviewed and approved by the Executive Committee of the WEDI Board on January 4, 2021. On behalf of the WEDI Board of Directors, I am sending them to you for consideration. WEDI appreciates the opportunity to collaborate with CMS and stands ready to assist in clarifying the attached as needed. Please contact me at nancy.spector@ama-assn.org or Charles Stellar, President and CEO of WEDI, at cstellar@wedi.org with any questions pertaining to WEDI's comments, which are enclosed.

Sincerely,

/s/

Nancy Spector
Chair, WEDI

cc: WEDI Board of Directors


**About WEDI**

WEDI was formed in 1991 by then-Secretary of HHS Dr. Louis Sullivan. Named in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as an advisor to the HHS Secretary, we have worked closely with every Administration. WEDI is a multi-stakeholder organization, whose membership includes ambulatory providers, hospitals, health systems, health plans, health information technology standards organizations, health care information technology vendors, and government entities. We continue our role of working with both the public and private sectors to reduce health care administrative costs and facilitating improvements in information exchange through voluntary collaboration.

WEDI has been an instrumental force in establishing and later enhancing HIPAA standards for electronic administrative transactions, data privacy, and data security; driving down the costs associated with manual, paper-based transactions; and increasing the confidentiality of patient information. Our robust workgroups, white papers, and other industry guidance, informative conferences, surveys, and online webinars provide critical industry education and foster collaborative partnerships among diverse organizations to solve practical, real-world data exchange challenges.

WEDI's Board of Directors include:

- Aetna
- American Dental Association
- American Hospital Association
- American Medical Association
- America's Health Insurance Plans
- Anthem
- Availity
- Blue Cross Blue Shield Association
- CAQH
- Centers for Medicare & Medicaid Services
- Change Healthcare
- Edifecs
- Health Care Service Corporation
- HL7 International
- JE Consulting
- Kaiser Permanente
- LabCorp
- Mayo Clinic
- Medical Group Management Association
- Michigan Health Information Network
- Minnesota Department of Health
- Montefiore Medical Center
- National Council for Prescription Drug Programs
- Office of the National Coordinator for Health Information Technology
- PNC Bank
- SS&C Health
- UnitedHealthcare
- WPS Insurance
- X12
- Zelis Payments

**Workgroup for Electronic Data Interchange (WEDI)**
**WEDI Comments on the Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications**

**As approved by the**
**Executive Committee of the WEDI Board on January 4, 2021**

**REQUEST FOR INTERIM FINAL RULE WITH COMMENT**

**WEDI Comment:** Due to the complexity of this proposed regulation and the potential impact on patients, providers, health plans, payers, and supporting vendors, **WEDI strongly urges** CMS to release the next iteration of this rule as another proposed rule or interim final rule and permit additional public comment.

**SECTION I. BACKGROUND AND SUMMARY OF PROVISIONS**

**Impacted Payers:** This rule proposes payers subject to this proposed rule include state Medicaid and CHIP fee-for-service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs). Other payers, including Medicare Advantage, Medicare FFS, QHP issuers offering only stand-alone dental plans (SADPs), QHP issuers only offering Federally-facilitated Small Business Health Options Program Exchanges (FF-SHOPs), and all other payers, are excluded from these proposed provisions, but are encouraged to consider adopting similar requirements. Payers with multiple lines of business may choose to implement these polices to support better internal alignment as well as to create more efficiencies and transparency for their patients.

> **WEDI Comment: WEDI urges** CMS to align the impacted payers in this proposed rule with the impacted payers in the CMS Interoperability and Patient Access final rule (85 FR 25563 through 25564), as this proposed rule is an extension of that final rule. WEDI also encourages including Medicare Advantage plans to widen the scale of this initiative by increasing the number of patients beyond the proposed impacted payers. Thus, further advancing the goal of reducing the burden of prior authorization in the health care system. By not including Medicare Advantage, health plans that offer both Medicare Advantage and one of the impacted health plans under this rule will have to administer the Patient Access API two different ways. It also further complicates the administration of coverage and care for dual-eligible members, contradicting other high profile CMS initiatives to align and integrate coverage administration of dual-eligible members. For the same reasons, Medicare Fee-For-Service (FFS) should be included to provide consistency across all Medicare plans.
>
> There are various and significant technology investments required by all stakeholders, i.e., providers, health plans, vendors, employer groups, to achieve compliance. Expanding the base of patients affected by the proposed rule by including Medicare Advantage and Medicare FFS has the potential to reduce the burden of prior authorization across a broader segment the industry and improve the ROI for all impacted parties.

**WEDI urges** CMS to include Medicare Advantage health plans and Medicare FFS in the next iteration of this rule, whether another proposed rule or an interim final rule with comment.

**Effective Dates:** The rule proposes an effective date of January 1, 2023 for most of the requirements.

**WEDI Comment: WEDI believes** there are several factors that should influence the effective date. First is the maturity level of the HL7 Implementation Guides (IG) cited as references to determine the implementation standards. It is our understanding that these IGs are not currently at the level of maturity required to support a successful implementation across the industry.

Second, **WEDI strongly believes** in the use of standards to streamline and automate care and payment processes. The cited Da Vinci and CARIN IGs are the appropriate standards, but the industry is currently experiencing issues with trial implementations using the current IGs that have been delivered "just in time." The extent and complexity of this proposed rule goes significantly beyond what is encompassed in the CMS Interoperability and Patient Access final rule (85 FR 25563 through 25564), which has an enforcement date of July 1, 2021.

WEDI is currently working with HL7 and other standards development bodies to support trial implementation of these IGs. During 2021, the industry will gain experience with trial implementations, production-level demonstrations, and the implementation of Patient API's associated with the current Interoperability Rule. This experience will sufficiently inform updates to these IGs to guarantee a successful roll-out in conjunction with a reasonable compliance date. Adequate time is needed for IG development and to incorporate feedback from early adopters.

Third, the payers impacted by this proposed rule are still implementing the requirements of the CMS Interoperability and Patient Access final rule (85 FR 25563 through 25564). These payers must also comply with the recent Transparency in Coverage Final Rule (CMS-9915-F) for plan years beginning January 1, 2023. There has been insufficient time to plan and complete that work and determine the additional impact of those requirements with the ones proposed in the draft rule.

For these reasons, **WEDI urges** CMS to reconsider the January 1, 2023 effective date and consider alternative options, such as establishing an effective date one year after these IGs are finalized by HL7 or creating a voluntary, one-year education and testing period between willing trading partners.

**SECTION II.A. PATIENT ACCESS API**

**II.A.1.b. Additional Information:** The rule requests comment for possible future consideration on whether impacted payers should be required to include information about prescription drug and covered outpatient drug pending and active prior authorization decisions with the other items or services proposed via the Patient Access API, the Provider Access API, or the Payer-to-Payer API.

**WEDI Comment: WEDI supports** the work by the National Council for Prescription Drug Programs (NCPDP) to enhance, as necessary, the NCPDP SCRIPT Standard electronic prior authorization transactions. It is our understanding that these transactions significantly reduce the approval time of prescription benefit prior authorizations, leading to expedited access to drug therapy for improved continuity of care. We further understand that real-time prescription benefit (RTPB) transactions

successfully give providers point-of-care information to support clinical decision-making for prescribing drugs, thereby negating the need to obtain a prior authorization, and reducing the overall administrative burden. WEDI is available and well positioned to assist in convening industry stakeholders to analyze the requirements to include prescription drug information in the proposed APIs.

**II.A.2.a. Patient Access API Implementation Guides (IGs):** The rule proposes to finalize the use of the following IGs for the impacted payers beginning on or after January 1, 2023, as applicable:

- HL7 Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG: Version STU 1.0.0 to facilitate the exchange of the claims and encounter data;
- HL7 FHIR US Core IG: Version STU 3.1.0 or HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG: Version STU 1.0.0 to facilitate the exchange of the clinical information as defined in the USCDI; and
- HL7 FHIR Da Vinci Payer Data Exchange (PDex) US Drug Formulary IG: Version STU 1.0.1 to facilitate the exchange of current formulary information

Additional comments are requested on the pros and cons of requiring the use of either the US Core IG or PDex IG or if only one of the two proposed IGs should be required and why.

**WEDI Comment: WEDI supports** the work by CARIN, as it is directly related to the CMS Blue Button initiative already in use. The CARIN IG provides a method for all payers to make available submitted and processed claims data to patients and has sufficient maturity to ensure a successful implementation.

WEDI has concerns about requiring more than one IG for specific types of care, such as proposing to permit payers to use the US Core and PDex IGs, and payment processes. We request that one guide be mandated. Otherwise, providers and their vendor partners will have to support both, adding burden by allowing different processes for different entities and the need to track which process to use with which payer. This overall solution would be more complicated and would require the supporting technology to be "context aware," making both development and implementation more challenging.

**WEDI is in strong support** of clear and unambiguous standards to achieve true interoperability. As with operating rules that constrain more general standards mandated under HIPAA, the HL7 accelerator groups, such as the CARIN Alliance and the Da Vinci Project, have further refined the more general HL7 FHIR US Core IG to align more tightly with the specific patient data exchange processes associated with burden reduction.

While WEDI is in favor of the use of these specified IGs, in line with our comments about the implementation date, WEDI is concerned that not enough stakeholder representatives with business process experience were involved in the initial development of these IGs as currently published. Consequently, there may be gaps and missing components in the workflow processes supporting the business functions within the scope of this proposed rule. Moving the data from point A to point B may appear simple, but payers will struggle with incorporating relevant data into their business processes once received. The HL7 accelerator groups have plans for production level stakeholder demonstrations in 2021. WEDI is confident the HL7 process will bring the necessary maturity to these IGs if given sufficient time to work.

**II.A.2.b. Additional Information:** The rule proposes to not include prescription drugs or covered outpatient drugs and requests comments on future considerations of these items.

> **WEDI Comment: WEDI is aware** of the work by NCPDP and its members to adopt and use standards that facilitate real-time exchange of medication prior authorization requests and responses. We believe the electronic, real-time formulary and benefit checks and prior authorizations for prescription drugs and covered outpatient drugs will significantly reduce administrative burden. Replacing time-consuming manual processes between providers and pharmacists will improve patient care by ensuring they obtain appropriate medications in a timely manner.
>
> When integrated into a pharmacy management system, electronic prior authorization streamlines the approval process and patients can start their medications sooner. The result is increased patient satisfaction, adherence to medication regimens, and fewer visits to the emergency room. Furthermore, automated processes are more efficient for payers.
>
> Also, per the Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P), Medicare Part D plans must offer a real-time pharmacy benefit tool showing physicians patient-specific drug coverage information, including alternatives, effective January 1, 2021.
>
> **WEDI urges** CMS to consider the important work NCPDP members have made in adopting and using standards that facilitate real-time exchange of medication prior authorization requests and responses. WEDI also offers our assistance to bring together industry stakeholders to identify opportunities to transform the medical prior authorization process into real-time, as seen in the pharmacy industry.

The rule proposes that impacted payers make available to patients information about any pending and active prior authorization decisions, and related clinical documentation and forms, for items and services via the Patient Access API conformant with the HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG no later than one (1) business day after a provider initiates a prior authorization request or there is a change of status for the prior authorization.

> **WEDI Comment: WEDI supports** this proposal that Payer A sends relevant information to Payer B about any coverage decisions, but with the following concerns:
>
> - Patients may not understand what is expected of them to follow or manage their pending prior authorizations and may be confused. Patients need to be aware of prior authorizations under review but should not be obligated to manage these requests. Continuity of the patient's care must be the priority.
> - Patients' access to information that a prior authorization request has been submitted may not result in any improvement to the processing and response time of prior authorizations. The focus should be on notifying the provider of the response to the prior authorization request.
> - The patient may not be made aware if a prior authorization request is pended by the payer for medical review and the specific reason for pending.

- The HL7 Da Vinci Patient Coverage Decisions Exchange (PCDE) IG, not the PDex IG, was developed with minimal payer input, which may result in the need for more time to understand and implement the standard.
- The PCDE IG only addresses the movement of data between the provider and payer. It does not address the back-end business systems that will need to ingest the new information and process it for continuity of care.
- Patients should not have to access multiple payer sources to access information about their prior authorization requests.

**WEDI urges** CMS to wait until these matters are addressed, particularly additional development of the PCDE IG, before this requirement becomes effective.

**II.A.2.c. Privacy Policy Attestation:** The rule proposes that impacted payers beginning on or after January 1, 2023, as applicable, must establish, implement, and maintain a process for requesting an attestation from third-party app developers that are requesting to retrieve data via the Patient Access API that indicates their app adheres to certain privacy provisions. The payer must inform the patient within 24 hours of requesting the attestation from the app developer of the status of the attestation – positive, negative, or no response, with a clear explanation of what each means. The patient would then have 24 hours to respond to this information.

**WEDI Comment: WEDI understands** the importance supporting CMS' dual goals of facilitating patient access to health information and ensuring the security and privacy of that information. We agree that payers should have the ability to clearly communicate information to their members about the degree to which third-party app vendors are committed to ensuring the privacy and security of patient information provided by payers, to third-party app vendors through the Patient API compliance requirement.

**WEDI supports** the idea that third-party app vendors must attest to payers, during an application registration process, certain facts about how they manage and protect the privacy and security of patient information both upon receipt and in an ongoing fashion. All patient rights regarding vendors' stewardship of the patient's information should be made clear to the patient when they act to download their information into the app and patients clearly need to have the right to rescind rights of access by vendors in real-time upon learning of the status of third-party app vendor attestation. These principles seem to be the intent of the proposed rule. Nonetheless, the process is not articulated well enough for successful implementation by payers bound by the existing final rule. It mandates, solely upon patient request, that payers provide third-party vendors with access to patient information regardless of the third-party vendor's practices and policies, known or unknown by the payer.

**WEDI advocates** that the proposed rule be modified to:

1. Provide clear and consistent guidelines regarding to what third-party vendors must attest (e.g., CARIN Code of Conduct, third-party use or sale of data, etc.). This description should ideally align with at least the spirit of the privacy and security language of HIPAA.
2. Include a clear description of a sample workflow for third-party vendors and payers to follow regarding the third-party app vendor registration and attestation process. As well, it

should at least reference a scalable, automatable manner in which standards can support the real-time access to attestation information that can be shared in a federated manner. The ONC FHIR at Scale Taskforce (FAST) group has proposed such methods and **WEDI strongly advocates** that any final rule incorporate that work into the language.

Without such clear guidance, especially with regard to automatable, scalable, and federated access to attestation information maintained in a repository and available via named standards, WEDI is concerned that any provisions regarding timeliness, i.e., requiring the payer to inform the patient within 24 hours of requesting the attestation from the app developer of the status of the attestation, positive, negative, or no response, with a clear explanation of what each means, is unreasonable and unworkable for both the industry and patients. In lieu of clear direction to support automation and standards, at the least, **WEDI proposes** extending the 24-hour requirement to a minimum of two business days. Similarly, the 24-hour period that the patient has to respond to this information should be extended to a minimum of two business days. Further, an infrastructure that supports automation and federation of the third-party app vendors attestation history should also support the publicly accessible websites where apps that have been vetted or have attested to meeting an established set of privacy and security requirements can be posted. This public approach could reduce the need for the back and forth between patients and payers regarding app attestations and serve as a market driver to encourage app developers to meet minimum privacy and security standards

Additional comments are requested on:

- The proposal of the payer's obligation to send the data regardless of whether the patient responds to the payer after notification of the app's attestation results, specifically notification if the app does not attest to meeting the above privacy provisions
- Whether the request for the app developer to attest to certain privacy provisions should be an attestation that all provisions are in place, as it is currently proposed, or if the app developer should have to attest to each provision independently.

**WEDI Comment: WEDI continues to be concerned** that patients will have their protected health information (PHI) inappropriately disclosed if they are not fully informed and aware of the potential dangers associated with sharing their PHI with third-party apps. The payer should not be required to take unreasonable steps to ensure the patient has access to the information the payer has gathered, or not been able to gather, from the app developer.

**WEDI supports** having the app developer attest that all provisions are in place and not be required to attest to each provision independently. Each item should be accorded in writing that they have been met, such as through a "user agreement" in the app with all the appropriate language. The process of all-in-one attestation and patient communication of the results will be challenging in its own right. Adding additional nuance to the attestation may result in a protracted process and could be confusing to patients.

At the least, if a proposed rule is prescriptive with regard to the minimum set of attestations to which a third-party app developer should respond, a "scoring" approach could be taken by the app registration services supplier, either the payer or a supplier of such services, to convey a curated evaluation of the a particular third-party app vendors policies and practices that reflects the

minimum attestation requirements set forth in a final rule and aligned with the spirit of HIPAA privacy and security definitions and regulations.

**II.A.2.d. Patient Access API Metrics:** The rule proposes to require impacted payers to report metrics about patient use of the Patient Access API to CMS quarterly starting in 2023, specifically:

- The total number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app; and
- The number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app more than once.

**WEDI Comment: WEDI requests** that additional information be provided to explain:

- What constitutes a "unique patient" so that payers can identify unique patients in the same manner? Given the configuration of a typical FHIR dialogue, a request could be counted in different ways and results could become skewed.
- What happens when a patient leaves a payer and then returns, such as occurs with Medicaid, e.g., should a payer assign a new patient identifier, is the patient considered new or existing?

Moreover, while payers could perhaps influence the number of unique visits through member outreach and education, the results of the metrics may not reflect the quality of the accessibility and exchange of data. These metrics will be influenced by regional, demographic, and member specific factors outside the payer's control, such as availability of broadband services, smart phone adoption, socioeconomic status, and member's desire to adopt and use new technology.

**WEDI urges** CMS to reach out to the payer community and collaborate on defining unique patients and identifying metrics that will be meaningful.

Additional comments are requested on:

- The burden associated with quarterly reporting versus annual reporting
- Benefits and drawbacks of quarterly versus annual reporting
- Other metrics CMS might require payers to share with CMS
- The potential burden if payers were required to report the names of the unique apps that access the payer's API each quarter or each year

**WEDI Comment: WEDI supports** having metrics in place and encourages CMS to work with the payer community to identify measures that will be meaningful.

In our opinion:

- Quarterly reporting seems overly burdensome.
- Baselines must be set to guarantee the metrics are truly comparable.

**II.A.2.f. Provider Directory API Implementation Guide:** The rule proposes to require that the Provider Directory API finalized in the CMS Interoperability and Patient Access final rule (85 FR 25563 through 25564) be conformant with the HL7 FHIR Da Vinci PDex Plan Net IG: Version 1.0.0 beginning January 1, 2023.

**WEDI Comment: WEDI believes** in standards-based methods for the electronic conveyance of health care information. This includes information included in provider directories. WEDI also believes that successful standards-based conveyance of digital health care information relies on clear and unambiguous standards that apply across the industry. Generally, this means a single standard for a particular health care process. The Da Vinci PDEX Plan Net IG meets this requirement.

**SECTION II.B PROVIDER ACCESS API**

**II.B.3. Proposed Requirements for Payers: Provider Access API for Individual Patient Information Access:** The rule proposes a Provider Access API that allows providers to have access to an individual patient's and multiple patients' information.

**WEDI Comment: WEDI offers** the following comments:

- CMS should consider working with ONC to establish specific requirements for electronic health records (EHR) developers to include these functions in their technologies for clinical data as part of the Certified Electronic Health Record Technology (CEHRT) program. In addition, CMS should consider including incentives for providers within the Advancing Care Information Performance category within the Merit-based Incentive Payment System (MIPS) program to use the Provider Access API in their workflows in parallel with the requirement on payers to create and maintain the API.
- The HL7 FHIR Bulk Data Access specification is designed to "periodically retrieve updated clinical data" and not for daily bulk claims and clinical transactions among changing cohorts or enrollees and provider relationships as discussed in the CMS proposed rule**.** Requiring payers to create and administer the FHIR Bulk Data Access specification for the Provider Access API, under the single business daytime requirement, while authenticating the requesting provider's treatment or care coordination interest in a health plan enrollee, to meet HIPAA privacy requirements, is a challenging technical and compliance standard. Mid-sized and small health plans, many of which are provider-sponsored, would particularly face significant implementation, administrative and HIPAA violation penalty costs to implement and administer this intricate and time sensitive data distribution structure correctly. **WEDI supports** limiting the Provider Access API to individual enrollee data requests, and that CMS not require the FHIR Bulk Data Access specification be adopted for the Provider API at this time at this time but consider it a later date when the specification has been more thoroughly tested by HL7.
- The proposed rule states that, "… impacted payers under this proposed rule will have largely prepared the necessary infrastructure and implemented the FHIR standards to support the patient access API." This is a flawed assumption on several levels. First, the current Interoperability Final Rule is essentially a "one-to-one" model with regard to security and authentication, i.e., a payer shares data with the patient to whom the data belongs. This proposed rule creates a one-to-many relationship that must be supported regarding security, authentication, and most importantly, patient consent. Further, because the proposed rule includes Bulk Data access, this capability is not required under the Patient Access API. The current IGs for Bulk Data transport have not been written to address this specific scenario and consequently there is a challenge with industry wide implementation. Additionally, this does not address the fact that the infrastructure required for Bulk Data access is substantially

greater than the infrastructure required for an individual patient API. An iterative approach is encouraged, beginning with individual enrollee data with successful results before expanding to bulk data access.

- The proposed rule preamble further states that, "A provider that is not in network would need to demonstrate to the patient's payer that they do have a relationship with the patient." **WEDI urges** a standard be identified by CMS for "demonstrating a care relationship" if patient consent is not required, particularly for out-of-network providers for whom a payer would have potentially no claims data. If a scheduled appointment is sufficient, then the final rule should require an API to confirm a scheduled appointment exists in the EHR.
- The rule, as proposed, gives insufficient time for payers to administer out-of-network provider requests. In addition to the complexity associated with verification of a care relationship discussed above, technical logic to automate out-of-network provider access API would significantly escalate the cost of compliance, and manual administration would increase health plan administrative costs. There are no user identifiers (ID) and password credentialing security data for most non-participating providers. For these reasons, **WEDI supports** an iterative approach that starts with health plan participating providers and adding out-of-network providers at a later date; or, at a minimum, increasing the one-day time requirement for out-of-network providers to five business days to better support electronic health information (EHI) data security and privacy.
- **WEDI also supports** CMS and state Medicaid and CHIP agencies implementing a technical, public key infrastructure (PKI) or blockchain structure, to efficiently authenticate out-of-network providers, establishing a digital certificate and public-key encryption among Medicaid providers.

**II.B.5. Proposed Requirements for Payers: Bulk Data Provider Access API:** The rule proposes to implement the Bulk Data Provider Access API approach for data maintained by the payer with a date of service on or after January 1, 2016, by January 1, 2023 or after, as applicable. Comments are also requested on whether this timeline is feasible and whether the benefits would out weight the costs of this Bulk Data Provider Access API proposal.

**WEDI Comment: WEDI urges** CMS to work with providers to ensure the Provider Access API returns useful and useable information. The concern with this proposal is that payers will need to make the costly investment to build this functionality with no guarantee providers will use it. Providers have historically questioned the value of "payer data" and in many cases where payers make data available, providers decide not to incorporate it into the EHR.

Secondly, **WEDI urges** CMS to consider focusing efforts on electronic provisioning of data from patients to providers. If patients can get all payer information via the Patient Access API, then the patient should also be considered an "agent of interoperability." In this context, patients can elect to make their payer data records available to any provider of their choosing if third-party app vendors and EHRs implement a Bulk Data transfer capability. In any case, providers will need EHR vendors to provider a "curation function" so providers and patients can selectively incorporate data into the longitudinal patient record. Without this capability, there will be a significant amount of duplicate and junk data and such a scenario will render the capability useless.

Additionally, more work is needed on the Bulk Data specification before it is mandated. The specification has not been adequately implemented to assess if it will be sufficient to meet the proposed need and timeframes in this proposed rule.

WEDI also has concerns with the technical functions of the Bulk Data specification and the assumption that it will be a benefit for large providers to use it annually to update their records. This is potentially a very large volume of data being transferred via API with many challenges to technical feasibility when including claims, clinical, and prior authorization data. Significant system resources may be consumed in fulfilling such a request, potentially creating contention for additional and potentially more urgent requests. If the large Bulk Data transfer fails, the same resources will be taxed by subsequent resubmissions and, in general, this potentially puts the payer in the position of providing technical support resources. Payers need to be able to put reasonable limits on such Bulk Data requests, or alternatively, CMS should remove the Bulk Data transfer from the initial requirements. Additional analysis is also needed on the specific data and timeliness of the data.

**II.B.6.a. Attribution:** The rule proposes that impacted payers must establish, implement, and maintain a process to facilitate generation of each provider's current beneficiary roster to enable this payer-to-provider data sharing via the Provider Access API.

**WEDI Comment: WEDI believes** that additional clarification is a critical pre-requisite to understanding the intended level and methodology of attribution for access to a patient's data and how payers should address attribution for providers who do not participate in their network. More standardization of the attribution requirements is necessary for successful implementation and more importantly the protection of patient privacy.

The mutual exchange of health information is necessary as it relates to attributed patients in shared-risk arrangements, particularly where the utilization management function is delegated to the provider entity assuming the risk.

Additionally, the requirements outlined in Section II.B.6.a. seems arduous and will require two separate processes for new and established patients. A lack of a standard for attribution will create confusion for providers as the data requirements and processes will potentially vary for every payer. This added burden on providers will likely result in reduced adoption. An electronic standard should be developed for verifying a patient relationship and confirming a patient has an upcoming appointment. As written, there is no electronic, automated method for such confirmation, putting tremendous burden on payers to confirm the relationship and potentially requiring complicated patient consent management to accomplish relationship establishment.

**II.B.6.b. Opt-in:** The rule proposes that impacted payers would be permitted to put a process in place for patients to opt-in to use of the Provider Access API for data sharing between their payer and their providers. Comments are also requested on:

- Whether payers would like to maintain the option to define their own process or if they would prefer CMS to suggest a process
- Whether stakeholders would prefer we finalize an opt-out versus an opt-in approach
- Whether either opt-out, or as currently proposed, opt-in, be permitted but not required

- The associated benefits and burdens with these different approaches

**WEDI Comment: WEDI supports** patients having access to their data through a Provider Access API, but also understands there needs to be a balance between the broader adoption of technology and patient autonomy with their data, accomplished better through an opt-in process, vs. increased accessibility of data for use by the payer and provider through an opt-out process. We urge CMS, payers, and providers to offer broad, easily accessible education to patients about their rights and abilities related to the use of the Provider Access API.

**II.B.6.c. Provider Resources:** The rule proposes that payers make educational resources available to providers that describe how a provider can request patient data using the payer's Provider Access APIs in nontechnical, simple, and easy-to-understand language. As proposed, this would include information on using both the individual patient request function as well as the Bulk Data request function. These resources would be made available on the payer's website and through other appropriate mechanisms through which the payer ordinarily communicates with providers.

**WEDI Comment: WEDI supports** payers making clearly understandable educational resources easily available for providers to learn how they can request patient health data using the payer's Patient Access API. WEDI also asks that prior comments regarding Bulk Data be considered herein.

**SECTION II.C. REDUCING BURDEN OF PRIOR AUTHORIZATION THROUGH APIs**

**II.C.2. Electronic Options for Prior Authorization:** The rule proposes requirements for payers to implement APIs to facilitate the exchange of information between payers and providers. Stakeholder input has confirmed that payers and providers do not take advantage of standards that are currently available for the exchange of electronic prior authorization transactions. Comments are requested on other steps CMS could take to further implementation of the X12 278 standard and what challenges would remain if the standard was more widely utilized.

**WEDI Comment: WEDI strongly supports** the adoption of an attachments standard and have called for this requirement for many years. An electronic attachment standard was mandated by Congress in HIPAA in 1996 and re-mandated in section 1104 of the Patient Protection and Affordable Care Act (ACA) in 2010. Yet, CMS has not issued a final regulation naming the standard. We have been made aware that an attachments proposed rule is in the CMS clearance process and is estimated to be published in Quarter 1 of 2021. **WEDI urges** CMS to expedite release of that regulation and ensure that it is harmonized with this proposed rule to align the requirements for the exchange of supporting documentation. It is imperative to avoid setting different processes per different rules.

The challenge of exchanging documents and attachments via API is evidenced by recent CMS implementation guidance issued for the Interoperability and Patient Access Final Rule (CMS-9115-F), where the agency indicated that electronic attachments, PDFs, and images are not required to be made available by health plans for clinical data under the Patient Access API. If CMS finalizes an electronic attachment standard, it should allow health plans and providers time to implement the new standard, so that attachments can be created by EHR systems and ingested by health plan care or utilization management systems before the agency mandates a Prior Authorization Support API.

It is widely known in the industry that the X12 Health Care Services Review (X12 278) transaction has not been widely implemented. Without an attachment standard, payers have developed web-based portals to provide a mechanism by which to submit documentation to support the prior authorization request. A mandated attachments standard is imperative for the prior authorization process regardless of which transactions are used to send and respond to requests. Additionally, using an API to move the data for the prior authorization request and response does not address the workflow issues for the provider or payer.

**WEDI concludes** that given the issues noted above, the effective dates set forth in the proposed rule for the Prior Authorization Support API are too aggressive.

**II.C.3. Proposed Requirement for Payers: Documentation Requirement Lookup Service (DRLS) API:** The rule proposes that impacted payers beginning on or after January 1, 2023, as applicable, implement and maintain a FHIR-based DRLS API conformant with the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) IG: Version STU 1.0.0 and the HL7 FHIR Da Vinci Documentation Templates and Rules (DTR): Version STU 1.0.0 IG, populated with their list of covered items and services for which prior authorization is required, and with the organization's documentation requirements for submitting a prior authorization request, including a description of the required documentation.

**WEDI Comment:** The WEDI Prior Authorization Subworkgroup is currently writing a white paper that will support the use of the X12 278 transaction as both the way for providers to determine if a service requires prior authorization and the documentation requirements. The CAQH CORE Prior Authorization operating rules, further described below, also support using the X12 278 transaction to provide documentation requirements. The concern with the CRD and DTR IGs is that they are not yet in production. **WEDI supports** additional testing of these IGs before requiring their implementation.

With much of the value of the DRLS process derived from its real-time capabilities, WEDI requests that CMS delineate how DRLS will be deployed within provider workflows in a manner that will best take advantage of its automation opportunities.

**WEDI urges** CMS to work with us on identifying the ROI with the DRLS technology and modeling how the current and new standards can work together. Additionally, testing and timing of availability for the new technology is necessary. While the new technology is needed today, the industry is looking for proven functionality.

Additional comments are requested on:

- A potential short-term solution to address the challenge of accessing payer requirements for prior authorizations.
- How payers currently communicate prior authorization requirements.
- The potential for payers to post on a public-facing website their list of items and services for which prior authorization is required and their associated documentation rules as in interim step while they implement the DRLS .
- How the posting of this information on payer websites would provide a satisfactory interim solution to accessing payer requirements for prior authorizations in advance of implementing the DRLS API.

**WEDI Comment: WEDI provides** the following information:

- Addressing the challenge of accessing payer requirements for prior authorizations would decrease provider burden and streamline the prior authorization process. Reducing these interactions would streamline the prior authorization process for all parties.
- Typically, prior authorization requirements are communicated to providers via websites, written and electronic bulletins, medical policy documentation, and emails to providers.
- One option for achieving this goal would be to standardize how payer requirements for prior authorizations are presented to providers. For example, the industry could develop a template that payers could voluntarily deploy listing the medications and medical services that require an authorization, and include the clinical documentation required by the payer to support the authorization. These templates could then be posted on the payer's public-facing website.
- This level of transparency would be very helpful for providers and should reduce the call volumes between payers and providers.
- The WEDI Prior Authorization Subworkgroup supports the use of the X12 278 transaction to communicate documentation requirements. While posting documentation requirements on payers' websites can be a short-term solution, it does not make significant progress to resolve the administrative burden for both providers and payers.

**II.C.4. Proposed Requirement for Payers: Implementation of a Prior Authorization Support API:** The rule proposes that impacted payers implement on or before January 1, 2023, as applicable, a Prior Authorization Support (PAS) API that facilitates a HIPAA compliant prior authorization request and response, including any forms or medical record documentation required by the payer for items or services for which the provider is seeking authorization.

**WEDI Comment:** As previously stated, **WEDI provides** the following comments:

- These HL7 IGs need to further mature and will likely require changes before they can be finalized.
- An attachments standard is necessary for payers to implement this function. Inclusion of forms, clinical documentation, and other information required by payers necessitates attachments otherwise the requirement is unable to realize the full benefit.
- For the industry to successfully achieve these benefits, a single document needs to be created to map from the Prior Authorization Support (PAS) API with the HIPAA-compliant X12 278. If not, there will be inconsistencies among payers resulting in providers having to track each payers' unique requirements and mappings. WEDI is willing to work with the standards organizations on the development of the mapping to ensure consistency. We can also assist with the education on business flows that will need to occur.
- Transparency of payers' requirements for prior authorization is imperative to streamline the requirements and reduce the current burden experienced by all stakeholders.

**II.C.4.a. Requirement to Provide a Reason for Denial:** The rule proposes that impacted payers include a specific reason for denial with all prior authorization decisions, regardless of the method used to send the prior authorization decision.

**WEDI Comment: WEDI strongly supports** requiring the payer to include a detailed reason for denial to the provider as soon as the determination is made. In addition to providing a reason for the denial, the API should provide a mechanism for reconsideration and appeal of a denied prior authorization. This will improve the current prior authorization process. Providers would better understand a payer's prior authorization requirements, which could lead to decreased call volumes between providers and payers.

The application of denial codes must be standardized to truly be an effective communication tool, decrease cost, and decrease the burden of implementation for payers, providers, and their vendor partners. **WEDI urges** CMS to work directly with X12, the entity that maintains code sets relevant to the X12 278 transaction, among others.

**II.C.6.c. Proposals to Address Timeframes for Standard Prior Authorization Requests:** The rule proposes that state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities on or after January 1, 2023, as applicable, provide notice of prior authorization decisions not later than 72 hours of receiving a request for expedited decisions. Notice should be provided no later than 7 calendar days after receiving a request for standard decisions. Medicaid managed care plans are allowed an extension of 14 days if the enrollee requests it or a health plan determines additional information is needed.

**WEDI Comment: WEDI recognizes** that a balance is necessary between accelerating the timing of a payer communication of prior authorization determinations to providers while not imposing unreasonable expectations on payers. As an example of a multi-stakeholder process that developed specific timeframes for payers to respond to providers prior authorization requests, **WEDI urges** CMS to review the work that was done by CAQH CORE on its prior authorization operating rules. The CAQH CORE 278 Prior Authorization Infrastructure Rule coupled with the CAQH CORE 278 Prior Authorization Data Content Rule set national expectations for prior authorization turnaround times using the HIPAA-mandated X12 278 standard to move the industry toward greater automation.

WEDI provides the following additional comments:

- The response timeframes need to consider the multi-system approach that these APIs would entail. The CORE operating rule timeframes apply only to the X12 278 transaction and are not transferrable to an API process that includes conversion to and from a X12 278 transaction.
- Without a critical mass of providers using the API, shorter timeframes will be challenging for payers to meet.
- Mandated response timeframes will promote consistency across all payer markets.
- Clarification will be necessary on how, if adopted, these response timeframes apply to and impact existing requirements.
- Automating the prior authorization process will enable faster response times, from a technical perspective.

**II.C.8. Public Reporting of Prior Authorization Metrics:** The rule proposes that publicly report, at least annually beginning March 31, 2023, prior authorization metrics on their websites or via publicly accessible hyperlink(s). The metrics would include, at a minimum, the following:

- A list of all items and services that require prior authorization;
- The percentage of standard prior authorization requests that were approved, reported separately for items and services;
- The percentage of standard prior authorization requests that were denied, reported separately for items and services;
- The percentage of standard prior authorization requests that were approved after appeal, reported separately for items and services;
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported separately for items and services;
- The percentage of expedited prior authorization requests that were approved, reported separately for items and services;
- The average and median time that elapsed between the submission of a request and a decision by the payer, health plan, or issuer, for standard prior authorizations, reported separately for items and services.

  **WEDI Comment: WEDI supports** metrics and providing transparency of meaningful information on the prior authorization process. We do have concerns at this time about the specific metrics being proposed and suggest that CMS work with the impacted payers to identify appropriate measures that will promote the use of prior authorization standards and reduce burden.

**II.C.9. Request for Comments on "Gold-Carding" Programs for Prior Authorization:** The rule seeks comment on potential future rulemaking on the incorporation of gold-carding into star ratings for QHP issuers on the FFEs. Comments are also sought on proposing gold-carding as a requirement in payer's prior authorization policies and on how such programs could be structured to meet such a potential requirement.

**WEDI Comment: WEDI supports** the concept of "Gold Carding" programs. A great reduction in administrative burden for payers and providers can be achieved by not requiring prior authorizations from high performing providers.

**WEDI urges** CMS to convene a cross-industry group to develop guidelines for a model program, including the measures by which to hold the providers accountable. WEDI is willing to assist in facilitating this effort.

**SECTION II.D PAYER-TO-PAYER DATA EXCHANGE ON FHIR**

**II.D.4 Enhancing the Payer-to-Payer Data Exchange – Payer-to-Payer API:** The rule proposes to require impacted payers, by January 1, 2023, as applicable, conduct the payer-to-payer data exchange via an API and make available, at a minimum, the USCDI version 1 data, claims and encounter data, and information about pending and active prior authorization decisions.

Additional comments are requested on whether in future rulemaking to require payers to:

- Demonstrate they have reviewed and considered previous prior authorization decisions and associated clinical documentation from a patient's previous payer before requiring patients to undergo a new prior authorization process

- Honor a previous payer's active prior authorization decision at the time the enrollee moves from one payer to a new payer for some length of time, such as 30, 45, or 60 days, or if there are situations where this may not be possible or appropriate and why

**WEDI Comment: WEDI generally supports** these proposed requirements and offers the following comments:

- The importance of prior authorization is the continuity of patient care and not disrupting therapies when a patient switches health plans. CMS should engage industry stakeholders on policies, e.g., state and federal laws, private accreditation standards, that can support this goal.
- Clarification is needed on how any future proposed changes would be different from the current standards, whether new standards would be specific to electronic prior authorizations through the PAS API, and whether new standards would be duplicative or replace existing standards.
- Clarification is needed to understand which prior authorization policies are required by the impacted payer, as policies currently differ by payers for warranted reasons.
- Since the APIs for Payer-to Payer Data Exchange do not currently contain prior authorization data, it is premature to identify a mandated date. These IGs must first be either updated or an IG specific to the missing data must be developed and factored into the workflow before any specific compliance dates are identified.
- The rule requires members' previous health plans to provide the required data to successor health plans within one business day, which would require impacted payers to maintain a process to obtain from a new member the name of their previous payer, and concurrent payer if member has more than one. Health plans continue to have privacy and security exposure for the member's prior health plan, in sharing data directly with another health plan, without the member's initiation or consent. Therefore, **WEDI proposes** that previous health plans be required to implement a process to authenticate the successor health plan's actual coverage of prior members. Additionally, CMS could require the impacted payers to provide a member's prior health plans with the successor health plan information, to better ensure authentication under the Payer-to-Payer API, and accurate identification of specific individual health plan data.

**SECTION II.E. ADOPTION OF HEALTH IT STANDARDS AND IMPLEMENTATION SPECIFICIATIONS**

**II.E.3. Proposal to Adopt the Standards for Use by HHS:** The rule proposes to adopt the latest version of the following standards:

- HL7 FHIR Da Vinci - Coverage Requirements Discovery (CRD) Implementation Guide: Version STU 1.0.0.
- HL7 FHIR Da Vinci - Documentation Templates and Rules (DTR) Implementation Guide: Version STU 1.0.0.
- HL7 FHIR Da Vinci - Prior Authorization Support (PAS) Implementation Guide: Version STU 1.0.0.
- HL7 FHIR Da Vinci - Payer Coverage Decision Exchange (PCDE) Implementation Guide: Version STU 1.0.0.

- HL7 FHIR Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide: Version STU 1.0.0.
- HL7 FHIR Da Vinci Payer Data Exchange (PDex) Implementation Guide: Version STU 1.0.0.
- HL7 FHIR Da Vinci - Payer Data Exchange (PDex) US Drug Formulary Implementation Guide: Version STU 1.0.1.
- HL7 FHIR Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide: Version STU 1.0.0.

**WEDI Comment: WEDI strongly supports** standards for automatable and scalable processes that eliminate burden and waste. WEDI supports FHIR and the work of Da Vinci and these resulting IGs.

**WEDI strongly supports** the automation of the prior authorization process. We do have concerns with these IGs, as currently they are standards for trial use (STU) and have not been widely tested in real-time scenarios. WEDI believes the HL7 IG development process will finalize these IGs in a reasonable timeframe. It is our understanding that these IGs support both direct and clearinghouse connections, do not require "Direct Connect," and are harmonized with the X12 278 transaction process.

**SECTION III. REQUESTS FOR INFORMATION**

**III.B Electronic Exchange of Behavioral Health Information:** This RFI seeks feedback on how best to support electronic data exchange of behavioral health information between and among behavioral health providers, other health care providers, and patients, as well as how to best inform and support the movement of health data, and its consistency, to behavioral health providers for their use to inform care and treatment of behavioral health services.

**WEDI Comment:** WEDI understands the challenges of balancing the confidentiality of sensitive patient information with its accessibility for care delivery. We strongly believe that behavioral health and other confidential information should be separate and apart from the general medical record information. Behavioral health and other confidential information, such as family planning, HIV, social risk, and other similar types of data should only be released on a need-to-know basis and only to designated, authorized individuals or organizations. WEDI urges CMS to convene a cross-industry group of impacted stakeholders to analyze the issues associated with this workflow and issue guidelines or best practices the industry can implement.

**III.C Reducing Burden and Improving Electronic Information Exchange of Prior Authorization:** This RFI seeks feedback on 1) barriers that exist for hospitals, and other providers and suppliers, to electronically transmit prior authorization requests and receive prior authorization decisions for patients receiving care and services by the applicable provider and 2) the addition of a MIPS improvement activity, and if this area will be appropriate to encourage clinicians to make certain improvements.

**WEDI Comment:** The current practice for providers is to fax, mail, or upload to proprietary websites prior authorization requests and submit the clinical documentation necessary to conduct prior authorizations. At the same time, the vast majority of inpatient and outpatient facilities have implemented EHRs, giving them unprecedented opportunities to automate the collection and transmission of clinical data in support of a prior authorization. Despite the high level of EHR adoption, in the past some providers have been reluctant to adopt new electronic solutions for

administrative transactions. To encourage providers to invest the resources necessary to implement electronic prior authorization, the solution must go beyond the initial communication to the health plan and include the ability to transmit supporting clinical documentation, reduce the variability of health plan requirements, be incorporated into the clinician workflow, include provider education, and have a clear ROI.

Electronic Attachments

We agree that one of the challenges to moving the industry to automated prior authorization solutions is provider adoption. The 2019 CAQH Index Report, released in 2020, suggests that industry adoption of the electronic prior authorization transaction lags significantly behind the other HIPAA-mandated electronic transactions, see below. Electronic claim submission (96% in 2019), coordination of benefits/crossover claim (86 percent in 2019), eligibility and benefit verification (84% in 2019), claim status inquiry (70% in 2019), claim payment (70% in 2019), and remittance advice (51% in 2019) are all higher than prior authorization transaction (13% in 2019).

We believe, however, that the low adoption rate of the X12 278 is not a sign that providers are unwilling to implement an automated solution to prior authorization but is due primarily to the fact that there is no standardized approach to transmitting the necessary clinical documentation to the health plan. An electronic attachment standard was mandated by Congress in HIPAA in 1996 and re-mandated in section 1104 of the ACA in 2010. CMS, however, has not yet issued a final regulation naming the standard. Creating a national standard for electronic attachments would streamline the prior authorization process and decrease administrative burden and cost by:

- Eliminating lost health plan requests for additional documentation and provider responses;
- Reducing cost associated with staff manual collection of supporting documentation and the cost of paper and postage;
- Decreasing health plan documentation requests as there would be improved predictability of plan content needs, i.e., plans could be specific in what they required to render an authorization decision, thus eliminating the “back and forth” that currently exists in the system; and
- Reducing pends, denials, appeals, all resulting in faster treatment approvals.

A national standard for the electronic attachment also opens the door for additional functionality that would have a direct impact on the delivery of patient care. For example, care coordination and care management, patient transitions of care, quality reporting, support for alternative payment models such as patient-centered medical homes and accountable care organizations, all will benefit from standardized and automated clinical data exchange.

Reduce Proprietary Approaches

Another incentive for providers to adopt electronic prior authorization solutions would be to reduce the ability of payers to require proprietary approaches. The current proposal from CMS applies only to Medicaid and CHIP managed care plans, state Medicaid and CHIP FFS programs, and Qualified Health Plans issuers on the Federally-facilitated Exchanges. With no mandated attachments standard, all other payers would continue being permitted to have their providers submit prior authorization requests via fax, phone, or online web portal. Should only a small percentage of a provider’s patient base be comprised of those covered by payers outlined in the proposed rule, it is

highly unlikely that providers would invest resources in a technology solution to address only a small fraction of their prior authorization volume.

Integrate Real-Time Solutions Directly into Provider Workflows

Real-time electronic prior authorization transactions have the potential of reducing cost for health plans and providers by eliminating manual, e.g., fax, phone, proprietary payer web portal, provider communications with the plan. These real-time decisions would be primarily for routine medical services and medications that are approved at an extremely high rate. These are medical services and medications that would not typically require the submission of a large amount of supporting documentation from the provider to the plan.

These real-time decisions for routine medical services and medications could mirror the current approach that providers and health plans leverage for verifying insurance eligibility and benefits. Under the 2011 CMS interim final rule, plans are required to support a real-time eligibility and benefits verification transaction with the supporting operating rule developed by CAQH CORE stipulating that the maximum response time when processing in real time mode must be 20 seconds or less.

In the ONC November 2018 report "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs," recommendations are identified for improving prior authorization processes. On page 19 of the report, ONC signals its clear support for real-time electronic prior authorization transactions when it makes the following recommendation: "*Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers and payers*."

Establish Return on Investment

Ultimately, the most effective way to incentivize providers to adopt electronic prior authorization solutions is to establish a clear ROI. Absent that ROI, especially in times of economic uncertainty, providers will be very unlikely to invest resources in untried and untested technologies. We note that increased use of the prior authorization electronic transaction would result in significant savings to both plans and providers. Data reported in from the 2019 CAQH Index Report, suggests that moving from manual to electronic prior authorizations would net the health plans a savings of $3.27 per transaction. For providers, moving from manual to electronic prior authorization transactions would net a savings of $9.04 per transaction. CAQH estimates that the combined net savings for the industry would be $12.31 per prior authorization transaction, see below. Promoting these savings opportunities will be critical in any effort to encourage providers to implement automation solutions.

Provider Education

Educating the provider community on the advantages associated with adoption of electronic attachments and electronic prior authorization would jump start the national implementation. Once automation solutions have been established, we encourage CMS to work directly with WEDI and the national provider associations to conduct outreach on the value proposition for adoption these new solutions and for implementation guidance.

Market Demand

EHR and practice management system software vendors are not covered entities under the law. For them to offer automation solutions they need to hear clearly from their customer base that this functionality is being requested by their customers. Establishing the ROI for these solutions will arm providers with the information they need to request that their vendor partners support automated prior authorization. In addition, to align with what ONC has required in its 2020 Interoperability final rule, CMS should consider limiting the fees EHR and practice management system software vendors can charge providers for meeting these regulatory requirements.

MIPS Improvement Activity

The Improvement Activity component of MIPS could be one lever to encourage eligible clinicians and group practices to adopt electronic prior authorization solutions, but we believe it would offer only a modest incentive at best. The Improvement Activity component is currently worth just 15 percent of the total MIPS score. We would propose that if adoption of a CMS-recognized electronic prior authorization solution is included in the list of qualified Improvement Activities, it should be assigned a high weight as further encouragement for eligible clinicians and group practices to implement these solutions.

Additional Proposals

- Evaluate and address other process and clinical workflow factors contributing to burden associated with prior authorization.
- Support automation of ordering and prior authorization processes for medical services and equipment through adoption of standardized templates, data elements, and real-time standards-based electronic transactions between providers, suppliers, and payers.
- Incentivize adoption of technology which can generate and exchange standardized data supporting documentation needs for ordering and prior authorization processes.
    - Encourage additional provider, health plan, and vendor input in the standards development process. It is critical that FHIR-focused initiatives include the perspectives of every impacted stakeholder group, including health plans, vendors, and providers from a variety of care settings.
    - Integrate FHIR into the current standards environment. While FHIR-based standards show great promise, there has been considerable investment made in the current X12 electronic transactions. We urge that FHIR-based standards be offered as an additional option, for willing trading partners, to the X12 standards, but not yet as a mandated replacement.
    - Identify administrative use cases. We urge the developers of FHIR-based standards close align their work with those engaged in alleviating clinician administrative burdens.
    - Focus on template and rules transparency. Transparency of health plan clinical documentation requirement templates and plan coverage rules as use cases will result in a significant reduction in administrative burden.
- Work with health plans and other stakeholders to support pilots for standardized electronic ordering of services.
- Avoid costly mandates on the industry: Adopting the technology and workflow modifications necessary to support any new standard requires considerable investment by stakeholders.

New standards need to be fully tested and EHR, practice management system, and other software vendors must incorporate them fully prior to any requirement to use them. The cost for stakeholders to implement any new standard must be considered prior to any mandate.

- Recognize that if there is low provider interest in the APIs named in this rule, it should not be seen as a lack of interest in automating prior authorization or the need for a federal mandate on providers. The limited patient population will likely discourage adoption. A low uptake after this rule will not be a reason to mandate FHIR PA on providers.

**III.D Reducing the Use of Fax Machines:** This RFI seeks feedback on how electronic data exchange could replace fax technology.

**WEDI Comment:** The biggest single issue with the fax machine in health care, other than that it takes a significant amount of time on both the sender's and receiver's part to collect, organize, document, and convey the requisite information relevant to a care process, is that it is still perceived by many providers as the most efficient method to accomplish the task at hand.

1. A fax machine is easy to naturally incorporate into the office flow, "when I have a minute, I can just fill out the form and drop it on the machine."
2. It is ubiquitous:
    a. Every care delivery site has a fax machine somewhere, making them inexpensive and dependable.
    b. All work exactly the same way, due to technology standards.
    c. They require no specialized training to operate.
3. Putting pen to paper is still the fastest way to collect, organize, document, and convey a concise body of rich narrative text that is structured "just enough" to communicate the minimum data set to address the purpose of the required information exchange transaction.

In our day-to-day lives, scanning did not significantly replace fax machines until the scanner was natively incorporated into our smart phones. The smart phone (especially when accompanied by application-based functionality like "Share" (), has virtually eliminated the fax. The "Share" process with scanning does not eliminate most of the pre- and post-transmission effort but it does significantly reduce the friction of the overall process and renders the expense and maintenance of the fax machine unnecessary.

The key is that it is easier for everybody. With the smart phone, we have an alternative that cleanly incorporates into the human experience, and there is almost no incremental cost to our adoption of the technology. The smart phone did not set out to eliminate fax machines, it just did.

The corollary for health care is that the fax machine is a symptom, not a cause. We should not set out to eliminate it as a goal. The goal is to optimize the overall care process with alternate but easily available technology. EHR and other health IT technology in use by providers, payers and other stakeholders is already on our desktops, e.g., smart phones. What is required are the carrots and sticks to cause the health IT developers to metaphorically add "" to the UI palette. The status quo supports a range of costly business practices and models. Much of this proposed rule moves the industry to adopt the software capabilities that would lead to the end-to-end automation of all

manner of requests for additional information. We encourage CMS to pursue the agenda that is apparent in this proposed rule and consider that the necessary industry activities and investments that will lead to the elimination of the fax machine are part of the overall effort to digitally enable administrative and care delivery processes from end-to-end. We do need to still recognize that small and rural providers may need to continue to rely on fax machines for the foreseeable future. These providers lack the current infrastructure and resources to implement FHIR-based technology and will need additional support to reach end-to-end automation.

**III.E Accelerating the Adoption of Standards Related to Social Risk Data:** This RFI seeks feedback on barriers the health care industry faces to using industry standards and opportunities to accelerate adoption of standards related to social risk data.

**WEDI Comment:** The health inequities experienced by individuals at risk for the social determinants of health (SDoH) during the COVID-19 pandemic highlighted the growing need for improved cross-sector sharing of social and medical care information. Common social determinants domains include collecting information about food, housing, education, utility assistance, employment, stress, anxiety, and depression. Stress, anxiety, and depression may be considered behavioral health conditions, more so than SDoH domains.

SDoH services exists outside the traditional health care delivery domain as defined by HIPAA and treatment payment and operations. For example, it can include food banks, 211 services, community support services, faith-based organizations, and social services organizations. These entities are not routinely included in the chain of trust associated with covered entities and their business associates. Therefore, what constitutes treatment, payment, and operations when determining to include these social services into the healthcare plan is often unclear.

Identified Need: Clarification and definition are needed of the type of entity that social services and community services represent in the HIPAA chain of trust and provision of examples of both appropriate sharing and information blocking.

Many care delivery organizations do already have standard protocols in place for collecting SDoH data and in some cases even mechanisms for SDoH outcome tracking. Despite the existence of operational protocols and organization specific mechanisms to track SDoH data, the collection systems vary widely and are unable to interoperate with other systems and care partners. This creates a barrier when clients seek services from multiple organizations. In addition to exchanging SDoH data at the individual client level for care coordination purposes, in order to make a long-term difference in the SDoH arena it will become increasingly important to share aggregated, i.e., bulk and de-identified SDoH data across communities and with public health officials, social services organizations, health payers, and researchers to improve our understanding of population health needs, make informed decisions on enhanced service delivery, and to produce social care models that can better support clinical and community linkages. Without data standardization across multiple organizations, including facilities collecting SDoH in proprietary manner today the ability to measure outcomes will remain a barrier.

The Gravity Project was initiated in November 2018 by SIREN with funding from the Robert Wood Johnson Foundation to convene broad stakeholder groups in identifying and harmonizing social risk factor data for interoperable electronic health information exchange. The national Gravity Project

collaborative has described a conceptual framework for SDoH data standards (https://confluence.hl7.org/plugins/servlet/mobile?contentId=91996855#TheGravityProject-Overview) that involves collection, exchange and use of three defined types of SDoH data, Screening, Diagnosis, and Intervention, all of which are necessary to enable accurate identification and management of social problems. At the present time, the Gravity Project remains the focal point for championing the standards for coding and data exchange in this arena.

Screening: Many organizations ask a series of screening questions related to the multiple social domains such as around food insecurity, housing, transportation, etc. The results of these screening questions must be appropriately coded to insure consistency and usability across organizations. The Gravity project has been championing work in this area. It is important to consider the answers to these screening questions as observations in the form of LOINC codes that are commonly used in EHRs. Observations should be captured and interpreted in the right context to ensure that no unintended bias has been introduced when attempting to leverage machine learning technology to auto risk stratify or categorize people. Another important barrier worth noting is that many small organizations do not have the equivalent of an EHR systems to capture and track information about clients. In contrast, state, county, or municipal funded social services programs do use robust platforms to track clients do electronically capture this type of information, unfortunately though most of these systems do receive some amount of federal financial support, they have not been required to be interoperable with community or medical care facilities. Broad integration of eligibility for social programs such as Supplemental Nutrition Assistance Program (SNAP), children's services, with healthcare programs remains a barrier. As in the healthcare delivery space social services also has challenges around client matching.

<u>Identified Need:</u>

- Support for the acceleration of the Gravity project's efforts.
- Appropriate expansion of the U.S. Core Data for Interoperability (USCDI) to include a social care class along with the recommended use of existing or the timely creation of new LOINC codes to capture social care and community organization observations. This effort should also ensure that a minimum set of SDoH screening question domain areas are established that can be mapped to the appropriate USCDI Class and data element definitions such that both EHRs and social work and community service organization electronic systems can retain the data.
- Encourage all HHS programs to promote interoperability across the continuum of social and health care.

Diagnosis: The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) has a series of Z codes that capture many of the SDoHs of health. Raising awareness of these codes and encouraging their reporting on claims will increase the ability to analyze this data. Claims function as the life blood for health plans to measure the cost of care and to utilize big data analytics to determine and assess the effectiveness of new services to improve quality or reduce the cost of care.

The incorporation of ICD-10-CM codes into claim forms has historically been limited to the requisite diagnosis codes necessary to justify and support the procedures provided. In recent years, additional ICD-10-CM codes that highlight additional risk have also been incorporated more routinely.

Unfortunately, the broad adoption of ICD-10-CM Z code inclusion on all claim submissions has not yet become pervasive.

Another barrier to understanding the financial impact of SDoH risk is that many community-based programs in a typical health care setting would be paid for by the health plan are instead covered by donations, a grant, or special community program, so no claims are submitted. This results in a gap in the data. The impact of this unintended consequence is that the health plan typically has some data about the individual that received the community services but remains blind to the additional services rendered. This lack of transparency can lead to a scenario where from a data perspective the community program does not show a value for the return and worse may appear to have resulted in lower quality due to the missing data.

Therefore, an opportunity occurs when a community organization receives grant funding from a third-party, such as a foundation, to provide community services expected to positively impact the long-term health of an individual and reduce overall cost. Frequently, the granting agency provides resources with the expectation that the community organization will demonstrate the value for the community service to reduce the long-term costs of care, e.g., emergency department utilization or hospital readmissions. The granting agency hope is that ultimately the funded program will develop a sustainable model to transition away from reliance on grant funds and evolve to resources from the traditional care delivery system. One reason this transition often fails is because these community-based services typically do not turn in claims to the health plans for such services and consequently the long-term financial benefit is difficult to measure. As the social care and health delivery system continue to align an opportunity for greater transparency into the services delivered in both domains exists.

Identified Need: Consider a series of CMS Innovation Center pilots that leverage an evolution of the Version 5010 X12 standards for HIPAA transactions to support a broader array of community-based services payment that align with SDoH Interventions.

Intervention: An activity linked to prior authorization in the traditional health care delivery process the ASC X12 Health Care Services Review. In this transaction Request for Review and Response (X12 278) is a paired transaction set consisting of a Request (X12 278) and a Response (X12 278). The Request for Review allows provider to request authorization from a health plan or utilization management organization for a referral to a specialist, a hospital admission, or a health care service or supply. In the community and social risk setting, there is no official standard for this type of referral activity.

In the social care and community space, after observations collection and the interpretation of the best diagnoses by a trained professional the next step is to select the most appropriate intervention and make a referral to this service. The optimal intervention must account for the individual's preferences in addition to a best practice. Typically, after diagnosis, a referral is made to one or more services. Discovery of available services requires the existence of some type of directory of services along with disclosure of any special requirements or limitations on who can use or qualify for the service. A barrier to interoperability is that there is no national directory for these types of social or community services. Multiple proprietary vendors occupy this space, but nothing akin to the National Plan and Provider Enumeration System (NPPES). A great deal of work has, however,

been completed on developing a taxonomy of services for human services by the Alliance for Information and Referral Services (AIRS).

The 211 LA County Taxonomy ("Taxonomy") is copyrighted by 211 LA County and available only to licensed subscribers. AIRS does not own, develop, or receive any financial benefit from the Taxonomy. Vendors that create information and referral (I&R) software that incorporates the Taxonomy and uses the software to maintain a resource database employing the Taxonomy are required to maintain a valid license. The Taxonomy is the North American standard for indexing and accessing human services resource databases. It is a hierarchical system that contains more than 9,000 fully defined terms that cover the complete range of human services. It serves as a common language that facilitates interoperability between different I&R resource databases and represents a tremendous gift to the I&R movement that has evolved over 20 years thanks to the commitment of 211 LA County and the Taxonomy's editor, Georgia Sales. U.S. English, Canadian English, and Canadian French versions of the Taxonomy can be accessed via the Taxonomy website at www.211taxonomy.org. A major barrier to integration with the care delivery system is that public health and medical care standards have not been harmonized with the 211 LA County Taxonomy.

A second challenge related to tracking the status of referrals is that organizations must either be on the same vendor solution or rely on Direct Secure Messaging, short message service (SMS), or fax communications to cross organizational boundaries. A benefit to being on the same system is easier tracking of the service request to completion. Sometimes called closed-loop-referral, this feature makes it easier for the caregiver to know that the client has received the service or assist with finding a new option if some unforeseen issue prevented the person from accessing the service. Consequently, an additional barrier to making referrals among health care delivery and community organizations is that no interoperable standard yet exists.

Identified Need:
Consider sponsoring a series of activities to pilot interoperable referrals across multi-vendor and unaffiliated organizations to advance the formation and adoption of referral standards. This would include sponsoring a series of efforts to better align the national efforts around provider directory standardization and NPPES with the 211 LA County Taxonomy human services work. For example, there is good work around the HL7 FHIR Referral/Request resource and the X12 278 transaction sets, however, there is significant need to bring the human services perspective that better reflects the issues of social risk into harmonization with the health delivery standards process.

Provider Workflow
As CMS considers how best to promote the collection and dissemination of SDoH data, it is imperative that provider workflow issues are incorporated. To be practical, useful, and actionable, SDoH data must be presented to the provider in a clear, unambiguous, and concise manner. SDoH data must be directly in the provider's workflow for it to be effectively acted upon. Primary care providers, the clinicians most likely to need and use SDoH data, have only a limited amount of time to spend with each of their patients. Unnecessary time spent searching for SDoH-related information will take time away from direct patient care. Optimally, SDoH data will serve as a trigger for the provider during the encounter to identify patient needs and specific solutions, e.g., the address of a local food bank.