BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

January 4, 2021

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via 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 Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications (CMS-9123-P)**

Dear Administrator Verma:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to respond to the Proposed Rule "Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information by Medicaid Managed Care Plans; State Medicaid Agencies, CHIP Agencies and Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications," published in the Federal Register on Dec. 18, 2020 (85 CFR 82586).

BCBSA is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield (BCBS) companies (Plans) that collectively provide health care coverage for one in three Americans. For more than 90 years, BCBS Plans have offered quality health care coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

BCBS Plans have a long-standing commitment to improving interoperability and transparency of health care information and believe that secure and seamless flow of health data among patients, doctors, hospitals and insurance companies is essential to driving outcomes. As leaders in advancing data interoperability and consumer access, BCBSA and Plans have engaged in numerous initiatives to empower patients by providing online consumer tools,

voluntary expansion of the Blue Button 2.0 initiative, serving as a founding member in the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) Application Programming Interface (API) standards development effort named the Da Vinci Project and being an active member in the Creating Access to Real-Time Information Now (CARIN) Alliance Common Payer Consumer Data Set (CPCDS) Workgroup.

Our comments below also reflect our extensive experience around data exchange and interoperability as the operator of the BlueCard program, one of the largest health claims processing and reimbursement programs in the nation, which provides BCBS members with seamless national access to physicians and hospitals that participate in BCBS Plans' health care networks.

Informed by our experience, we agree that actionable, secure, reliable and interoperable data that is shared using standards-based APIs will enable a higher quality, more efficient and effective health system. This is important to everyone – from employers to providers to consumers. BCBSA supports the Center for Medicare & Medicaid Services' (CMS) overall goal of providing patient access to actionable data that is meaningful to consumers, with implementations paced to the availability of data standards, data security and technical infrastructure. These elements are essential to achieving full interoperability and consumer transparency.

Despite our support for these policy objectives, we have significant concerns regarding the limited time afforded to stakeholders for meaningful review of and comment on this Proposed Rule. As outlined in our Dec. 16 letter to Secretary Azar, we strongly believe that additional time is needed to allow impacted payers to complete a comprehensive technical review of the Proposed Rule, along with the incorporated implementation guides, data elements and FHIR API capabilities among all member health insurance providers as well as the workflow assessments needed to provide feedback on administrative burden. A 14-business day comment period is not sufficient time to analyze a proposed regulation that will result in up to $2.8 billion in total costs over 10 years. We recommend instead, additional 60 days to comment prior to finalizing the Proposed Rule.

With this in mind, we highlight below key issues for your heightened attention, and we urge CMS to incorporate our recommendations into the Final Rule and future rulemaking:

- **Extend the effective date of all of the proposed API requirements by 24 months.** Although we share CMS' sense of urgency in advancing interoperability, there are industry realities that may stall the successful implementation and use of APIs, data standards and clinical data by all stakeholders involved. Additional standards development and adoption is needed prior to full implementation of the proposed Patient Access API, Provider Access APIs, Payer-to-Payer Exchange (particularly the enrollment use case), Document Requirement Lookup Service (DRLS) API, and Prior Authorization Support (PAS) API. BCBSA strongly recommends extending the timeline for the new API requirements.

- **Prioritize consumer privacy and require vetting of third-party applications**. Having a process in place as APIs come online will be important to establishing public confidence in the privacy, confidentiality and security of consumer data moving through these applications. BCBSA encourages the Administration to work with Congress to develop a framework for ensuring that data shared with third-party applications is protected. We recommend that CMS not finalize the provision that requires payers to develop and implement third-party privacy attestation processes. Instead, we suggest CMS work with the Federal Trade Commission (FTC) on regulations aimed at protecting patients from third-party abuses. These regulations should be consistent with federal Health Insurance Portability and Accountability Act (HIPAA) privacy standards.

- **Clarify accountability for getting the right data to the right person.** CMS should provide liability protection (i.e., a safe harbor) to parties who are required to provide data through the Patient Access API and the Provider Access APIs when the data originated elsewhere or after the data is passed forward to other users. Payers and providers should not be held accountable for the quality or accuracy of data for which they are not the original source nor should they be accountable for secondary uses by downstream entities.

- **Develop provider incentives to encourage continued electronic sharing of prior authorization requests.** Payer connectivity and infrastructure is an important piece of the information sharing landscape, but it is only one piece. Providers must be incentivized to use the digital infrastructure being built by health plans, including the DRLS API and the PAS API. We strongly urge CMS to offer incentives to providers for adopting electronic technology (e.g., incorporation into Promoting Interoperability requirements) and to undertake significant provider education initiatives.

- **Launch "fact finding" efforts prior to implementing new requirements, such as inclusion of prescription drug information in the Payer-to-Payer API.** BCBSA recommends that CMS conduct listening sessions and/or engage in other information gathering efforts before further expanding the Payer-to-Payer Data Exchange requirements to new forms of data (e.g., prescription drugs).

- **Allow impacted payers to capture compliance costs as a quality improvement activity in medical loss ratio (MLR) calculations.** Developing and implementing APIs is a substantial effort for payers. CMS should allow qualified health plan (QHP) issuers and Medicaid Managed Care Organizations (MCOs) to include the costs of compliance with this regulation as quality improvement expenses in their MLR calculations, just as it did for ICD-10 compliance.

We welcome the opportunity to discuss our comments with you and provide additional details on any of the recommendations discussed below. If you have questions, please contact Lauren Choi, Managing Director for Health Data and Technology Policy, at Lauren.Choi@bcbsa.com.

Sincerely,

Kris Haltmeyer
Vice President, Legislative and Regulatory Policy
Office of Policy and Representation

BCBSA Detailed Comments and Recommendations on the Proposed Rule: "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"

Section II (A): Patient Access API

Issue #1: Implementation Timeline

CMS proposes to require impacted payers to update and add new information (e.g., prior authorization information) to their Patient Access APIs by Jan. 1, 2023 (or for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after Jan. 1, 2023).

Recommendation:

BCBSA recommends delaying implementation of the proposed updates and additions to the Patient Access API by 24 months.

Rationale:

BCBSA is concerned that the proposed Jan. 1, 2023, timeline does not adequately reflect the time that will be needed incorporate the policy changes proposed in this rule into the existing standards and Implementation Guides (IGs), and/or to develop new IGs as needed to facilitate the information exchange contemplated by CMS. We anticipate that 12-24 months will be needed to complete the standards development process, after which plans will need at least 24 months to develop, connect and test their API with providers. In addition to the significant investment required to build new FHIR API repositories to support these requirements and the amount of time required to map the data from legacy systems that do not align to new data policies, there are significant regulatory compliance hurdles to providing the access CMS is requiring in compliance with health information privacy laws, particularly sensitive data laws which might not permit the broad payer and provider data sharing contemplated.

CMS also could consider a staggered implementation/roadmap approach across all of the APIs included in this rule. This would give payers time to test the APIs in a real-world setting in phases and address challenges incrementally rather than attempting to implement all of these requirements simultaneously.

Issue #2: Conformance to Implementation Guides

CMS proposes to require impacted payers to use the CARIN IG for Blue Button, the Payer Data Exchange (PDex) IG, and the PDex US Drug Formulary IG for clinical data exchange to share information through the Patient Access API. CMS also seeks comments on the pros and cons of allowing the use of either the US Core IG or the HL7 FHIR Da Vinci PDex IG to facilitate making available the required clinical data via the Patient Access API.

Recommendation:

BCBSA supports the use of the HL7 FHIR Da Vinci PDex for conformance and consistency across the payer landscape. BCBSA supports the use of one IG, the HL7 FHIR Da Vinci PDex IG, to facilitate making available the required clinical data via the Patient Access API. BCBSA does not support a payer's choice to conform to either the US Core IG or the HL7 FHIR Da Vinci PDex IG.

Rationale:

While we support conformance with the PDex IG for clinical data, it does not currently include prior authorization data and will need additional development. Additional development time will be needed to add prior authorization information into the Patient Access API via the CARIN IG for Blue Button and the PDex IG. Further, the proposed requirements, as specified, will require the use of multiple FHIR IGs, including the Coverage Requirements Discovery (CRD), Documentation Templates and Rules (DTR), and Prior Authorization Support (PAS) IGs. Because these IGs were created for operational uses of information exchange between providers and payers, they do not include the patient use case and will need additional development time in order to do so.

To facilitate making available the required clinical data via the Patient Access API, BCBSA supports the use of one IG, PDex. Unlike the US Core IG, PDex provides guidance to payers on how to make information available in the areas of Provenance appropriate for payer data exchange, the addition of dispensed medications and medical devices, and guidance on exchanging payer USCDI data. By allowing a choice, BCBSA is concerned that recipients of the data (i.e., third-party apps) will be required to accommodate data delivered via both APIs, which would be an incremental, add to their development and support costs.

Issue #3: Information Sharing with Medicaid Beneficiaries

CMS proposes to require Medicaid fee-for-service (FFS) programs and Medicaid managed care entities to share information with Medicaid beneficiaries through the Patient Access API.

Recommendation:

CMS should establish a stakeholder workgroup to identify best practices in data sharing with Medicaid beneficiaries prior to requiring information sharing through the Patient Access API.

Rationale:

The Medicaid population has unique needs that are unlike individuals enrolled in commercial or QHP coverage. We agree that providing Medicaid beneficiaries with access to meaningful, actionable data that supports their engagement in their own care is critical. However, the provision of this data with Medicaid beneficiaries must be done in a thoughtful way to avoid unintended consequences like beneficiary confusion and non-adherence with treatment protocols.

For example, Medicaid beneficiaries are generally not financially liable for their use of treatment or services. Instead, payers (i.e., state Medicaid agencies and Medicaid MCOs) are responsible for the payment of services utilized by Medicaid beneficiaries. Providing data like claims or billing information in a way that clearly and easily notifies Medicaid beneficiaries that they are not financially responsible for these services is important. Alternatively, confusion around

comprehensive documentation provided to Medicaid beneficiaries during appeals processes has often resulted in beneficiary confusion and non-adherence with treatments and services due to fear of financial responsibility.

Data shared with Medicaid beneficiaries by the payers or as part of the Patient Access API must be meaningful and actionable and provided in a way that does not result in beneficiary confusion, concerns for financial liability, or non-adherence with treatment protocols. In order to reduce the likelihood of unintended consequences with Medicaid beneficiaries, CMS should assemble a stakeholder workgroup, comprised of state Medicaid agencies, providers, Medicaid MCOs and Medicaid beneficiaries to determine which data is most meaningful and actionable for Medicaid beneficiaries and to balance health literacy needs with the presentation of such data.

Issue #4: Clinical Data Standardization to USCDI

CMS proposes to clarify that the clinical data that must be made available through the Patient Access API is "clinical data, as defined in the USCDI version 1."

Recommendation:

BCBSA supports the technical change that the existing requirement that APIs make available "clinical data, including laboratory results" would be replaced by "clinical data, as defined in the USCDI Version 1," which includes lab results.

Rationale:

BCBSA supports the use of USCDI as the clinical data standard in required APIs once the data set is fully developed and updated to include encounter data for unstructured data and appropriate testing has been conducted. USCDI is a good representation of the data consumers may need to facilitate their care. BCBSA recommends that CMS work with the National Coordinator for Health IT (ONC) to include multi-stakeholder input to determine in future versions of USCDI the appropriate encounter/event data related to any unstructured data. We continue to have concerns about the inclusion of administrative data in the USCDI data set, including the use of Unique Device Identifiers (UDIs).

Issue #5: Timing for Incorporation of Prior Authorization Information

CMS proposes to require that information about prior authorization decisions be made available to patients through the Patient Access API in addition to the accessible content finalized in the CMS Interoperability and Patient Access Final Rule. CMS specifically proposes to require impacted payers to 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 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.

Recommendation:

BCBSA recommends that CMS require information to be made available within a timeframe that is practically feasible and upon receipt of the prior authorization transactions/HIPAA X12 278 request, rather than within one day of the request.

Rationale:

We agree that moving toward industrywide adoption of electronic prior authorization transactions based on existing national standards has the potential to streamline and improve the process for all stakeholders. However, there is generally a delay between the request and the payer's receipt of the prior authorization transactions / HIPAA X12 278.

Further, and as noted elsewhere in our comments, we remain concerned about the lack of certification process for third-party applications and the potential consequences for patients if their data is breached or used inappropriately. Including additional information on a member's pending and active prior authorization decisions heightens the need for greater security around third-party applications.

Finally, we believe that a longer timeframe is needed before plans are required to make information available because plans are unlikely to have anything significant to share within one business day, other than the fact that the request is under review. The status of the decision may not change from "pending" to "approved" or "denied" until the very end of the allowed timeframe. The unchanging "pending" status for multiple days could cause additional confusion and stress for enrollees, who may conclude that their request is not moving forward although it, in fact, is.

Issue #6: Content of Required Prior Authorization Information

CMS proposes to require impacted payers to make available through the Patient Access API information about any pending and active prior authorization decisions (and related clinical documentation and forms).

Recommendation:

BCBSA recommends that CMS not require payers to make clinical documentation and forms available through the Patient Access API. CMS should provide additional clarification and specificity about exactly what prior authorization information needs to be available.

Rationale:

CMS should withdraw the requirement that the pending and active authorizations include "the related clinical documentation and forms." The supporting documentation is often in the form of lengthy and cumbersome PDF documents that are not easily readable and translatable to applications through FHIR API. CMS has already stated that PDFs do not quality as "unstructured data" for clinical data requirements for similar reasons.

CMS also should require only the approved number units (such as approved visits) for a specific prior authorization and not the units and services used to date. CMS should not require active authorizations to include the units and services used to date because in order to be accurate and useful to those accessing the data through the API, the data would need to be updated in real

time (or when a claim is received that indicates the service was used). It would be time consuming and labor intensive to implement the required mapping, tracking and updating of prior authorization data each time an approved unit or service is consumed within the proposed timeframe.

CMS also should clarify what precise information must be available on pending authorization data. Will the date of the request, the nature of the request, and that it is pending be sufficient? In addition, CMS should ensure that these new requirements align with other existing requirements (e.g., CAQH operating rules phase V for prior authorizations).

Issue #7: Privacy Policy Attestations

CMS proposes to require impacted payers to establish, implement and maintain a process for requesting an attestation from a third-party application developer requesting to retrieve data via the Patient Access API that indicates that the application adheres to certain privacy provisions. CMS proposes that impacted payers must request the third-party application developer's attestation at the time the third-party application engages the API. The payer must inform the patient within 24 hours of requesting the attestation from the application 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. If the application developer cannot attest that the application's privacy policy meets minimum requirements as outlined by CMS, or if there is no response to the payer's request for the attestation, the payer can inform the patient there may be risk associated with sharing their information with the application. If the payer does not respond or indicates that they would like their information to be shared regardless of the risk, CMS proposes that the payer would be obligated to make the data available via the API.

Recommendation:

BCBSA requests that CMS not finalize its proposal to require payers to collect privacy policy attestations from third parties. Instead, we recommend that the FTC work in concert with the Department of Health and Human Services (HHS) to develop a process under which apps are vetted for the adequacy of the consumer disclosures, as well as the privacy and security of the information once it is no longer governed by HIPAA. For example, HHS could name a national organization, like the Council for Affordable Quality Healthcare (CAQH), to manage a hub for third-party applications to register and attest for their applications.

Rationale:

Payers have no contractual or legal nexus to third parties and, thus, are not the appropriate entity to enforce third-party privacy protections. Additionally, collecting privacy policy attestations would be a burdensome and duplicative requirement on plans, requiring substantial technical builds and maintenance; a more effective policy would be to leverage a commonly used hub to manage third-party applications. If CMS moves forward with its proposed policy, privacy attestation should be a one-time occurrence, not required every time the patient accesses data. Additionally, HL7 should develop specifications related to this information exchange and implementation of this process should be delayed until these standards are ready. Each payer should not be individually

required to duplicate this effort, as this would inevitably have varying results/processes that would be confusing for both patients and third-party applications.

CMS should not require plans to share information with a third-party application unless they receive an affirmative response from the member after communicating information about the third-party application's privacy policy attestations to the member. If the patient does not respond, it would be highly inappropriate and a data breach risk for Personal Health Information (PHI) to be shared with a third party if the payer does not know that the patient has explicitly agreed to share their data. The patient must have confidence that they know and understand how, when and with whom their information is shared. BCBSA believes that impacted payers should offer patients multiple options for confirming that they wish to share their data, through duplicate communications if necessary.

This is particularly true for the Medicaid population. This vulnerable population would be particularly difficult to reach within the allotted 24-hour timeframe. Incorrect email addresses, bad phone numbers and lack of consistent access to these forms of communications are characteristic of the Medicaid population. Paper communications also would not work. Given the 24-hour timeframe and often lack of accurate address information, CMS should provide additional clarity on how plans would notify enrollees.

CMS also should identify standards for appropriate documentation of the privacy policy attestation process, including efforts underway within the ONC FAST, specifically the Security Tiger Team. HHS should create a "safe harbor" for plans that share information with third-party applications that use the ONC-developed Model Privacy Notice, and/or CMS should clearly communicate payer compliance requirements for the following minimum elements of the attestation:

- Privacy policy is written in plain language
- Description of how the patient's information is accessed, exchanged, used, shared or sold
- Receipt of verification of consent for access, exchange, or use of the data, and a separate express consent for PHI to be shared or sold
- Indication of whether the application will access information from a patient's device
- Notice that the patient can discontinue app access and the policy/process for disposing of a patient's data

Finally, we believe all stakeholders should play a role in patient education regarding data sharing. CMS' experience makes it well positioned to leverage lessons learned and apply them to broader consumer education efforts. Model consumer notifications and educational materials should be developed and made available for insurance and health care providers to use voluntarily. Educational materials should clearly advise consumers when HIPAA protections do not, or will no longer apply, and that the insurance or health care provider furnishing the data on their behalf are not responsible for the privacy and security of the data obtained by applications or sold for secondary use.

Issue #8: Patient Use Reporting Metrics

CMS proposes to require impacted payers to report metrics about patient use of the Patient Access API to CMS on a quarterly basis, beginning March 31, 2023. Proposed metrics include

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

Recommendation:

BCBSA recommends that CMS delay implementation of these provisions by 24 months.

Rationale:

For these metrics to be meaningful, additional foundational work needs to be done to compel patients to access their electronic health data. Before there is considerable uptake on the use of the Patient Access API, consumers need to better understand the value of their health information from both a patient care and financial perspective. Foundational efforts to encourage consumer adoption of the Patient Access API must be broad based and consider social, financial, privacy and security-related factors. These metrics would be influenced by regional, demographic and member-specific factors outside the health insurance provider's control such as availability of broadband services, smart phone adoption, socioeconomic status and member's desire to adopt and use new technology. These factors are particularly relevant for the Medicaid population who often experience barriers such as limited cell phone service and data.

Personal health record tools have long been available to consumers, yet adoption is low and has more recently been supplanted by EHR portals. These portals have emerged as a primary solution for consumer access to their own health information. However, although nearly 57 percent of U.S. health care providers report already having a portal in place, less than 7 percent of health care consumers are using them (Tavares and Oliveira, 2016). CMS should consider the utility of ensuring that information is available to and used by consumers as compared to the burden of creating new options for access.

Additionally, CMS should review and determine a current accurate baseline before starting collection of metrics.

CMS should convene an industry workgroup to establish reasonable and well-defined metrics to achieve CMS' goals (e.g., research, accountability, improvement, patient engagement, etc.) CMS also should develop a national set of reporting tools to reduce the burden associated with reporting this metrics and collect measures on an annual basis rather than quarterly. Annual reporting would be less burdensome on the impacted payers and would be less influenced by potential seasonal variations in the data (e.g., newly enrolled members being more motivated to request data).

Issue # 9: Provider Directory API Conformance with Specified IG

CMS proposes a new requirement for Medicaid state agencies and CHIP state agencies that the Provider Directory API be conformant with the HL7 FHIR Da Vinci PDex Plan Net IG: Version 1.0.0.16.

Recommendation:

BCBSA recommends that CMS not move forward with this requirement at this time. Instead, we recommend that CMS require the use of either the HL7 Plan Net IG or an API that makes equivalent data available.

Rationale:

While we agree with the goal of standardization, we are concerned that codifying this specific version of the HL7 Plan Net IG into regulation will limit innovation going forward. We support a long glide path for standards development that gives sufficient time for development, testing and scaling of new requirements.

We also have several concerns about requiring use of this specific version of the Plan Net IG. First, Plan Net does not codify many of the things that payers do through Provider Characteristics or the disclaimer designation code, so how that information is conveyed will be unstructured free text. Second, payers capture some data differently. Third, it is unclear how payers will implement this IG given that it was just finalized this month.

Section II (B): Provider Access APIs

Issue #1: Requiring Payers to Act as Data Intermediary

CMS proposes to require impacted payers to establish a Provider Access API capable of facilitating information sharing on individual patients and bulk data provider access for information requests for more than one patient. CMS proposes that the data made available through the Provider Access API should mirror the data made available through the Patient Access API with the exclusion of cost data such as provider remittances and enrollee cost sharing. Data maintained by the payer with a date of service on or after Jan. 1, 2016, would need to be available through the Provider Access API by Jan. 1, 2023.

Recommendation:

BCBSA recommends that CMS provide liability protection (i.e., a safe harbor) to parties who are required to provide data that originated elsewhere through an API they are hosting, because payers and providers should not be held accountable for the quality or accuracy of data of which they are not the original source. Likewise, there should be liability protection from secondary, unintended uses of the data by downstream entities once the data is delivered to the API.

Rationale:

Unless and until there is a “safe harbor” for the use of HL7 FHIR, those defined data transfers may not be feasible for inclusion in the Provider Access API standard, and payers and providers should have no obligation to include them as structured, interoperable data. Payers are concerned that they would be responsible for the quality and accuracy of these data, even though they are not the data originators. Similarly, providers are concerned that the breadth of data to be made available through an API would mean that they would be a proxy for the provision of claims and other data through their hosted APIs. Providers do not want to be seen as the source of the claims data.

Similarly, payers may be a source of clinical data that may be pushed through the APIs and would be acting as proxies for the originator of these data (providers). As such, payers should not be held responsible for the quality, authenticity and reliability of these clinical data (as noted above, the same is true for data that providers make available that they do not originate, such as claims data).

In addition, such data should be self-attesting. When payers (and providers) act as a proxy in this way, they have no control over data accuracy or quality. Additionally, data stored outside the source system of record can become out of date when retroactive updates or adjustments in the system of record are not synchronized to all proxies, resulting in divergent and inaccurate information. For these reasons, we believe payers and providers should not be held liable for providing data for which they are not the originator.

Issue #2: Standardization to HL7 FHIR Standard

CMS proposes to require impacted payers to implement payer-to-provider data sharing using the HL7 FHIR Bulk Data Access (Flat FHIR) specification – a Bulk Data Provider Access API.

Recommendation:

BCBSA supports conformance and consistency across the payer landscape. Each IG should speak to guidance for consistent use of HL7 FHIR Bulk Data Access

Rationale:

BCBSA supports the use of the HL7 FHIR Da Vinci PDex in concert with HL7 FHIR Bulk Data Access to allow for batch and individual data exchange for conformance and consistency across the payer landscape. The proposed requirements as specified will require the modification of multiple FHIR IGs, including the CRD, DTR, and Prior Authorization Support (PAS) IGs.

Issue #3: FHIR IG for Claims and Encounters

CMS proposes the Provider Access API would have to meet the same requirements as the Patient Access API regarding technical standards, API documentation, and discontinuation and denial of access.

Recommendation:

BCBSA recommends CMS define the use of the PDex IG to allow for the exchange of claim and encounter data between payers and providers.

Rationale:

PDex provides a mapping of the claims and encounter information to clinical resources. As payers must provide PDex capability to support the Patient Access API, they will have built the capability. With this approach, payer and provider data would be exchanged via one API rather than two. This approach would require less development and support and maintenance costs for the provider community.

Issue #4: Identifying Patient-Provider Relationship

CMS proposes that providers accessing data through the Provider Access API may or may not have a provider agreement with or be in- or out-of-network with the payer that is providing the information. CMS states that out-of-network providers would need to demonstrate to the patient's payer that they have a care relationship with the patient.

Recommendation:

CMS should provide direction on acceptable options on how a non-network participating provider can "demonstrate that they have a care relationship with the patient."

Rationale:

CMS should clarify what patient consent is required for providers to access records through the Provider Access API. Payers typically know this information for their in-network providers, but typically do not for out of network providers making the need to provide options on how non-network participating providers can demonstrate a care relationship more important.

Issue #5: Attribution for Bulk Data Provider Access

CMS proposes that each payer establish, implement and maintain for itself a process to facilitate generating each provider's current patient roster to enable the proposed payer-to-provider data sharing via the Provider Access API.

Recommendation:

CMS should only require payers to accommodate the Bulk Download Use Case when a Da Vinci use case for a roster of patients for providers is available. There is an existing DaVinci use case, Risk Based Contracts Member Attribution, which defines Bulk FHIR data exchanges for this purpose.

Rationale:

Attribution is a notoriously challenging aspect of health care management, and patient preferences may not match the results of algorithmic approaches. With respect to standards, HL7 is currently developing the Data Exchange for Quality Measures (DEQM) for requesting HEDIS and Star clinical data on a roster of patients, but development work has not been completed. Payers and providers also may benefit from additional CMS guidance to require use of the existing specification for the proposed Da Vinci Risk Based Contracts Member Attribution List IG, which is currently in the publication process.

This IG includes the use of bulk data and is an example of the importance of specifying bulk data queries and responses within an IG and not broadly with a single bulk data IG. It is recommended the bulk data exchange approach should be common to all IGs. We suggest that the term provider should be interpreted as either an individual provider or a provider organization.

Issue #6: Patient Opt-In

CMS 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. CMS is considering whether to suggest a specific process for all payers who choose to implement

this opt-in. CMS also is considering alternatives to opt-in, such as permitting and/or requiring an opt-out process or defaulting to data sharing with patient engagement in the process consistent with the HIPAA Privacy Rule.

Recommendation:

CMS should instead require an annual patient opt-out, and/or compliance with state and federal law in cases where an opt-out approach is not permitted.

Rationale:

Payers and health information exchanges have had extensive challenges and poor experiences with patient participation with opt-in approaches. An annual opt-out process is an effective way to have adequate and broad engagement and to protect patient rights. Patients would have the right to opt-out at any time and when changing plans as well as when an out-of-network provider seeks their data. From an adoption perspective, it is critical that the Final Rule support the following industry best practice of opt-out functionality.

However, an opt-out approach may not be feasible in all situations. Data laws often do not permit the sharing of sensitive data without patient authorization, even for treatment purposes. Administrative and technical capabilities for tagging, segmenting and segregating sensitive data at both the provider and payer levels do not currently exist to support an opt-out model.

Issue #7: Provider Incentives and Education

CMS proposes that payers make educational resources available to providers that describe how a provider can request patient data using the payer's Provider Access API in nontechnical, simple and easy-to-understand language. CMS proposes that these resources be made available on the payer's website and through other appropriate mechanisms through which the payer ordinarily communicates with providers.

Recommendation:

CMS should provide meaningful incentives for providers to adopt this new technology, especially if the HHS ONC does not require Electronic Health Record (EHR) vendors to adopt the same standards and implementation is not seamless for the provider.

Rationale:

Health plans will need to work with the providers in their networks to ensure understanding of the availability of this API and how to use it. At the same time, incentives also will likely be needed to encourage provider adoption and use. Providers also may need support with the necessary investments to upgrade their EHRs to exchange data in this more sophisticated way rather than through a patient portal. Providers may need support from CMS and/or state Medicaid agencies to make these investments.

Section II (C): Documentation and Prior Authorization Burden Reduction through APIs

Issue #1: Electronic Options for Prior Authorization in Future Rulemaking

CMS notes that CAQH, which develops operating rules for HIPAA standards, submitted two operating rules for the HIPAA referral certification and authorization transaction for consideration to the National Committee on Vital and Health Statistics (NCVHS.) CMS notes that if HHS adopts these operating rules, it would evaluate their effect, if any, on the proposals in the Proposed Rule.

Recommendation:

BCBSA recommends additional stakeholder engagement prior to requiring the CAQH operating rules for prior authorization.

Rationale:

BCBS Plans vary widely in size, markets and geography. However, despite these differences, Plans report little variation in experience for a particular transaction; the challenges and barriers to adoption of that transaction by trading partners and the overall adoption rate of mandated standards are fairly consistent across the Plans.

Plans indicate that the operating rules in general are likely to increase the reliability and performance of data exchange without affecting the data content of the standards. However, Plans have identified concerns that these operating rules are likely to add to administrative costs for both Plans and their providers. Plans anticipate that the connectivity provisions, which limit submitter authentication to a single method of digital certificates, will be costly to implement with little return on investment. The total costs to implement will vary depending on the submitter authentication methods Plans have implemented currently. Most providers continue to opt for the login/password option from earlier phases of operating rules. The version C3.1.0 connectivity rule safe harbor provisions allow providers to continue to use other methods even when Plans must implement digital certificates to be in compliance. Plans are then faced with using contracts or participation agreements to move providers towards the newer method. Providers choosing to move to this methodology for some or all transactions will need system changes also. Maintaining multiple methods as they vary across Operating Rule Phases creates additional system impacts for all trading partners.

Plans also expressed concerns that the security protocols named within the connectivity rule are outdated and are not considered to be secure. We suggest that further, broader research on the timing and costs associated with all stakeholders moving to a more secure methodology for all transactions, needs to be conducted. While this is ultimately preferable to better address security concerns, it is essential that such a move is orchestrated across all standards and all trading partners rather than applying to some of the parties and a few transactions.

Issue #2: Document Requirement Lookup Service (DRLS) API

CMS proposes to require impacted payers to implement and maintain a FHIR-based DRLS API conformant with the HL7 FHIR Da Vinci Coverage Requirements Discovery IG and the HL7 FHIR Da Vinci Documentation Templates and Rules IG, populated with their list of covered items and services, not including prescription drugs and/or covered outpatient drugs, 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.

Recommendation:

BCBSA recommends that CMS extend the timeline for this API by 24 months and consider subsequently phasing-in the requirement for information to be made available through the DRLS API either by making it voluntary for a period of time, or by requiring it for a defined set of items and services, such as the initial 500 items and services defined in the Transparency in Coverage (TCR) Final Rule or items and services that account for 90 percent of the prior authorization requests for a covered plan.

Rationale:

Most Plan prior authorization requirement documentation is available today through Plan websites, which may require access through a provider portal. As prior authorization requirements are directly related to medical policy, it is a challenge to make this information available to non-participating providers.

Implementing automation for medical services is significantly more complicated given the scope of treatment and services, conditions and sites of care to which a prior authorization request can apply. This opportunity requires a commitment from all parties involved in its success, primarily providers, health plans and EHR vendors. Comprehensive automation is resource intensive to implement and can only drive meaningful improvement if it effectively meets the needs of all users and is adopted by all users. To support the successful adoption:

- Health plans must work together and with EHR vendors to ensure these products can work across different payer prior authorization processes and systems, and where needed, health plans may need to standardize processes.
- Providers must engage with health plans and EHR vendors to ensure the implementation is most effective for their workflows, and more importantly, providers must commit to implementing and using these tools once fully developed.
- EHR vendors must work with plans and providers to design these solutions with the end users in mind and make the tools affordable and simple to implement.

Payers will have to build a rules engine to populate their prior authorization data requirements, as well as any conditional requirements. Further, meeting the proposed requirements as outlined by CMS requires standards for attachments, reports, and images. These standards are currently being worked on by DaVinci, but are not finalized. The more lines of business included (e.g., Medicaid, CHIP, FFE), the more mapping will be required, which is a time-intensive effort that requires substantial lead-time.

Issue #3: Prior Authorization Support API

CMS proposes that impacted payers implement a 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. If finalized, the payer would be required to implement the API and, when sending the response, include information regarding whether the organization approves (and for how long), denies, or requests more information for the prior authorization request, along with a reason for denial in the case of a denial.

Recommendation:

BCBSA recommends that CMS extend the timeline for this API by 24 months and consider subsequently phasing-in the requirement for the PAS API either by making it voluntary for a period of time or by requiring it for a defined set of items and services, such as the initial 500 items and services defined in the Transparency in Coverage (TCR) Final Rule or items and services that account for 90 percent of the prior authorization requests for a covered plan.

Rationale:

The PAS API, as outlined by CMS, contains data gaps that will need to be addressed, e.g., the proposed standards are not built to display an authorization result, but rather contain only "approved" or "denied." It also does not accommodate changes to the status of a prior authorization. Additional profiles will be needed to meet the requirements of the Proposed Rule.

Finally, the proposed requirements appear to contemplate integration with the provider's clinical EHR. We expect that the proposed requirements would require integration with a range of different EHRs, which will take time and customized development as not all EHRs have the same workflows for notification. Further real-world testing is needed to ensure data needs are met and systems can connect and move the data correctly between the FHIR and X12 standards.

Issue #4: FHIR API and X12N 278 Prior Authorization

CMS proposes that the PAS API be conformant with the HL7 FHIR Da Vinci PAS IG beginning Jan. 1, 2023. As envisioned by CMS, when a patient needs authorization for a service, the payer's PAS API would enable the provider, at the point of service, to send a request for an authorization. The API would send the request through an intermediary (such as a clearinghouse) that would convert it to a HIPAA-compliant X12 278 request transaction for submission to the payer. The payer also may convert the request to a HIPAA-compliant X12 278 transaction, and, thus, the payer acts as the intermediary. The payer would receive and process the request and include necessary information to send the response back to the provider through its intermediary, where the response would be transformed into a HIPAA-compliant 278 response transaction. The response through the API would indicate whether the payer approves (and for how long), denies, or requests more information related to the prior authorization request, along with a reason for denial in the case of a denial

Recommendation:

For purposes of the PAS API requirements, BCBSA recommends that CMS grant an exception under HIPAA for those implementers that wish to move the data from the API directly into prior authorization processing systems, but not require this approach for all implementers.

Rationale:

As noted in the Proposed Rule, the X12N 278 has been problematic because it does not have all the information needed for plans to make prior authorization decisions in many cases, and requires additional data in many cases, which has led to it not being commonly used.

With regard to our recommendation of a phase-in approach to the FHIR-based standards development for a FHIR-based prior authorization API solution, we are aware that there is currently an adopted HIPAA Administrative transaction required for prior authorization electronic queries (ASC X12N 278 Version 5010). We understand that in order to conduct active development of an alternative standard that involves the actual transmission of real patient data, an exception would have to be granted by CMS under the regulations at 42 CFR 162.940, exceptions from standards to permit testing of proposed modifications.

Plans still report much lower volumes of 278 transactions from providers and the value proposition for implementation is very low. Providers report not using the 278, as the response does not have what the provider fully needs, which necessitates additional communication to the payer. CMS should consider incentivizing provider use of the X12N 278 transaction to address barriers to adoption.

The barriers to adoption continue to include the complexity of the transaction and the lack of an attachment standard. Prior authorizations often require a more conversational approach to exchanging information between the provider and the health plan. Initial requests may prompt follow-up "questions" which are not as readily exchanged in an electronic environment, especially when providers use a batch approach. Even when providers use a real-time approach, Plans found that some inquiries required responses that were not able to be processed for approval in an automated real-time fashion, due to the need for manual medical review.

While a real-time prior authorization can be more conversational, Plans indicate their providers find having that exchange through a web portal more convenient to their office workflows. The X12N 278 has greater clinical data content and necessitates greater involvement by clinical staff than administrative staff to see greater benefit. Flexibility to use newer business technologies to exchange information, e.g., FHIR to CML via a web portal, would accommodate the need for a more iterative process for authorizations as there is often the need for additional questions and follow-up (i.e. an ongoing exchange between the clinical staff and the health plan).

Issue #5: Incentives for Provider Use of DRLS API and PAS API

CMS does not propose in this rule to create any provider incentives (positive or negative) for use of either the DRLS or PAS APIs.

Recommendation:

BCBSA recommends that CMS consider specific provider incentives for encouraging uptake of the DRLS API and PAS API.

Rationale:

BCBSA is concerned that Plans may invest considerable resources in development and implementation of the DRLS API and the PAS API without realizing the benefits of significant provider uptake of this new digital infrastructure. We urge CMS to establish specific incentives for EHR vendors to include these functions in their EHR systems, as well as incentives for providers to use these APIs in their workflows in parallel with the requirements in the Proposed Rule.

Moreover, as more providers move to value-based care approaches and take on increasing amounts of risk, they subsequently will depend more on their own internal utilization review measures – and less on payer prior authorization processes. As such, the prior authorization APIs and enhancements proposed in this rule may be of diminishing utility to providers moving forward. Before requiring payers and providers to take on significant investments to develop, maintain and leverage these new APIs, we ask CMS to reconcile the longer-term implications of this work with the future of value-based care.

Issue #6: Prior Authorization Denials

CMS proposes that impacted payers send certain response information regarding the reason for denying a prior authorization request. Specifically, CMS proposes that impacted payers transmit, through the proposed PAS API, information regarding whether the payer approves (and for how long), denies or requests more information related to the prior authorization request. CMS also proposes that impacted payers include a specific reason for denial with all prior authorization decisions, regardless of the method uses to send the prior authorization decision.

Recommendation:

BCBSA recommends that CMS not finalize this policy.

Rationale:

CMS should instead convene a stakeholder group to develop a baseline standard denials reason to be used across payers, building on the standard denial reason codes that are part of the HIPAA standards. While payers are already required to send a notification with a reason for the denial of a prior authorization request, there will be wide variation of denial reasons across health plans in the absence of a baseline taxonomy standard. The standards included in the Proposed Rule are not currently built to display an authorization result, but rather contain only “approved” or “denied.” The standard also does not accommodate changes to the status of a prior authorization. Additional profiles will be needed to include this information in the proposed PAS API.

Issue #7: Prior Authorization Timeframes

CMS proposes to require that state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities provide notice of prior authorization decisions as expeditiously as a beneficiary’s health condition requires and under any circumstances not later than 72 hours after receiving a request for expedited decisions. Notice should be provided no later than seven calendar days after receiving a request for standard decisions.

Recommendation:

BCBSA recommends that CMS not finalize these policies as proposed, and instead work with stakeholders to ensure prior authorization requirements are aligned to prevent confusion for providers and beneficiaries.

Rationale:

We are concerned that achieving shorter timeframes will be challenging unless a critical mass of providers are positioned to link to an API. Plans currently experience challenges in having

providers submit the necessary information for a PA request in a timely manner. We support a transition period in which a more flexible timeframe is available to make prior authorization decisions, and enable more providers to adopt electronic platforms in collaboration with payers. We are concerned that shorter timeframes could result in higher overturn rates and that there may be challenges with obtaining all of the necessary documentation to make the prior authorization decisions under short timeframes, given the lead-time that will be needed for providers to familiarize themselves with use of the new APIs.

We support CMS efforts to ensure timely communication between plans, providers and patients to support high quality care. However, in the agency's efforts to ensure timely communication and to reduce burden, it is important to not shorten plans' prior authorization timeframes without also addressing the issue of timely response times from providers in cases of incomplete information.

Many plans are already complying within these parameters. However, this approach does not address the causes of delay in prior authorization determination. Making changes to shorten timeframes without addressing the root causes could result in higher denials and do little to solve the issues CMS aims to address. Most often, the reason for a prior authorization denial is due to incomplete or insufficient documentation submitted by the provider, requiring the Plan to go back to the provider and subsequently lengthen the time to complete the determination.

To make the proposed timeframes in Medicaid of 72 hours for expedited requests and seven calendar days for standard requests effective requires complimentary changes related to provider request for information timeframes. If CMS implements these standards, we request that CMS also implement timeframes for provider response when asked to provide additional documentation. Without the provider standards, there will likely be increased denials, leading to abrasion for members and potential delays in care. CMS also should clearly define the terms "expedited" and "standard" in reference to the bifurcated timeframe requirements for processing prior authorization requests. Additionally, as CMS noted, if finalized, this proposal would create misalignments between Medicaid and Medicare that could affect dually eligible individuals enrolled in both a Medicaid managed care plan and a Medicare Advantage (MA) plan. CMS should work with stakeholders to ensure prior authorization requirements are aligned to prevent confusion for providers and beneficiaries.

Issue #8: Post Service Claim Denials for Items and Services Approved Under a Prior Authorization

CMS seeks comment on what requirements would be appropriate to include in a policy to ensure that claims that meet certain guidelines for approved authorization are not denied.

Recommendation:

BCBSA recommends that CMS consider the program integrity, patient safety and quality of care reasons for a retrospective denial of an item or service that has been given prior authorization in any development of a future proposal on this topic.

Rationale:

Failure to consider the range of reasons for a retrospective denial of an item or service could lead to an increase in improper payments and program costs.

Issue #9: "Gold Carding" Programs

CMS encourages payers to adopt gold-carding approaches that would allow prior authorization exemptions or more streamlined reviews for certain providers who have demonstrated compliance with requirements.

Recommendation:

CMS should consider challenges in exploring any potential future policies on "gold carding" programs, not be overly prescriptive in future rulemaking, and provide payers with the necessary flexibility to customize such programs based on the specific needs and characteristics of their provider partners.

Rationale:

Encouraging the use of programs that differentiate the application of prior authorization based on provider performance on quality measures and adherence to evidence-based guidelines or other contractual agreements (e.g., risk-sharing arrangements) can be helpful in targeting prior authorization requirements where they are needed most and reducing the administrative burden on high-performing health care providers. However, as mentioned above, there are several challenges to the widespread use of such programs, including a lack of well-defined criteria, regular post-service review, and inconsistent adherence.

Issue #10: Public Reporting of Prior Authorization Metrics

CMS proposes to require impacted payers to report certain prior authorization metrics on their websites at the state-level for Medicaid and CHIP FFS, at the plan-level for Medicaid and CHIP managed care, and at the issuer-level for QHP issuers on the FFE. Each metric would be reported separately for each item and service, not including prescription drugs and/or covered outpatient drugs, and the data would be required to be publicly reported for each metric. CMS proposes that, beginning March 31, 2023, these data be publicly reported annually, by the end of the first calendar quarter each year for the prior year's data.

Recommendation:

BCBSA requests CMS not finalize this proposal.

Rationale:

BCBSA has a number of concerns with the proposed data requirements. We agree that access to care is a critical factor for patients to consider when choosing a plan, but we do not believe these metrics will provide members with meaningful transparency. Sharing the percent of prior authorization approval or denial rates could misguide patients, especially with no uniform reporting guidelines. As has been seen with the reporting requirements for qualified health plans, the information is not uniformly organized, collected or interpreted across health plans so there is likely to be variability in how the metrics are calculated and reported. These variances would obscure any true performance differences between plans that might be helpful to the public.

Furthermore, even if the variances in methodology and reporting can be addressed, the mechanics of the prior authorization process would confuse the value of the information being displayed. Often, denials reflect a lack of information being submitted for a request rather than a denial of the request itself, and require follow up with the provider. The average time between submission and determination varies depending on how quickly the provider submits the request and through what method (e.g., electronic requests are faster than fax requests). Then, there can be multiple denials on a single request if the follow-up information is not provided in its entirety. Reporting each of these follow-ups as a denial in metrics for public consumption would provide a misleading representation of the overall approvals versus denials for unique requests. These variables are often more administrative than clinical and are a part of a mutual responsibility of plans and providers to share information accurately and in a timely manner. Rolling these figures up into global metrics and attributing responsibility solely to health plans would not give consumers or providers even, valuable information on a plan's policies or processes.

If CMS moves forward with this proposal, we recommend longer claims run out – e.g., a June posting date rather than a March posting date. We also recommend that CMS baseline metrics so that they are meaningful for use by consumers, if CMS, in fact, intends to make this information public for consumer use. Finally, we also recommend that these metrics be reported to CMS rather than to the public.

Issue #11: Exceptions and Exemptions Limited to State Medicaid and CHIP FFS Programs

CMS proposes a process through which states may seek an extension of and, in specific circumstances, an exemption from the Provider Access API, DLRS API, PAS API, and Payer-to-Payer Exchange requirements. CMS does not propose to provide extensions or exceptions for Medicaid or CHIP MCOs.

Recommendation:

BCBSA recommends that all impacted payers have the opportunity to apply for an exception or exemption across all APIs.

Rationale:

The Proposed Rule includes provisions allowing state Medicaid and CHIP FFS programs to apply for a one-time exception and/or an annual exemption from certain API requirements; Medicaid MCOs and CHIP managed care entities are ineligible for exceptions and/or exemptions. We support CMS' proposal to provide an exceptions and exemptions process for state agencies and further urge CMS to establish both an exception and exemption process across all APIs for all impacted payers. All plans will have to go through a budgetary process, select vendors and potentially hire staff, not just states.

Section (II) (D): Payer-to-Payer Data Exchange on FHIR

Issue #1: Implementation Timeline

CMS proposes to require impacted payers to comply with new requirements for the Payer-to-Payer Data Exchange, including establishing a FHIR-based API and adding the enrollment use

case, by Jan. 1, 2023 (or for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after Jan. 1, 2023).

Recommendation:

BCBSA recommends extending the timeline for complying with these new requirements, delaying enforcement of the Payer-to-Payer exchange requirements as outlined in the CMS Interoperability, and Patient Access Final Rule until this rule takes effect.

Rationale:

BCBSA is concerned that the proposed Jan. 1, 2023, timeline does not adequately reflect the time that will be needed incorporate the policy and technical changes proposed in this rule. Further, we are concerned about the fragmentation that will result if different sets of requirements are phased in for different payers over different periods of time.

Issue #2: FHIR Requirement

CMS proposes to require a FHIR-based API for this data exchange. Specifically, CMS proposes to codify a requirement that payers use the HL7 FHIR Bulk Data Access (Flat FHIR) specification for the Payer-to-Payer API.

Recommendation:

BCBSA recommends that the IGs defined for a Payer-to-Payer API be modified to allow the exchange of Bulk Data.

Rationale:

This is an improvement over requiring such exchange without requiring standards-based FHIR APIs. Specifying FHIR-based APIs for Payer-to-Payer exchange moves payers in the direction of standardized data exchange with specifications required in other areas of the CMS Patient Access and Interoperability Final Rule.

However, it will require additional specification and development of existing implementation guides that include cost data. The addition of pending and active prior authorization decisions and related clinical documentation and forms expands the scope of data that payers will have to map to standards. Additional development and guidance also will be needed regarding how/if patient consent is reflected in the Flat FHIR specification and how this requirement is supported under the Payer-to-Payer API. Like the payer to provider exchange, bulk query data exchanges should be defined within an IG and not broadly with a single bulk data IG, although it is recommended the bulk data exchange approach should be common to all IGs.

Issue #3: Payer-to-Payer Data Exchange for Medicaid and CHIP

CMS proposes to extend the payer-to-payer data exchange to state Medicaid and CHIP fee-for-service programs, which were originally excluded from this requirement in the CMS Interoperability and Patient Access Final Rule.

Recommendation:

BCBSA requests that CMS not finalize this requirement at this time.

Rationale:

Adding state Medicaid and CHIP FFS to the scope of payer-to-payer exchange adds significant magnitude of actors and complexity across states that may not be offset by the benefits of FHIR APIs for patient access when extended to payer-to-payer exchange. It is important to consider the maturity of scalable solutions (e.g., ONC FAST solutions) to accommodate the expanded scope, and these factors must be accounted in establishing a realistic effective data. Without advancement of FHIR at scale standards during 2021, development of FHIR-based APIs for payer-to-payer exchange may not be effective by 2023 for state Medicaid, CHIP FFS, and other payers and patients. Minimally, CMS should phase in these requirements over time to allow for the complexity of exchanging data across states.

Issue #4: Inclusion of Prior Authorization Data in Payer-to-Payer Exchange

CMS proposes that the Payer-to-Payer API, at the patient's request, must make not just clinical data as defined in the USCDI available, but also claims and encounter data (not including cost information), and information about pending and active prior authorization decisions. The information about pending and active prior authorization decisions is to include "related clinical documentation and forms."

Recommendation:

BCBSA recommends that CMS not finalize this requirement at this time.

Rationale:

Incorporating prior authorization information from other payers would be a significant systematic burden. Barriers include different medical policies across payers; different benefits and coverage policies across payers; and differences across providers, including network status. Such a requirement also would require extensive system enhancements to capture and use data from the prior payer in current prior authorization adjudications.

If CMS chooses to move forward, CMS should require that payer-to-payer exchange of prior authorization decisions be conformant with the DaVinci Payer Coverage Decision Exchange (PCDE) IG as well as PDex IG. However, further development of the PCDE IG is likely required.

Further, the Payer-Payer API should include the requirement to exchange information that is not in the API format (that is required to be exchanged "in form and format in which it was received") by using the FHIR Document Reference resource. By doing this the payer-to-payer exchange will utilize only the Payer-Payer API and not require other exchange methods for information received and exchange in the form and format in which it was received.

We recommend that any USCDI information available from a claim or encounter must be available via the Payer API as defined in the PDex IG. Requiring that any USCDI information available from a claim or encounter must be available as defined in the PDex IG means that payers as data recipients of other payer data will only be required to code one interface.

Limiting inclusion of prior authorization data to items and services that exclude prescription drugs and/or covered outpatient drugs may be a way to reduce the volume of data to useful information and may exclude authorizations with the greatest costs. Having a clearer approach to phasing in the excluded types of prior authorizations would improve the value of the exchange of data on prior authorization decisions. Further, there are many factors that CMS should consider before including prescription drugs in this API, including how often the drug list changes and whether combining medical and pharmacy benefits is useful from a holistic approach. CMS should hold stakeholder listening sessions and conduct other fact gathering such as Requests for Information or an Advance Notice of Proposed Rulemaking prior to implementing any such requirement.

When CMS considers including prescription drugs in Payer-to-Payer Exchange, it should account for the use of intermediaries, delegated vendors and payer processes and notes that the PDex IG must be extended to support as defined in the Proposed Rule.

Issue #5: Enrollment Use Case

CMS proposes a second payer-to-payer data exchange policy that would use the Payer-to-Payer API to facilitate data sharing between payers at enrollment, for payers that have a specific annual open enrollment period, or during the first calendar quarter of each year. When a patient enrolls with a new payer or when a patient identifies concurrent coverage, CMS proposes that the patient would have an opportunity to opt-in to this data sharing. Unlike the Payer-to-Payer Exchange finalized previously, where the patient must make a request to initiate the data sharing, under this proposal the patient would be presented with data sharing as an option at enrollment.

Recommendation:

BCBSA recommends that CMS not implement this proposal at this time.

Rationale:

There is currently not an IG to facilitate payer-to-payer information sharing at the time of enrollment. Further, given that enrollment generally occurs within a defined period of time, we believe that sharing information at the time of enrollment could overwhelm IT systems if, for example, systems are required to transmit information on hundreds of thousands of former members within a single business day.

If CMS moves forward with the enrollment use case, plans should be given more time to request and transmit data, such as 10 business days. Additionally, the opt-in process for a new payer to request data from the previous payer via the Payer-to-Payer Exchange function should allow for the new payer to request data after the new patient enrollment has become effective.

We also urge CMS to consider several policy and operational questions before implementing this new requirement. For example, would the states or MCOs initiate this under Medicaid and CHIP? Further, how would the opt-in interact with broader data-sharing options offered to consumers when signing up for Medicaid/CHIP?

Section II (E): Adoption of Health IT Standards and Implementation Specifications

Issue #1: Adopting and Naming Specific IGs

ONC proposes to adopt the implementation specifications described at 45 CFR 170.215 – Application Programming Interfaces – Standards and Implementation Specifications as standards and implementation specifications for health care operations.

Recommendation:

BCBSA supports adoption of specific IGs in this rule.

Rationale:

Specifying the adoption of specific IGs moves payers in the direction of standardized data exchange. However, it is critical to consider the maturity of the specific IGs to accommodate the expanded scope, and these factors must be accounted in establishing realistic effective dates. We also believe that providers and EHR vendors must be held to comparable standards in order for the Provider Access API, DLRS API, and PAS API to connect seamlessly with the impacted payers. CMS and ONC should ensure that comparable standards are adopted by providers and vendors at the same time, as they are required for impacted payers.

Section III (A): RFI on Methods for Enabling Patients and Providers to Control Sharing of Health Information

Question #1:

How can patients be engaged in these decisions and acquire adequate understanding of how their data are being shared without burdening them?

Response:

BCBSA supports patient access to their clinical health care data from providers, as well as access to usable claims information from payers. In particular, data points provided to consumers today through their explanation of benefits (EOBs) – such as amounts providers charge, amounts insurers pay, amounts patients are responsible to pay, and information on where patients are with respect to meeting their deductible and out-of-pocket limits – are of interest to consumers. Other types of claims data, such as data on denials or appeals, are not as useful to consumers and may distract from the data that are of most interest.

Further, there is a difference between clinical data available from a provider and claims data available from a payer. Current coding, billing and data integrity/quality systems that support the processing of the information by a payer does not happen in real time. Requirements on payers for data availability timing need to account for the various steps in the processing of claims information (e.g., coding of the health records, billing and payment cycles) to be completed so that the consumer has access to complete and accurate information. Providing consumers with incomplete information could lead to misunderstanding of the information for their use with third-party applications. In addition, to implement this principle effectively, refining the scope of claims data provided to reflect only data that are meaningful and actionable for consumers is essential.

Question #2:

Are there specific situations, use cases or considerations that should limit how the impacted entity responds to a data segmentation request to either restrict uses and disclosures of some of the data or to obtain access to some of the data from a patient or provider? Are there unintended consequences of such data segmentation requests or options? If so, how can they be addressed?

Response:

When it comes to privacy, data segmentation is complex. It is challenging to know what data a health plan can and cannot share and to share only the permitted data in an automated way. It is even more complex when considering sharing sensitive information with applications that are outside HIPAA, as envisioned by this Proposed Rule. Health plans will need to build significant capacity to implement data segmentation and to ensure data segmentation preferences follow the data throughout the health care ecosystem. This will add significant costs.

Data segmentation of condition data should be a consistent regulatory requirement instead of determined by the actions of each member. If CMS chooses to pursue patient choice as a determination for segmentation, that choice should be focused on external disclosures, as it is much more difficult to control data availability within a health system. Further consideration of how to educate patients on how to segment their data and understand privacy options is necessary, and we recommend presenting patients with a limited set of segmentation options. CMS also should be prescriptive on the user interface to help ensure a common approach. This could be accomplished by clarifying a standard method for third-party applications to request segmentation by the patient, which would be reflected in the certification requirements for the app.

Finally, we support the changes to 42 CFR Part 2 recently passed by Congress in the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, including provisions that adjust consent requirements to better align with HIPAA and to reduce the number of times a patient has to consent to share the same sensitive information. We also support alignment of third-party privacy policies with HIPAA as much as possible.

Section III (B): RFI on Electronic Exchange of Behavioral Health Information

Question:

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?

Response:

We recommend that CMS consider mechanisms for incentivizing providers to share information electronically. This is particularly important in the behavioral health context as behavioral health practitioners were not incentivized to adopt and use EHRs in the Health Information Technology Economic and Clinical Health (HITECH) Act and have lower uptake of EHRs. Furthermore, provider education is a key component in convincing behavioral health providers of the security of electronic data exchange and to help providers shift their practice workflows. Finally, member

consent policies must permit bi-directional data sharing and comport with applicable state and federal law.

Section III (C): RFI on Reducing Burden and Improving Electronic Information Exchange of Documentation and Prior Authorization

Question:

Should CMS consider adding a measure to the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals and the MIPS Promoting Interoperability performance category for clinicians and groups to encourage the use of electronic prior authorization through a payer's PAS RFI?

Response:

As discussed elsewhere in our comments, we recommend that CMS consider mechanisms for incentivizing providers to use the DLRS and PAS APIs. We urge CMS to identify and establish assistance and incentives for providers to use these APIs in their workflows in parallel with new requirements for impacted payers. Given that the provisions in this Proposed Rule do not apply to Medicare fee-for-service or Medicare Advantage, we are concerned that including this in the Promoting Interoperability Program and/or MIPS may result in a disconnect between the incentive and the desired behavior change.

Section III (D): RFI on Reducing the Use of Fax Machines for Health Care Data Exchange

Question #1:

What challenges might payers and providers face if use of the fax technology for health care data exchange is completely eliminated? Are there particular types of providers or health care settings that would be more negatively impacted than others? What solutions might mitigate these challenges?

Response:

A key challenge for payers, providers and their respective vendors is that all data collected on faxes is not available in standardized, interoperable, structured and unstructured data. Moreover, many forms that are faxed contain content and data that is not readily captured in payer and provider systems. We recommend CMS consider policy updates that give payers and providers the flexibility to use HL7 standards to replace faxes and that CMS consider short-term digital solutions such as electronic exchange via a portal and direct secure messaging.

In considering policy levers to eliminate use of the fax machine, it is key to focus initial efforts on faxes that contain data for which all or most of the data contained: 1) has an existing "home" in common payer/provider systems (i.e., EHR or population health systems); 2) is already defined in existing industry standards; and 3) can alternatively be provided in a PDF format.

Key standards resources include the CDA R2 Attachments Implementation Guide that defines the requirements for sending and receiving standards-based electronic attachments and has an

existing LOINC coded list of common attachments, as developed with cross-industry input, the FHIR Clinical Data Exchange IG, and the use of FHIR Bulk Data IG.

Question #2:

What recommendations are there for balancing the goal of improving efficiencies in health care data exchange through reducing the use of fax while ensuring that health care providers without ready access to internet can still share information?

Response:

To balance the goal of reducing the use of fax while ensuring that providers without ready access to the internet can still share information is to use FHIR-based APIs and related interoperable standards, for which smartphones on existing cellular network can operate in most geographies without internet access. However, this would require that existing or new FHIR IGs and/or resources be available to accommodate the priority faxes intended to eliminate.

Section III (E): RFI on Accelerating the Adoption of Standards Related to Social Risk Data

Question #1:

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, food)?

Response:

One of the biggest challenges is standardization across different screening tools especially as different tools ask variants of similar questions. In order to provide any meaningful data, Plans not only have to work on ingesting all of this data, but also bringing all the elements together into a cohesive profile of our member/population.

Question #2:

What are the barriers to the exchange of social risk and social needs data across providers? What are key challenges related to exchange of social risk and social needs data between providers and community-based organizations?

Response:

HIPAA is a key barrier to making sure community-based organizations (CBOs) are allowed to receive referrals from health plans/providers. Entities covered by HIPAA may be hesitant about or restricted from sharing and exchanging this information with other providers (although not all Social Determinants of Health (SDOH) data is subject to HIPAA). We believe the Proposed Modifications to the HIPAA Privacy Rule to Support and Remove Barriers to Coordinated Care and Individual Engagement which provides an express permission for covered entities to disclose PHI to social services agencies, community based organizations, home- and community-based services and other third parties that provide health-related services to individuals for individual-level care coordination and case management should be finalized as proposed to help eliminate this barrier. Defining parameters for the use and management of individuals' consent – consistent

with HIPAA requirements and with individuals' expectations – is necessary. Accounting for dynamic consent management, which accommodates evolving individual preferences, can help alleviate individuals' concerns about having SDOH data automatically shared with new health care providers with whom they do not have an existing relationship and entities' hesitancy to share this data. It also can allay individuals' legitimate fears of bias or discrimination in subsequent interactions.

A second challenge is the fragmented communication/coordination between sectors providing clinical, social and human services and with individuals and communities served. This fragmentation limits the effectiveness of resource availability and allocation, impacting quality of care and health outcomes and can be a source of frustration or confusion for individuals needing services. Individuals should be enabled to share their individual SDOH information at the point they interact with any service provider (e.g., during program enrollment for social services or health benefits program or during an encounter with a services provider). Individuals must have access to their own care plan data and other relevant information, enabling them to be active partners and improving the quality of the information, and it needs to be easily shareable with partner organizations, with appropriate consent and protections.

A third challenge is how health plans should vet CBOs so they can stand behind referrals and avoid any harm coming to members because community resources weren't well-vetted.

An additional challenge in exchanging social risk data from different commonly used screening tools is the capacity of the social care workforce (particularly CBOs who are already time/resource strapped) to input social risk data, often for the same individuals/families, into multiple different screening or data collection tools. Training, funding and other supports should be considered for SDOH data collection and sharing efforts to be implemented successfully. There is an opportunity to develop a consensus around a set of technical standards for collecting social needs information using federated models, which could be scaled for national use. Any effort deployed should be coordinated and standardized across sectors (e.g., housing and transportation) and should be responsive to the individuals who may not want or be comfortable with their social need and risk information being collected and stored.

General challenges include underlying data issues, such as existing practices that may lead to unintended consequences and bias. Additionally, there is no single proxy to identify specific SDOHs or outcomes.

Question #3:

What mechanisms are currently used to exchange social risk and social needs data (EHRs, Health Information Exchanges (HIEs), software, cloud-based data platforms, etc.)? What challenges, if any, occur in translating social risk data collected in these platforms to Z codes on claims?

Response:

In general, BCBSA believes technology platforms should be able to securely track awareness and utilization of solutions by population segment, including aging populations in underserved

areas. Understanding whether and how populations engage with the platform builds evidence regarding the platform's effectiveness and overall impact.

Several issues inhibit data sharing including verifying individuals uniquely, proprietary technical infrastructure, lack of technical infrastructure (access to human services administrative data is generally not stored or shared outside of government agencies and there is not an existing modern technical infrastructure to support it), and lack of real-time eligibility and enrollment information for state-administered social and human service programs.

With respect to challenges occurring from translating social risk data into Z codes on claims, plans currently rely on Z codes and utilizing non-EHR data. Plans are exploring LOINC codes as a way to standardize EHR data, but not all providers are codifying their EHR data around social needs this way, and not all providers are using LOINC standards.

There are federal policies that limit the industry's ability to deploy and scale such technology-driven solutions for the underserved. In order to foster technology-driven solutions, we suggest the following:

- **Support development of national data standards and implementation guides to scale:** The development of national standards and technical implementation guides are necessary to drive care management efficiency and leverage critical data to improve patient outcomes. To foster deployment of novel technologies to scale, BCBSA and BCBS Plans are actively engaged in industry-led efforts, such as the HL7 Gravity Project – a multi-industry effort to reduce current barriers to integration of social risk data into clinical decision-making to improve health outcomes, while increasing safeguards and privacy protections to enhance the appropriate use of sensitive consumer information.

- **Invest in interoperable and secure data infrastructure that connects with community-based organizations:**

    - CBOs serve as critical links in the collection of standardized SDOH data. Historically, CBOs have been subject to requirements as business associates under HIPAA rules in order to receive personal health information from a covered entity, which has posed a significant operational barrier to data exchange for care coordination to address consumers' social needs (i.e. non-medical). Newly proposed HIPAA regulations may provide more flexibility for data sharing with community-based organizations to reduce this as a barrier. We encourage agencies to look for opportunities to continue to provide greater flexibility and reduce burden, while aligning HIPAA protections for non-HIPAA-covered entities.

    - Development and investment in a data infrastructure that engages these culturally appropriate networks allow opportunities to get the right information in addressing diverse communities' health risk factors. These community networks also play a critical role in recruiting and training lay community health workers (CHWs) who can help not only decipher the appropriate data points, but also introduce

technology-based health improvement tools and strategies to underserved community members.

Question #4:

How can health care payers promote exchange of social risk and social needs data? Are there promising practices used by public or private payers that can potentially be further leveraged in other settings?

Response:

Health care's transition from a fee-for-service model to value-based care adds an additional imperative for SDOH. SDOH elements will become increasingly necessary to establish appropriate and equitable reimbursement of health care service providers and advance reimbursement models for CBOs. Without standards and code sets for SDOH, health plans will be challenged to evolve their value-based reimbursement programs to include social risk.

In addition to the industry need for SDOH to address the challenges of COVID-19, there is tremendous value in having standardized SDOH data. Payers and providers need to collect and share interoperable SDOH data for research and analytics that would support and document the provision of greater technical and financial resources to critically important CBO – as a means to help ensure robust CBO participation in the health care ecosystem.

One way to incent the collection of and to utilize social risk data is to allow expenses incurred in collection of that data to be built into rates and included in the numerator of the medical loss ratio calculation, as opposed to categorizing those expenses as administrative costs. This would help reflect the true value of social risk data services and ensure patients are receiving the care they need.

Payers that have been successful in promoting exchange of social risk/needs data either provide financial incentives for providers to assess and address and/or have set up their own programs for managing social needs, which falls outside of the traditional payer sphere. However, payers are in a unique position to get information across several providers/sources, and are equipped with analysts/actuaries/data scientists who are experienced at deriving value out of data. If coding SDOH data becomes the norm, payers will have that 360 view from all types of providers.

However, this does not address the issue of people who are not utilizing care due to barriers in social needs unless they have reached crisis mode. For this, payers have the ability of knowing who has insurance but is not utilizing care. Pairing this with additional insights derived from external sources about where a member lives and/or other sources, and payers would have the ability to identify members who can likely benefit from extra support. However, getting members to resources is the challenge both in terms of how it is funded, how sources are vetted, and how the end-to-end process is tracked.

Other mechanisms that are helpful include individual-centric and purpose-specific data sharing, strict privacy and security practices, transparency, open standards-based, flexible architecture and operational structure, an interoperable, federated exchange model and a multi-directional exchange approach.

Novel technology-driven approaches can leverage diverse data sets to measure the impact of social and environmental conditions on health care resource utilization and outcomes. Such technology contributes to the ability to forecast the risk of individuals developing certain disease conditions given the SDOH present within communities, coupled with medical factors derived from claims data. These analyses also may incorporate access barriers, which have been exacerbated by the current COVID-19 pandemic. These technologies can lead to actionable insights on social and environmental determinants of health by providing clarity on barriers present within communities.

BCBS Plans are actively leveraging technology, where appropriate, to provide innovative solutions and services to members. Some examples include:

- **Identifying data through industry collaboration:** We encourage HHS to review the work of HL7's Gravity Project and its efforts around identification of SDOH data sets necessary for addressing the needs of underserved communities in chronic disease management. The HL7 Gravity Project is currently in the process of developing a new SDOH data class for inclusion in the second version of the U.S. Core Data for Interoperability (USCDI V2) to create national standards for representing SDOH data in EHRs. The Gravity Project seeks to identify coded data elements and associated value sets to represent SDOH data documented in EHRs across four clinical activities: screening, diagnosis, planning and interventions. The project focuses on three specific social risk domains: food insecurity, housing instability and quality, and transportation access, but also will include education, employment, veteran status, interpersonal violence, stress, social isolation and financial strain.

- **Neighborhood partnerships:** One such example is a neighborhood partnership co-founded by the Horizon Blue Cross Blue Shield along with six other partners to help providers reach high-risk members and inform state health policies. The Horizon Neighborhood Program leverages community health workers and advanced analytics to ensure at-risk members' medical and social needs.

- **Online social resource tool:** Employers and employees can get help through Anthem's engagement with an online social resource tool powered by an outside vendor called Aunt Bertha to assist members with urgent needs. The site includes a directory of community benefit organizations and other nearby resources that users can find by ZIP code. Members executed thousands of searches within the first five months of COVID-19 pandemic, with most searches focused on assistance with food, housing and health and dental services.

- **Raise awareness of community resources:** Several other BCBS Plans are leveraging data and analytics to better understand and address health disparities. For example, several have developed educational programs for at-risk communities to help create awareness of available health services and community resources, as well as supporting local community health centers whose patients are from ethnic and racial minorities and who are disproportionately impacted by chronic conditions such as diabetes.

Finally, public-private partnerships are essential to addressing SDOH by leveraging the adoption of technology-driven solutions that can improve outcomes for at-risk populations. Government should lead the effort to establish a broad-based collaboration between the public and private sectors (comparable to ONC's FAST or HL7 Da Vinci) with a focus on key initiatives to accelerate the development, implementation and adoption of national SDOH standards to support screening, diagnosis, planning and interventions across critical domains of SDOH (as discussed above).

More specifically, the federal government should offer a unique, multi-agency, multi-million dollar challenge grant program with the health care industry and include a formal, supplemental challenge to payers, providers and payers to offer a private sector "match" that would include participation by the local community-based organizations as a key element to reach the underserved. The federal grant program should be modeled after the existing 2020 HHS Administration for Community (ACL) Social Care Referrals Challenge for technology solutions to support partnership between health care and social services. The scope of this program should extend beyond the ACL challenge, be broader than referral for resources and include the following:

- Programs for community health workers
- Alignment of social data standards of the Gravity Project
- Involve broad coordination within the federal government
- Incent community partners with value-based care reimbursement models to drive adoption and utilization of technology while building community trust and addressing equity

Section (IV): Regulatory Impact and Costs of Complying with New Requirements

Issue: Accounting for Compliance Costs in Medical Loss Ratio (MLR) Calculations

The Proposed Rule does not address the costs of complying with the new requirements in this Proposed Rule. Such costs should be accounted for in MLR calculations.

Recommendation:

BCBSA recommends that CMS allow Medicaid MCOs and QHP issuers to include the cost of compliance with this regulation as a quality improvement expense in their MLR calculations.

Rationale:

Developing and implementing these APIs constitutes a substantial effort for payers. CMS allowed payers to include costs associated with ICD-10 compliance as a quality improvement expense in their MLR calculations, which is an appropriate analogy to the costs that payers will incur to build the technical infrastructure and data exchanges included in this rule.